MINUTES OF 295th MEETING OF REGISTRATION BOARD HELD ON 8th to 11th June, 2020.

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

295th meeting of Registration Board was held on 08th- 11th June, 2020 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad. The meeting was chaired by Dr.Obaidullah, Director, Pharmaceutical Evaluation & Registration Division, DRAP. The meeting started with recitation of the Holy Verses.

The meeting was attended by following:-

1.	Dr. Rafeeq Alam Khan, Meritorious Professor, Faculty of Pharmacy, Ziauddin University, Karachi.	Member
2.	Maj.Gen. (R) Dr.Tahir Mukhtar Sayed, Inspector General (Hospitals), Fauji Foundation, Rawalpindi	Member
3.	Mr. Iftikhar A.Choudhary, Hospital Pharmacist, Lahore	Member
4.	Dr. Qurban Ali, Ex-Director General, National Veterinary Laboratories, Islamabad	Member
5.	Dr. Amanullah Khan, Director, Drugs Testing Laboratory, Quetta. Government of Balochistan	Member
6.	Dr. Muhammad Khalid Jawed, Director, Drugs Testing Laboratory,Peshawar Government of Khyber Pakhtunkhwa	Member
7.	Mr. Muhammad Aslam, Deputy Draftsman-II, Representative of Ministry of Law & Justice, Islamabad	Member
8.	Mr. Ghulam Mujtaba, Deputy Director (Patent) Representative of IPO, Islamabad.	Member
9.	Dr. Noor-us-Saba, Director, Biological Evaluation & Research Division, DRAP	Member
10.	Mr. Abdullah, Additional Director (PE&R), DRAP.	Member/ Secretary

Following members attended the meeting via video link.

11.	Lt.Gen.(R) Prof.Dr. Karamat Ahmed Karamat (HI-M, SI-M) Former Surgeon General Pakistan	Member
12.	Dr. Hafsa Karam Ellahi, Additional Director, Representative of QA&LT Division, DRAP	Member

Mr. Asif Jalil, Incharge PEC and respective Assistant Directors, presented the agenda of PE&R Division. Director, BE&R assisted by respective Assistant Directors to present the agenda of Biological Evaluation & Research Division. Additional Director, QA&LT was assisted by respective Assistant Directors to present the agenda of QA & LT Division.

Mr. Ehsan Awan, Mr. Hamid Raza, Mr. Tipu Sultan Sattar, Mr. Arshad Mehmood & Mr.Iftikhar Hussain (PPMA) and Mr. Nadeem Alamgir (Pharma Bureau) and Mr. M.Asad Malik (PC&DA) attended the meeting as observers.

Before formal starting of the agenda, the Board was apprised about the sad demise of Dr.Ghulam Sarwar who was august member of Registration Board for two tenures. The Board recognized his services rendered during his tenures. The members offered Fateha and prayers for the departed soul. May Allah bless him in eternal peace Ameen.

Item No. I: Confirmation of Minutes of 294th Meeting of Registration Board.

294th meeting of Registration Board was held on 09th April, 2020. Initially draft partial minutes of 294th meeting were circulated among the members of Registration Board on 11th April, 2020. Later, complete draft minutes were circulated on 22nd April, 2020 with the request for perusal/approval within five (05) days. None of the members disagreed the draft minutes except Syed Adnan Rizvi, Director DTL, Govt. of Sindh, Karachi who commented on both the partial and complete draft minutes.

The partial & complete minutes in fair, along with comments and response prepared were submitted before Chairman Registration Board for perusal/approval. The Chairman Registration Board after perusal of comments and response approved the partial and complete minutes. The same were circulated to concerned divisions/sections for implementation.

The comments and response is hereby tabulated for information of Board as under: -

Commnets/Response on Partial Minutes	
Comments	**Response**
Item No.II Division of Pharmaceutical Evaluation & Registration. ***Item No.1:*** Priority approval/ registration of drugs during COVID-19 Pandemic. All are approved except serial No. 7, 16, 18, 19, 38, 46, 72, 90, 94, 115, 125, 137, 143, 149, 166, 168, 170, 174, 179, 180, 181, 189, 190,194, 200, 208, 217, 233, 234, 235, 237, 251, 259, 261, 263, 265, 266, 273, 293, 296, 300 and 308 are approved with change of Brand names.	Brand names are checked before issuance of registration letters and will be followed in these cases as well
More important is that labelling should be in base form instead of Hydroxychloroquine H_2SO_4 200mg equivalent to 155mg base. As labelling of plaquenil clearly mentioned that Plaquenil (Hydroxychloroquine sulfate) tablets contain 200mg Hydroxychloroquine sulfate equivalent to 155mg base.	• The reference product Plaquenil contains hydroxychloroquine in its "sulphate" salt form and the numerical figure of "200" accounts for the total quantity of hydroxychloroquine sulphate rather than hydroxychloroquine alone. • Equivalency statement of "200mg Hydroxychloroquine sulfate is equivalent to 155mg base" is an additive elaboration made in the PIL (patient information leaflet or detailed literature), while the product is always prescribed with the numerical figure of 200, which accounts for the "Hydroxychloroquine sulphate". Also the dose recommendations are made using the figure of 200. • Hence, the equivalency of salt form to the base may be given in the PIL (which is already conditioned to be same as that of innovator), while for label claim correct statement has already been mentioned.
Item No.II: Registration-I section ***Case No.1:*** Opinion regarding letter of DG Health Punjab. This may be given one time permission as the financial year being closed and all the firms may be given time for registration of the larger packs if required and registration may be given in time in public interest.	Needs no comments as deferred by Registration Board for further deliberation
Item No. III ***Case No. 1:*** Any alternation, ornamenting, finishing comes under the heading of 'manufacture' in the Drug Act, 1976. This permission should be given in emergency only from the license premises having DML with cold chain facility not at drug sale license premises.	Needs no comments as same has been decided by Registration Board

Item No. IV: ***Case No. 2:*** Novartis applied for exemption from local testing of their product "Tablet Exforage", containing Valsartan, the product is imported in finished form by the Firm. As the policy is decided after reported carcinogenic activity of NDMA by the registration board in 291st meeting that, product registration holders shall ensure and are bound to test the APIs & the finish products for impurities, than why an exemption is considered for a finished product to be imported into Pakistan. The importers of finished products containing Valsartan shall also be asked to provide analysis report of both APIs & Finished product at the time of import for each batch. Either the firm ensure and give affidavit that finished product doesn't contain the NDMA impurity and they will test every 10th batch of finished product for the said impurity. As impurity of NDMA develop during formulation of finished drug (Zantac) not during basic manufacturing of API may also be considered before giving exemption of testing finished product for NDMA in larger public health interest.	It has been established by reference regulatory authorities that NDMA found in Valsartan is a process related impurity generated during the API manufacturing and is not a degradation impurity generated during finished product manufacturing or FPP storage, hence the amount of NDMA detected at the API batch release level is likely to be carried out in the Finished Product at the same level. Accordingly, it was established by M/s Novartis that the API Valsartan used by Novartis in formulation of FPP has been tested and found compliant for NDMA contents and has also undertaken that same API has been used for manufacturing of FPPs and exported. It is also pertinent to mention that for local manufacturers, NDMA testing has been made mandatory for the API only and not for the FPPs. Unlike Valsartan, in case of Ranitidine NDMA was present in both the finished drug product samples and the active pharmaceutical ingredients (APIs). Moreover the USFDA's recent laboratory testing results demonstrated that levels of NDMA in some ranitidine finished drug products increase over time at room temperature hence giving a hint that the NDMA in Ranitidine may be a degradation impurity which may arise in FPP during storage.

Comments/Response on Complete Minutes	
Comments	**Response**
Item # II: The word growth promoter should be removed at Sr.No.24 in pharmacological group.	The word growth promotor is removed.
at serial # 36 the word NSAID should be incorporated in place of anti inflammatory as Flunixin is potent analgesic, antipyretic and anti-inflammatory.	Flunixin is categorized only as Anti-inflammatory and Antirheumatic Products as per WHO ATC Vet Index. Therefore, no change is required.
Serial # 42,43,45,46 contained Gentian Violet which is carcinogenic in nature it should be removed in composition.	Gentian violet applications are of spray dosage form for external use and Board has considered on the basis of evidence of already registered generic drug(s). However, comments are taken for future strategy and course of action keeping in view the availability in RRA and use of said molecule in veterinary formulation.
Serial # 46 pharmacological group may kindly be corrected as anti biotic instead of diuretic.	Pharmacological group is already mentioned as Antibacterial / antiseptic.
At serial # 78 is approved with change of brand name.	Brand names are checked before issuance of registration letters & will be followed in these cases as well
Serial # 75,76,77 & 78 approval of DPI (storied) in general section is against the policy of 290th meeting of registration board.	The approval of these products is as per the decision of 290th meeting of RB wherein the Board decided that if applied formulation includes a steroidal drug then firm shall require separate section for "Dry Powder Inhaler Capsule" to avoid chances of cross contamination and the same is complete in the instant cases.
Serial # 141, 142, 143, 144, 145, 146, 147, 159, 160, the word expectorant should be edit beside the anti bacterial in pharmacological group.	Case 141, 142, 143, 146 & 159 are already deferred, so no action is required. Case 144, 145 corrections done. Case 147, 160 no expectorant is used in the

	formulation. So no action is required.
Serial # 258 the word anthelmintic with anti biotic in pharmacological group.	Pharmacologic group is mentioned, so no action is required.
Serial # 74 approve the registration of indigo with innovator's specification. Manufacturer will place first three production badges of long term stability studies throughout proposed shelf life and on accelerated studies for six month in the public interest at large.	The case is deferred since the applied formulation is a subsequent generic (the innovator was first approved in 254th meeting).
Item # 08 **Case # 02** **Serial # 265:** I was as member in the penal, the penal checked authenticity / geniuniousness of the stability data. the dissolution studies were performed three trial budges for the intervals (initial, 1,2,3 & six month) at accelerated as well as on long term the dissolution test were within the specification i.e. 80% (Q) in 30 minutes. The 15 minute dissolution interval is required in comparative dissolution studies which is already being performed and test results complied the requirements. The data and test results were checked by penal the GNP certificate of API manufactures were also shown by the farm therefore the registration of sofosbuvir tablets 400mg my kindly be granted to the farm.	As per decision of 293rd meeting of Registration Board. For rapidly dissolving drug products (i.e. those products for which the dissolution time adopted by innovator/reference product is 15 minutes or less). a. The firms should exactly follow the same dissolution time as adapted by innovator / reference product. b. For already submitted stability studies and those cases in which stability batches are manufactured before 01-06-2020, wherein the dissolution testing was performed at more than 15 minutes time point, the firm shall perform dissolution testing at 15 minutes time point at initial and one month time point at both accelerated and real time stability conditions for 2 batches. The decision of the Board is in the light of its decision taken in 293rd meeting. Furthermore, the conclusion of the report point (2) specifies that Valid GMP Certificate of API Manufacturer is hereby attached for reference, while no GMP certificate is attached with the report therefore the case is deferred for GMP certificate.
Import & Vet I- II Section **Case#01:** Acceptance of Eudra GMDP for manufacture out side of EU. As Eudra GMDP data base provide GMP status of Reference and non Reference country therefore this exemption should not be given as the registration board already made policy in 275th meeting approved 21 RRAs in the interest of public health, also kept the decision in C.P. 3093/2019 M/s Hakimsons Vs Federation of Pakistan and others and C.P. 3094/2019 Sindh Medical Store Vs Federation of Pakistan and others in which exemption was not granted by the Honorable High Court Sindh to the petitioners. Therefore, inspection exemption of manufacturing facilities on the basis of Eudra GMDP data base should not be given.	The GMP certificates available at Eudra GMP database are based on the inspection reports conducted by national competent authorities of EU EMA. The reports as well as certificates are owned, maintained and operated by EMA. Further, policy for inspection of manufacturer abroad (for imported drugs) recognizes facility (dosage form manufacturing facility or whole product facility) approved by regulatory authorities of EU EMA. Hence, instant decision is in line with the decisions of DRAP's Policy Board and Registration Board taken in its 275th meeting. Moreover, in the referred cases no such orders have been passed by the Honorable Sindh High Court as mentioned by Director DTL.

Decision: Registration Board confirmed the minutes of 294th meeting.

Item No. I: Cases Related to Covid-19 Management.

A. Division of Pharmaceutical Evalautaion & Registration (P. E & R)

Priority Approval / Registration of Drugs During the COVID-19 Pandemic:

The world is currently facing one of the biggest public health outbreak of coronavirus disease 2019 (COVID-19), which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The outbreak was first identified in Wuhan, Hubei, China, in December 2019. The World Health Organization (WHO) declared the outbreak to be a Public Health Emergency of International Concern on 30th January 2020 and recognized it as a pandemic on 11th March 2020. More than 723,500 cases of COVID-19 have been reported in over 190 countries and territories, resulting in approximately 34,000 deaths till date.

Many clinical trials are under way for treatment / prevention of COVID-19 which uses different type of pharmaceutical / biological drugs. Many drugs have been allowed for investigational use in hospitals under medical care for the COVID-19 patients.

The authorities from all over the world have considered the use of several drugs under their respective national emergency management plans. Clinical Management Guidelines for COVID-19 Infections issued by Ministry of National Health Services, Regulation & Coordination (available at http://covid.gov.pk/guideline) also recommends the use of these drugs in the management of mild to moderate and severe cases of COVID-19 patients. Further, USFDA has also given Emergency Use Authorization for chloroquine and hydroxychloroquine tablets for COVID-19 patients (available at: https://www.fda.gov/media/136534/download). Further Centers for disease control and prevention (CDC) USA also issued Information for Clinicians on Therapeutic Options for Patients with COVID-19 (available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html). Similarly Italian Medicines Agency (AIFA) considers it essential to provide clinical elements useful to guide the prescription and to define, for each drug used, a relationship between benefits and risks for the individual patient. *Off-label* use is only permitted under the national emergency management plan for treatment of COVID-19 by using Lopinavir / ritonavir (available at: https://www.aifa.gov.it/emergenza-covid-19).

Keeping in view the above information, Drug Regulatory Authority of Pakistan (DRAP), exercising its powers under Rule 26of Drugs (LRA) Rules amended via SRO 713(1)/2018 dated 8th June, 2018, has made following decision in its meeting dated 3rd April, 2020.

1. Allowed to submit registration application on form 5, form 5A, form 5D or form 5E instead of form 5F for following formulations as approved by the reference regulatory auhtories;
    a. Chloroquine Phosphate
    b. Hydroxychloroquine Sulfate
    c. Lopinavir/Ritonavir
    d. Oseltamivir
    e. Ascorbic Acid
2. The applicant can submit their application till 2nd May 2020 but the date was extended till 5th May, 2020 vide letter No.F.76-DRAP/2020(PE&R) dated 30th April, 2020.
3. These applications will be considered out of queue.
4. The validity of registration period for above mentioned drugs registered during this time will be one only.
5. The registration holder will submit data of product development of 3 and 6 months within one year. The data will be considered by Registration Board for extension of validity period of registration for further period.
6. Applicant shall submit affidavit for compliance of point and 5 above.

The Authority further extended the time lines till 31-07-2020 for submission of registration applications on Form 5 / Form 5-A / Form 5-D for molecules already approved by the Authority for the management of Covid-19.

Discussion & Decision:

In continuation to discussion and decision of 294th meeting, Registration Board decided to adopt same approval pathway and accordingly decided as follows:

a. **The registration applications of following formulations, as approved by Reference Regulatory Authorities, will be considered out of queue on priority basis:**
   - **Chloroquine Phosphate**
   - **Hydroxychloroquine Sulfate**
   - **Lopinavir/Ritonavir**
   - **Oseltamivir**
   - **Ascorbic Acid**

b. **As present, registration applications are without product development and stability data, thus registration shall be valid for 01 year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in 293rd meeting and shall submit to PE&R Division within one year time for consideration by Registration Board for extension of validity period of registration for further period. The same shall be applicable for the 5D applications of above formulations.**

c. **Registration Board also clarified that no therapeutic claim regarding treatment of COVID-19 shall be made for above formulations until unless approved by any Reference Regulatory Authority and the same is approved by Registration Board as well. Presently above formulations shall only be used as part of the clinical trials or its management of COVID-19 under strict supervision of relevant medical experts.**

d. **Registration Board further directed to issue an advisory wherein self-medication and other related matters related to COVID-19 shall be addressed.**

With reference to the decision of Drug regulatory Authority of Pakistan, following applications were received and evaluated by PEC and now presented before the Board. Registration Board considered these applications in light of its above cited decision:

1. Hydroxy Chloroquine Sulfate Tablet 200mg:

Composition:

Each Film Coated Tablet contains:
Hydroxychloroquine sulfate……200mg

International Availability:

PLAQUENIL 200mg film coated tablet by M/s Concordia, USFDA Approved.

Me too: HCQ 200 Tablets by M/s Getz Pharma, Reg. No. 45471

Specifications: USP Specification

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
1.	M/s Wellborne Pharmacchem and Biological, Plot# 51/1-52/1 Phase II, Industrial Estate Hattar.	Hcqwell 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy. No. 6519 Dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 07/11/2018, Satisfactory level of cGMP compliance.

2.	M/s Arsons Pharmaceutical Industries (pvt) Ltd. 2.5km defence road, off Multan road, Lahore.	Hydroximol 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy.No. 6535 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection dated 18/09/2019, satisfactory GMP compliance for; ➢ Tablet (General & Psychotropic) ➢ Capsule General ➢ Cream/ointment /Gel (general)
3.	M/s Eros Pharmaceuticals (pvt) ltd, 94/23, Korangi industrial Area, Karachi.	Ero HCQ sulphate 200 tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy.No. 7268 dated 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 26/03/2018, panel recommended resumption of production.
4.	M/s Pliva Pakistan (pvt) ltd. B-77, H.I.T.E, Balochistan.	Pliquine Tablet 200mg	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy.No. 7136 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Renewal of DML was granted vide letter No.F.4-1/89-Lic(Vol-V) dated 7th November, 2019.
5.	M/s ISIS Pharmaceuticals & Chemical Works, Karachi.	IS-HCQ tablet 200mg	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy.No. 6749 dated 10/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report of dated 08-07-2019 showed good level of GMP compliance.
6.	M/s Avant Pharmaceuticals, M-028 HITE Lasbela Balochistan.	Avequine 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy.No. 7610 15/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 07/12/2017, good GMP.
7.	M/s Mafins Pharma, A-5, SITE Super highway Industrial Area, Karachi.	Hydroqueen 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy. No.6524 09/04/2020 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection conducted on 24/07/2019, appropriate GMP compliance.
8.	M/s Amarant Pharmaceuticals Private Limited, 158, D. Tore, Gadap road Super Highway, Karachi.	Amaquine-H 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy. No.7154 13/04/2020 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Good GMP compliance, inspection date 24/07/2018.
9.	M/s Jinnah Pharmaceuticals (pvt) ltd. 13km Lahore Road, Multan.	J-Quine H200 tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy.No. 7110 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel recommended renewal of DML, inspection date 03/05/2019.
10.	M/s BJ Pharmaceuticals 18-km Mandiali stop, Lahore-shiekhupura road Lahore.	Hicloq 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy.No. 6758 dated 10/04/2020 Rs. 20,000/- Form 5	As per SRO	**Firm has required** equipment/ machinery, HVAC system and qualified staff, firm showed good intention to further improvements in future. Overall hygienic condition of the firm is satisfactory at the

						time of inspection. Inspection date 15/01/2020.
11.	M/s N.S Pharma, Plot # 576-577 Sundar Industrial estate Lahore.	NS-Chlor 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy.No. 6273 08/04/2020 Rs. 20,000/- Form 5	As per SRO	DML issued on 14/09/2017.
12.	M/s Hicon Pharmaceuticals, 131-Industrial Estate Hayatabad.	Oroquine Advance 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy. No.6566 9/04/2020 Rs. 20,000/- Form 5	As per SRO	Good level of GMP, inspection date 26/07/2018.
13.	M/s MBL Pharma, B-77-A, HITE, HUB, Balochistan.	Mb Hcquine tablet 200mg	Each Film Coated Tablet contains: Hydroxychloroquine sulfate……200mg	Dy. No.7932 16/04/2020 Rs. 20,000/- Form 5	As per SRO	Good GMP compliance, inspection date 28/02/2018.
14.	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir	Quinex Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7307 dated 14/04/2020 Rs. 20,000/- Form 5	As per SRO	As of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. Inspection date 22/02/2019.
15.	M/s Goodman laboratories (Pvt) Ltd, Plot#5, Street# S-05, National Industrial Zone Rawat.	Quinogood 200mg tbalet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy. No. 5856 Dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP certificate issued on the basis of inspection conducted on 08/08/2018.
16.	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad	Hydromax 200mg tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 6568 dated 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Good level of GMP compliance, inspection date 21/02/2019.
17.	M/s Warafana Pharmaceuticals (Pvt) Ltd. Plot#125-126-127, Industrial triangle kahuta road, Islamabad.	War Quin 200mg tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 6522 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated on 12-07-2017 concluding that firm is operating at fair level of compliance with GMP.
18.	M/s Evolution Pharmaceuticals (pvt) ltd Plot # 25&26, street S-3, RCCI, National Industrial zone, Rawat, Islamabad.	Quenil 200mg tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 6532 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	**Inspection date** 25/10/2018, As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite

						manufacturing facility for manufacturing of Pharmaceuticals.
19.	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Qinsave 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7770 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 02/10/2019.
20.	M/s Jawa Pharmaceuticals Pvt Ltd, 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore	Curequine 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8382 dated 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Inspection date 21/02/2020 & 04/03/2020. Satisfactory level of GMP compliance.
21.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi.	B-Quine H 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8329 dated 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Inspection date 17/09/2019, Acceptable levelof GMP compliance.
22.	M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road, Lahore.	Medoxy 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8330 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	19/11/2019 inspection date. The panel recommended renewal of DML.
23.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Dox-Q 200mg Tablet	Each tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8334 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	GMP ceritificate issued on 11/07/2019 on the basis of inspection conductded on 31/07/2018.
24.	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad	H-Chloqin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7994 17/04/2020 Rs. 20,000/- 17-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
25.	M/s Relizon Pharmaceuticals. 118 Sunder Industrial Area, Lahore	Rel-HCQ 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7982 17/04/2020 Rs. 20,000/- 17-04-2020 Form 5	As per SRO	GMP certificate issued on 20/3/2019 on the basis of inspection conducted on 15/03/2019.
26.	M/s Aneeb Pharmaceuticals Pvt Ltd, 24-Km, Bedian Road, Lahore	Plaquinol-Q 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8110 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Inspection date 29/10/2018. The panel recommended renel of DML.
27.	M/s Harmann Pharmaceuticals Laboratories Pvt Ltd 16-KM, Multan	Hydroquine 200mg Tablet	Each tablet contains: Chloroquine phospate…250mg which is eq to 155mg	Dy.No. 8107 20/04/2020 Rs. 20,000/- 20-04-2020	As per SRO	GMP status cannot be confirmed.

	Road, Lahore		chloroquine base	Form 5		
28.	M/s Mediate Pharmaceutical Pvt Ltd., Plot#150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan	Chloro-Med 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7793 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 04/03/2020, Acceptable level of GMP compliance.
29.	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan	Raquin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8841 dated 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection date 19/09/2018, The panel recommended issuance of GMP certificate. The firm has revised the formulation from uncoated to film coated as per reference product along with the submission of rs. 5000/- dated 29/04/2020 vide challan number 1918816.
30.	M/s Legacy Pharmaceuticals pvt Ltd., 111-A, Industrial Estate Hayatabad Peshawar	Legoquine-H 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8778 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection date 18/07/2019. The Panel recommended renewal of DML.
31.	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab	Qlor 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8769 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	03/05/2019 inspection dated. The panel recommended renewal of DML.
32.	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad	Medquin-H 200mg Tablet	Each tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7944 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 16/10/2018, the panel recommended renewal of DML.
33.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi.	Medquin-s 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7947 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	Rs. 3000/- per 30's	Inspection date 19/07/2019, GMP compliance level is rated as good.
34.	M/s Medipak Limited 132, Industrial Estate, Kot Lakhpat Lahore	Mediquin-H 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8914 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	**Inspection date** 11/07/2019, The panel observed that the firm had rectified most of the deficiencies pointed out in inspection dated 13/04/2016, Further improvements would be verified in the next inspection due for renewal of DML.

35.	M/s Fredmann Pharmaceuticals Plot No.82-83, B, Old Industrial Area Mirpur	H-Quin 200mg Tablet	Each tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8915 24/04/2020 Rs. 20,000/- 24-04-2020 Form 5	As per SRO	Inspection date 10/01/2020. The panel is of the opinion that the report may be forwarded to the competent authority for resumption of production.
36.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Hiquenta 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8924 24/04/2020 Rs. 20,000/- 24-04-2020 Form 5	As per SRO	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tabklet General, Capsule General, Liquid Syrup General).
37.	M/s Shawan Pharmaceuticals, Plot#37, Road: NS-01, National Industrial Zone, Rawat, Rawalpindi	Chloro-HQ 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8555 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	04/03/2020, Good GMP compliance.
38.	M/s Jaskan Pharmaceuticals Pvt Ltd, 5- Sundar Industrial Estate, Lahore	Malavir 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8549 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	The firm was inspected on 13.03.2018, wherein resumption of production was recommended by the panel.
39.	M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.	HCQS 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8545 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	GMP certificate issued on 31/07/2019 on the basis of inspection conducted on 03/07/2019.
40.	M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore	Coron 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8540 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	Inspection date 01/03/2019 & 13/05/2019, the panel recommended renewal of DML for Tablet (general) and Capsule (General) sections.
41.	M/s Panacea Pharmaceuticals. Plot No.4, Street No.S-6, National Industrial zone Rawat, Islamabad	Panoquin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8538 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	The firm was GMP compliant as per the letter received from QA&LT division's letter no. F.4-5/2007-QA dated 26/08/2019. Inspection date 04/01/2019.
42.	M/s Linz Pharmaceuticals Pvt Ltd, Plot No 31-G & 31-H, Sector 15	Q-Linz H 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8327 22/04/2020 Rs. 20,000/- 20-04-2020	As per SRO	Inspection date 09/01/2020, GMP of the firm is rated as Good.

	Korangi Induatrial Area Karachi			Form 5		
43.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad	Fequin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8536 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	Inspection date 21/05/2019, The panel recommended renewal of DML.
44.	M/s Iceberg Pharmaceuticals Pvt Ltd Plot No.144, Nowshera Industrial Estate, Rislapur.	Hiquine 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7922 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 27/03/2019, The panel recommended resumption of production.
45.	M/s Newton Health care Pvt Ltd. Plot No. 8,9. H.I.T.E, Hub Balochistan	HOC 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8388 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Inspection date 05/08/2019, Good GMP compliance.
46.	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad	Kanaquin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8449 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	irm has submitted copy of GMP inspection report conducted on 06-03-2019 concluding GMP compliance.
47.	M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan	Pharmedic Hy-Chlor 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8451 21/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Inspection date 07/08/2018, 04/09/2018, 22/11/2018, Fair compliance.
48.	M/s Epharm Laboratories.A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi	Ephaquine-HS 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8455 dated 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Inspection date 17/09/2019, GMP rated as good.
49.	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Karachi	Chlorovid 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8458 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Inspection date 24/12/2019 Overall rating of the firm is good.
50.	M/s Danas Pharmaceuticals Pvt Ltd, 312, Industrial Triangle, Kahuta Road, Islamabad.	Danque-H tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 6529 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines.
51.	M/s Miracle Pharmaceuticals Pvt Ltd, Plot No.08, Street no-S-5, National Industrial Zone Islamabad	Mir Q Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7139 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Minimal level of GMP compliance/, inspection date 28/02/2019.

52.	M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar	Quin-H Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 6751 10/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection conducted on January 24th, 2019 concluded that firm is operating at satisfactory level of GMP compliance.
53.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	Quinco H Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 6778 10/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance.
54.	M/s. Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.	Kunaquin Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7146 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Good compliance of GMP, inspection date 26/12/2019.
55.	M/s Sante Pvt Ltd 245/2-Z, Block 6, PECHS, Karachi 75400	Santoquine 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7060 13/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Good compliance of GMP, inspection date 07/07/2019.
56.	M/s PharmaWise Labs pvt Ltd 25-M.Q-A Industrial Estate, Kot Lakhpat, Lahore	Quenil wise Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7064 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 16/10/2019, firm is GMP compliant.
57.	M/s Nimrall Laboratories Plot 24, Street SS-3, Rawat, Industrial Area, Islamabad	Hydroquin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7145 13/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel recommended resumption of production, inspection date17/07/2019 & 24/07/2019.
58.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi	Hoq 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7118 13/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel recommended renewal of DML, inspection report 26/02/2019.
59.	M/s Ambrosia Pharmaceuticals,Plot # 18, Street # 09, National Industrial Zone, Rawat.	H Quin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7141 13/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm was found working in compliance to GMP, inspection date 08/10/2018.
60.	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi	MyQuin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7257 14/04/2020 Rs.20,000/- 13-04-2020 Form 5	As per SRO	Good level of GMP compliance, inspection date 21/02/2019.
61.	M/s Heal Pharmaceuticals Pvt Ltd. W-33, Industrial Area, Hayatabad Peshawar	Healaquenil 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7482 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Satisfactory level of GMP, inspection date 08/11/2019.

62.	M/s Jaens Pharmaceutical Industries Pvt Ltd. 28-km Lahore-Sheikhupura Road, Sheikhupura	Quisul 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7478 14/04/2020 Rs.20,000/- 13-04-2020 Form 5	As per SRO	GMP certificate issued on 03/04/2019 on the basis of inspection conducted on 14/01/2019.
63.	M/s Maple Pharmaceuticals Pvt Ltd, Plot No.147, Sector 23, Korangi Industrial Area, Karachi	Doxin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7259 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 22/12/2019.
64.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore	Hyqlor 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7486 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued in 25/04/2019 on the basis on inspection conducted on 07/03/2019.
65.	M/s Venus Pharma. 23 km, Multan Road, Lahore	Hydroquine 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7477 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP ceritifcate issed on 28/11/2019 on the basis of inspection conducted on 05/09/2019.
66.	M/s Himont Pharmaceuticals Pvt Ltd. 17-km, Ferozepur Road, Lahore.	Hiquin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7114 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	GMP certificate issued based upon evaluation conducted on 04-10-2018 & 05-10-2018.
67.	M/s Simz Pharmaceuticals Pvt Ltd, Plot No.574-575, Sundar Industrial Estate, Raiwind Lahore.	H-chlorosim 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7629 dated 15/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017.
68.	M/s Curatech Pharma Pvt Ltd 35-Km, Multan Road, lahore	CuraCovid 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7067 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 16/03/2018.
69.	M/s Opal Laboratories Pvt Ltd. LC-41, L.I.T.E., Landhi, Karachi	HC-Quine 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7059 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Good level of GMP, inspection date 19/09/2019.
70.	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore	H-clor 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7491 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 21/02/2020 on the basis on inspection conducted on 07/11/2019
71.	M/s Amson Vaccines & Pharma Pvt Ltd.115, Industrial Triangle, Kahuta Road, Islamabad.	Amsoquin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7287 14/04/2020 Rs.20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 04/02/2020, the panel recommended renewal of DML.

72.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura.	Aedes 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7083 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 30/05/2019, good level of GMP compliance.
73.	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore	Hydrox 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8385 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	GMP certificate issued on 30/03/2020 on the basis of inspection conducted on 19/03/2020.
74.	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi	Quinox 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8373 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	GMP certificate issued on 11/03/2019 on the basis of inspection conducted on 05/03/2019.
75.	M/s Medifine Laboratories Pvt Ltd Mirpur	Hydroxychloroquine sulfate 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8377 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Inspection date 09/11/2018, the panel recommended renewal of DML.
76.	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi	Hydro-CQS 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7782 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 06/08/2019. The panel recommended resumption of production.
77.	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan.	Hydroquin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7764 16/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	Inspection date 03/01/2019, Good level of GMP compliance.
78.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi.	Palquin 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7777 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 08-05-2018."
79.	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar	Astequine 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7788 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	13/11/2018, Good GMP compliance.
80.	M/s Convell Laboratories Saidu Sharif Swat KPK.	Oxycon tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 6396 08/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 02/03/2019, the panel recommended renewal of DML.

81.	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.	Coroquin 200mg tablet	Each film coated tablet contains: Hydroxychloroquine sulfate …… 200mg	Dy.No. 9011 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 28-02-2019 recommended renewal of DML.
82.	M/s ISIS Pharmaceuticals & Chemical Works, Karachi	Is-Hcq Tablet	Each Tablet Contains: Hydroxychloroquine Sulphate…200mg	Dy.No. 6749 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Last inspection report of dated 08-07-2019 showed good level of GMP compliance.
83.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan	Biochlor Tablet 200mg	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…200mg	Dy.No. 5872 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	Inspection date 25/11/2019 & 12/12/2019, the panel recommended renewal of DML.
84.	M/s Fedro Pharmaceuticals Lab Pvt Ltd. 149-Industrial Estate, Hayatabad,Peshawar	HCS Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9575 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP inspection dated 26-06-2018, Satisfactory level of GMP compliance.
85.	M/s Medicaids Pakistan (pvt) Ltd. Plot No 10, Sector-27 Korangi Industrial Area, Karachi	MEDIQYN Tablet 200mg	Each tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9708 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on evaluation conducted on 09th August, 2018.
86.	M/s Mediceena Pharma (Pvt) Ltd. 27 Km Raiwind Road Lahore	MEDIQUIN Tablet 200mg	Each tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9567 dated 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 24-9-2019.
87.	M/s Asian Continental Pvt. Ltd. D-32, SITE II, Super Highway, Karachi.	HYDROCQ Tablet 200mg	Each tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9462 30/04/2020 Rs. 20,000/- 30/04/2020 Form 5	As per SRO	GMP inspection dated 25-06-2019, current GMP compliance level is rated as good.
88.	M/s The Schazoo Zaka (Pvt) Ltd. Kalalwala, Zaka Ur Rehman State, Plot No. 1, 20 km Lahore-Jaranwala Road, Sheikhupura.	ERAQUIN Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9712 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Panel inspection dated 21-10-2019, the firm has maintained a Good level of GMP compliance.
89.	M/s Popular Chemical Works Pvt Ltd, 9KM, Lahore-Sheikhupura Road, Lahore	Quinsid Tablet 200mg	Each tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9722 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Panel inspection dated 29-05-2019 recommends renewal of DML.
90.	M/s Karachi Chemical Industries (Pvt) Ltd, F/25, Estate Avenue, S.I.T.E., Karachi	H-Chloro Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9727 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 30th January, 2020.

91.	M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore	H-OXIN Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9735 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	GMP inspection report dated 01-01-2019, firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations
92.	M/s Baxter Pharmaceuticals, A-1/A, Scheem No.33, Phase-1, S.I.T.E, Super Highway, Karachi	Oxiquin Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9433 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 21-09-2019, the compliance level is rated as satisfactory.
93.	M/s Faas Pharmaceuticals (Pvt.) Ltd. F-748/L, S.I.T.E Karachi, Pakistan	Faasquine-Q Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9007 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	GMP inspection dated 13-11-2019, the firm is operating at good level of GMP compliance.
94.	M/s Citi pharmaceuticals Pvt Ltd, 3-KM, Head Balloki Road, Phool Nagar District Kasur	Chloronil-S Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…250mg	Dy.No. 9220 28/04/2020 Rs. 20,000/- 28-04-2020 Form 5	As per SRO	The firm has copy of GMP certificate based on inspection dated 19-03-2019.
95.	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi	COVIMAX Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…250mg	Dy.No. 9221 28/04/2020 Rs. 20,000/- 28-04-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 19-09-2019.
96.	M/s Nenza Pharmaceuticals Pvt Ltd, 33-A, Industrial Estate Hayatabad Peshawar	Quinen-H Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9311 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 26-09-2018, overall GMP compliance of the firm is satisfactory
97.	M/s Hi-Med Pharmaceuticals, 208-C, Sundar Industrial Estate Raiwind Road, Lahore	HI-CHLOR Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7127 13/04/2020 Rs. 20,000/- 13/04/2020 Form 5	As per SRO	GMP inspection dated 27-04-2018, recommends grant of DML by way of Formulation.
98.	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur	FH-Chlor Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9320 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 03-10-2018, firm is maintaining satisfactory level of cGMP.
99.	M/s Zephyr Pharmatec Pvt Ltd. Plot No. A-39, S.I.T.E II, Super Highway, Karachi.	Oxyquin Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…...…200mg	Dy.No. 9419 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 25-09-2019 overall GMP compliance is rated as GOOD.
100.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	Hydrofold Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9983 05/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	GMP inspection dated 20-02-2019, panel recommends grant of GMP certificate.

101.	M/s Lowitt Pharma Pvt Ltd. 24-Industrial Estate, Hayatabad, Peshawar	Hy-CQuine Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9964 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	Panel inspection dated 12-05-2020 recommends grant of GMP certificate.
102.	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore	Koved-H Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8990 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	Panel inspection dated 12-06-2019, 17-07-2019 & 30-09-2019, recommends grant of renewal of DML.
103.	M/s Zanctok Pharmaceuticals Laboratories F-5 Site Hyderabad	Zentaquine Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8990 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	GMP inspection dated 21-03-2019, current GMP compliance level is rated as Good.
104.	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Plavaquine Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8125 20/04/2020 Rs. 20,000/- 15/04/2020 Form 5	As per SRO	The firm has been granted GMP certificate based upon evaluation conducted on 06-7-2017.
105.	M/s Winthrox Laboratories Pvt Ltd.K-219/A, SITE, Super Highway, Phase-II, Karachi,	Winque Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8118 20/04/2020 Rs. 20,000/- 15/04/2020 Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018.
106.	M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi, Pakistan-75700	Eplaquine Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9972 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	GMP Inspection conducted on 16-07-2019, the firm is considered to be operating at Good level of GMP compliance.
107.	M/s AJM Pharma pvt ltd Plot No. 44, Sector No. 27 Korangi Industrial Area Karachi.	Ajquine 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7928 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Panel inspection dated 13-03-2019 recommends grant of renewal of DML. Firm has submitted fee of Rs. 5,000 for revision of formulation to film coated tablet from uncoated tablet
Decision: Registration Board approved registration of above applications from Serial No. 1 to 107. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete

Sr. No.	**Name of applicant**	**Brand Name**	**composition**	**Diary no. / Date / fee / form**	**Pack Size / Price**	Remarks/ GMP status	**Decision**
108.	AAA Health Pharmaceuticals Laboratories, Plot# 9A, Street # N-5, National Industrial Zone, Rawat, Islamabad	Hydro-A 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 8322 22/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Inspection date 09/10/2019, The inspection is conducted and firm's request acceded to complete the work and appoint technical staff as	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**

						required along with instrument required.	
109.	M/s Hassan Pharmaceuticals (pvt) Ltd. 99-A Industrial Estate, Hayatabad, Peshawar.	H-Quin 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate ……200mg	Dy.No. 7620 dated 15/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP compliance is NOT satisfactory, Inspection date 01/02/2018.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
110.	M/s Biorex Pharmaceuticasl plot No. 251-A, Industrial Triangle Kahuta Road, Islamabad.	Bioquine 200mg tablet	Each Film Coated Tablet contains: Hydroxychloroquine sulfate ……200mg	Dy. No.7617 dated 15/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report is older than 3 years. The firm has applied for uncoated tablet in contrast to innovator's product.	**Deferred for the following:** • **Submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** • **Referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
111.	M/s Novae Pharmaceuticals. 123, Phase 5, Industrial Estate,	Novachlor Tablet	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate	Dy.No. 6224 dated 08/04/2020 Rs. 20,000/-		Inspection report not provided.	**Registration Board referred the case to QA &**

	Hattar, Pakistan		…200mg	08-04-2020 Form 5			**LT Division to conduct GMP inspection of Firm on priority.**
112.	M/s Rogen Pharmaceuticals. Plot No. 30, Street # S-4, National Industrial Zone, Rawat, Islamabad	Chlorogen 200mg Tablet	Each Tablet Contains: Hydroxychloroquine Sulphate …200mg	Dy.No. 5857 dated 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5		Inspection date 25/01/2019, The firm is operating in compliance with GMP. The firm has applied for uncoated tablet while the reference product is film coated.	**Deferred submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
113.	M/s Synchro Pharmaceuticals 77-Industrial Estate Kot Lakhpat, Lahore	HISYN Tablet 200mg	Each tablet contains: Hydroxychloroquine sulfate …200mg	Dy.No. 9425 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Not confirmed	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
114.	M/s Unimark Pharmaceuticals Plot No.7-A, Street No.S-7, National Industrial Zone Rawat	Uniquin-H Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9439 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Not confirmed.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**

115.	M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK	Loxiquin Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9953 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	Not confirmed. Application submitted for renewal which is pending.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
116.	M/s CSH Pharmaceuticals Pvt Ltd, 32-Km, Ferozepur Road, Lahore By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Hydroxy Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9315 dated 29/04/2020 Rs. 50,000/- 29-04-2020 Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, Plot No. 578, 579, Sundar Industrial Estate, Lahore GMP of CSH Pharma is required. List of products already approved on contract manufacturing. Number of sections approved for CSH Pharmaceuticals The firm has revised the formulation from uncoated to film coated with out submission of fee.	**Deferred for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.** • **Submission of requisite fee for revision of formulation as per the reference product.**
117.	M/s IPP Pharmaceuticals (Pvt) Saidu Sharif, Swat	IPQUIN Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9955 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	Not confirmed.	**Registration Board referred case to QA & LT Division to conduct GMP inspection of Firm on priority.**

118.	M/s Swat Pharmaceuticals Saidu Sharif, Swat, 19130 Pakistan	Swaquin Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 9957 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	Not Confirmed.	**Registration Board referred case to QA & LT Division to conduct GMP inspection of Firm on priority.**
119.	M/s Orta Labortaories Pvt Ltd, 24 KM Multan Road, Off Defence Road Mohlanwal Lahore	OROQUIN Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate …200mg	Dy.No. 9966 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	Not confirmed.	**Registration Board referred case to QA & LT Division to conduct GMP inspection of Firm on priority.**
120.	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Niaz Baig, Raiwind Road, Lahore	Quindrol Tablet 200mg	Each Tablet Contains: Hydroxychloroquine Sulphate …200mg	Dy.No. 6202 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm has applied for uncoated tablet while the reference product is film coated.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
121.	M/s Obsons Pharmceuticals 209-S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore	Obquine Tablet 200mg	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7167 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection date 18/02/2020 Due to area constraint, the firm was unable to expand or rectify certain manufacturing areas related to installation of machinery/equipments, emergency exits, However	**Registration Board referred the case to QA & LT division for updated status of GMP.**

						\other shortcomings were rectified.	
122.	M/s Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industral Estate, Hattar	Fasquin H 200mg Tablet	Each film coated tablet contains: Hydroxychloroquine sulfate…200mg	Dy.No. 7158 dated 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection report dated 14/11/2017, 15 recommendations were made regarding QC, production, microbiological lab, cleaning validation, stability chambers etc.	**Registration Board referred the case to QA & LT division for updated status of GMP.**

2. Chloroquine Phosphate 250mg Tablet:

Composition:

Each Film Coated Tablet contains:

Chloroquine phosphate……..250mg

International Availability:

Chloroquine phosphate (250mg & 500mg) film coated tablet by M/s Hima Pharma, USFDA Approved. While the product approved in MHRA is uncoated.

Me too:

1. RESOCHIN 250MG TAB by M/s Bayer Karachi, Reg. No. 25

Specifications: USP Specification

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
123.	M/s Medipak Limited 132, Industrial Estate, Kot Lakhpat Lahore	Mediquine Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8913 dated 24/04/2020 Rs. 20,000/-. 23-04-2020 Form 5	As per SRO	Inspection date 11/07/2019, The panel observed that the firm had rectified most of the deficiencies pointed out in inspection dated 13/04/2016,Further improvements would be verified in the next inspection due for renewal of DML.
124.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan	Chlorowin Tablet 250mg	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 8122 dated 20/04/2020 Rs. 20,000/- 15/04/2020 Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-8-2018.
125.	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Hivaquin Tablet 250mg	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 8128 20/04/2020 Rs. 20,000/- 15/04/2020 Form 5	As per SRO	The firm has been granted GMP certificate based upon Evaluation conducted on 06-07-2017.
126.	M/s S.J.G. Fazul Ellahi (Pvt) Ltd., E-46, SITE, Karachi	Rexachlor 250mg Tablet	Each Film Coated Tablet contains: Chloroquine phosphate….250mg	Dy.No. 9144 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 15-01-2020 The firm is recommended grant of GMP certificate.

127.	M/s Medifine Laboratories Pvt Ltd Mirpur	Chloroquine Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8378 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Inspection date 09/11/2018, the panel recommended renewal of DML.
128.	M/s Jawa Pharmaceuticals Pvt Ltd, 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore	Welchlor Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8381 dated 21/04/2020 Rs. 20,000/-. 21-04-2020 Form 5	As per SRO	Inspection date 21/02/2020 & 04/03/2020. Satisfactory level of GMP compliance.
129.	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore	Clor tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg (Chloroquine base)…150mg	Dy.No. 7490 dated 14/04/2020 Rs. 20,000/-. 14-04-2020 Form 5	As per SRO	GMP certificate issued on 21/02/2020 on the basis on inspection conducted on 07/11/2019
130.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura.	Foschlor Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 7084 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 30/05/2019, good level of GMP compliance.
131.	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi	Ephaquine P Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8456 dated 21/04/2020 Rs. 20,000/-. 21-04-2020 Form 5	As per SRO	Inspection date 02/10/2018, Good GMP compliance.
132.	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Karachi	Quivid Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8462 dated 21/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Inspection date 24/12/2019 Overall rating of the firm is good.
133.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Clor Q Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8346 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	GMP certificate issued on 11/07/2019 on the basisi of inspection conducted on 31/07/2019.
134.	M/s Iceberg Pharmaceuticals Pvt Ltd Plot No.144, Nowshera Industrial Estate, Rislapur.	Icequine Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 2923 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 27/03/2019, The panel recommended resumption of production.
135.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi	Chloro-Q Tablet 250mg	Each uncoated tablet contains: Chloroquine phospate….250mg	Dy.No. 8554 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Inspection date 04/03/2020, Good GMP compliance.

136.	M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.	Kofos Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8547 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	GMP certificate issued on 31/07/2019 on the basis of inspection conducted on 03/07/2019.
137.	M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore	Quin Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8542 dated 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	Inspection date 01/03/2019 & 13/05/2019, the panel recommended renewal of DML for Tablet (general) and Capsule (General) sections.
138.	M/s Linz Pharmaceuticals Pvt Ltd, Plot no, 31-G & 31-H Sector 15, Korangi Industrial area, Karachi.	Qlinz Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8326 dated 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Inspection date 09/01/2020, GMP of the firm is rated as Good.
139.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Bquin Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8328 dated 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Inspection date 17/09/2019, Acceptable levelof GMP compliance.
140.	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad	Cloqin Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 7993 dated 17/04/2020 Rs. 20,000/-. 17-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
141.	M/s Relizon Pharmaceuticals, 118 Sunder Industrial Area, Lahore	Requine Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 7984 17/04/2020 Rs. 20,000/- 17-04-2020 Form 5	As per SRO	GMP certificate issued on 20/03/2019 on the basis of inspection conducted on 15/03/2019.
142.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakist	Qoroze Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 5577 06/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Last inspection report dated 30-01-2019 confirms that firm is operating at a Good level of GMP compliance.
143.	M/s Legacy Pharmaceuticals pvt Ltd, 111-A, Industrial Estate Hayatabad Peshawar	Legoquine Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8777 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection date 18/07/2019. The Panel recommended renewal of DML.
144.	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad	Medquin Tablet 250mg	Each tablet contains: Chloroquine phospate….250mg	Dy.No. 7943 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 16/10/2018, the panel recommended renewal of DML.
145.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway,	Mediquine Tablet 250mg	Each tablet contains: Chloroquine phospate….250mg eq to Chloroquine phosphate 155mg	Dy.No. 7946 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	Rs. 1800/- per 30's & 6000/-	Inspection date 19/07/2019, GMP compliance level is rated as good.

	Karachi, Pakistan		base		per 100's.	
146.	M/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi	Malarigood Tablet 250mg	Each tablet contains: Chloroquine phospate….250mg	Dy.No. 7936 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on the basis of inspection conducted on 08/08/2018.
147.	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi	Chloquine Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 7781 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 06/08/2019. The panel recommended resumption of production.
148.	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan.	Arquin Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 7765 dated 16/04/2020 Rs. 20,000/-. 09-04-2020 Form 5	As per SRO	Inspection date 03/01/2019, Good level of GMP compliance.
149.	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Qinphos Tablet 250mg	Each tablet contains: Chloroquine phospate….250mg	Dy.No. 7769 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 02/10/2019.
150.	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad	Siquin 250mg tablet	Each tablet contains: Chloroquine phospate….250mg	Dy.No. 7763 dated 16/04/2020 Rs. 20,000/-. 16-04-2020 Form 5	As per SRO	Date of inspection 18/02/2020 and 20/02/2020, the panel recommended issuance GMP certificate.
151.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi	Chloropex Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 7776 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 08-05-2018."
152.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Quenta Tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 8927 dated 24/04/2020 Rs. 20,000/- 24-04-2020 Form 5	As per SRO	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tablet Gen., Capsule Gen., Liquid Syrup Gen.).
153.	M/s Don valley Pharmaceuticasl (pvt) Ltd. 31-kilometer main ferozpur road Lahore.	Devoquine tablet 250mg (alternate: D-Quin tablet Quinidine tablet)	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No. 7057 Dated 13/04/2020 Rs. 20,000/-	As per SRO	Good compliance of GMP, inspection date 13/02/2020.

154.	M/s Wellborne pharmacchem and biological, Plot # 51/1-52/1 Phase II, Industrial Estate Hattar.	Cqwell 250mg tablet	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No. 6518 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 07/11/2018, Satisfactory level of cGMP compliance.
155.	M/s Arsons Pharmaceutical Industries (pvt) Ltd. 2.5km defence road, off Multan road, Lahore.	Chlorisol 250mg tablet	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy.No. 6537 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection dated 18/09/2019, satisfactory GMP compliance for; • Tablet (General & Psychotropic) • Capsule General • Cream/ointment/Gel (general)
156.	M/s Mafins Pharma, A-5, SITE Super highway Industrial Area, Karachi.	Chloroqueen 250mg tablet	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No.6523 09/04/2020 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection conducted on 24/07/2019, appropriate GMP compliance.
157.	M/s Amarant Pharmaceuticals Private Limited, 158, D. Tore, Gadap road Super Highway, Karachi.	Amaquin 250mg tablet	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No.7157 13/04/2020 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Good GMP compliance, inspection date 24/07/2018.
158.	M/s Paramount Pharmaceuticals , Plot No. 36, Industrial Triangle, Kahuta road, Islamabad.	Teraquine tablet 250mg	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No.5572 13/04/2020 dated 06/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP certificate issued on 28/02/2019.
159.	M/s Pearl Pharmaceuticals, plot # 204, street 1, I-10/3, Islamabad.	Plasochin tablet 250mg	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No.7611 15/04/2020 Rs. 20,000/- Form 5	As per SRO	Satisfactory GMP compliance, inspection date 23/07/2018.
160.	M/s Demont Research Laboratories 20KM, Loharoe-Sharikpur Road, Sheikhupura.	Anti-Covid-250mg tablet	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No.6525 9/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm was last inspected on 23.02.2018 & 26.02.2018, GMP compliance is satisfactory.
161.	M/s Hicon Pharmaceuticals, 131-Industrial Estate Hayatabad.	Oroquine 250mg tablet	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No.6567 9/04/2020 Rs. 20,000/- Form 5	As per SRO	Good level of GMP, inspection date 26/07/2018.
162.	M/s MBL Pharma, B-77-A, HITE, HUB, Balochistan.	MB Chloroquine tablet 250mg	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy. No.7933 16/04/2020 Rs. 20,000/- Form 5	As per SRO	Good GMP compliance, inspection date 28/02/2018.
163.	M/s Linear Pharma, plot NO. 18, street #S-4, National Industrial Zone (RCCI) Rawat Islamabad.	Malaram-P 250mg tablet	Each Film Coated Tablet contains: Chloroquine phosphate…250mg	Dy.No. 6564 dated 09/04/2019 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 30/01/2019, satisfactory level of GMP compliance.
164.	M/s Evolution Pharmaceuticals	Reconil 250mg tablet	Each Tablet contains: Chloroquine	Dy.No. 6533 dated	As per	Inspection date 25/10/2018, As the

	(pvt) ltd Plot # 25&26, street S-3, RCCI, National Industrial zone, Rawat, Islamabad.		phosphate…250mg	09/04/2020 Rs. 20,000/- Form 5	SRO	operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals.
165.	M/s Curatech Pharma Pvt Ltd 35-Km, Multan Road, lahore	Curaquine 250mg Tablet	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7068 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 16/03/2018.
166.	M/s PharmaWise Labs pvt Ltd 25-M. Q-A Industrial Estate, Kot Lakhpat, Lahore	CQ-WISE 250mg Tablet	Each tablet contains: Chloroquine phospate…250mg	Dy.No. 7062 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	GMP certificate issued on 13/12/2019.
167.	M/s Simz Pharmaceuticals Pvt Ltd, Plot No. 574-575, Sundar Industrial Estate, Raiwind Lahore	Chlorosim 250mg Tablet	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7630 dated 15/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017.
168.	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan	Qunia 250mg Tablet	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7166 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 21/11/2017, fair level of GMP compliance.
169.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	Quinco 250mg Tablet	Each tablet contains: Chloroquine phospate…250mg	Dy.No. 6776 10/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance.
170.	M/s Rasco Pharma. 5.5 Km, Raiwind Road, Lahore	Chlorvid 250mg Tablet	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7108 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 04/02/2019, the panel recommended renewal of DML.
171.	M/s Himont Pharmaceuticals Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan	Kinofos 250mg Tablet	Each tablet contains: Chloroquine phospate…250mg	Dy.No. 7115 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	GMP certificate issued based upon evaluation conducted on 04-10-2018 & 05-10-2018.
172.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan	Qlor 250mg Tablet	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7485 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued in 25/04/2019 on the basis on inspection conducted on 07/03/2019.
173.	M/s Scilife Pharma Pvt Ltd.Plot # FD-	C Quin Tablets	Each film coated tablet contains:	Dy.No. 7310 14/04/2020	As per SRO	10-07-2018./ GMP compliance level is

	57/58-A2, Korangi Creek Industrial Park, Karachi	250mg	Chloroquine phospate…250mg	Rs. 20,000/- 14-04-2020 Form 5		rated as GOOD
174.	M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Isalamabad	Daviquin 200mg Tablet	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7263 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on the basis of inspection conducted on 01-10-2019
175.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Eniqor Tablets 250mg	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 6790 10/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	GMP certificate issued on 21/05/2019 on the basisi of inspection conducted on 23/04/2019.
176.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	N-CQ Tablets 250mg	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7081 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance.
177.	M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad	Mariquine Tablet 250mg	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7256 dated 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Good level of GMP compliance, inspection date 21/02/2019.
178.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi	CLQ Tablet 250mg	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7116 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel recommended renewal of DML, inspection report 26/02/2019.
179.	M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	CQP Tablet 250mg	Each tablet contains: Chloroquine phospate…250mg	Dy.No. 7147 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Good compliance of GMP, inspection date 26/12/2019.
180.	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Quick Tablet 250mg	Each tablet contains: Chloroquine phospate…250mg	Dy.No. 6752 10/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel recommended renewal of DML, inspection date 20/04/2018.
181.	M/s Hi-Med Pharmaceuticals.208 C Sunder Industrial Estate, Lahore	Medchlor Tablet 250mg	Each tablet contains: Chloroquine phospate…250mg	Dy.No. 7126 13/04/2020 Rs. 20,000/- Form 5	As per SRO	DML was issued on 13/06/2018.
182.	M/s British Pharmaceuticals Pvt Ltd, 23-KM, Shekhupura Road, Lahore	Brichlor P 250mg Tablet	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7133 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel recommended grant of DML, inspection date 19/08/2019 & 27/12/2019.
183.	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir	Lorquine Tablet 250mg	Each film coated tablet contains: Chloroquine phospate…250mg	Dy.No. 7306 dated 14/04/2020 Rs. 20,000/- Form 5	As per SRO	As of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. Inspection date 22/02/2019.

184.	M/s N.S Pharma, Plot # 576-577 Sundar Industrial estate Lahore.	Quin-NS 250mg tablet	Each tablet contains: Chloroquine phospate…250mg	Dy.No. 6272 08/04/2020 Rs. 20,000/- Form 5	As per SRO	DML issued on 14/09/2017.
185.	M/s Danas Pharmaceuticals Pvt Ltd, 312, Industrial Triangle, Kahuta Road, Islamabad.	Danque-P tablet 250mg	Each film coated tablet contains: Chloroquine phospate….250mg	Dy.No. 6530 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines.
186.	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1, S.I.T.E, Super Highway, Karachi	Baxaquine 250mg Tablet	Each film coated Tablet Contains: Chloroquine Phosphate Eq. to Chloroquine…250mg	Dy.No. 9429 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Inspection date 21/09/2019, satisfactory level of GMP compliance.
187.	M/s Aventek Pharmaceuticals Pvt Ltd, 44-C, Sunder Industrial Estate, Lahore	Avequin 250mg Tablet	Each tablet contains: Chlroquine Phosphate which is Eq. to 155mg of Chloroquine Base…250mg	Dy.No. 9734 dated 04/05/2020 Rs.20,000/- 04-05-2020 Form 5	As per SRO	GMP certificate issued on 03/04/2019 on the basis of inspection conducted on 01/01/2019.
188.	M/s Schazoo Zaka Pvt Ltd. Lahore Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura	Qunizak 250mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate Eq. to Chloroquine..150mg	Dy.No. 9711 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	Rs. 2.2/- per tablet	Inspection date 30/05/2019, good level of GMP compliance.
189.	M/s Fedro Pharmaceuticals Lab Pvt Limited. 149-Industrial Estate, Hayatabad, Peshawar	Fequin 250mg Tablet	Each Film Coated Tablet Contains: Chlroquine Phosphate which is Eq. to 155mg of Chloroquine Base …..…250mg	Dy.No.9576 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Inspection date 26/06/2018. Satisfactory level of GMP compliance.
190.	M/s Mediceena Pharma Pvt Ltd. 27 Km, Main Raiwind Road, Lahore, Pakistan	M.Quin 250mg Tablet	Each Tablet Contains: Chloroquine Phosphate…250mg	Dy.No.9569 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP certificate issued on 27/09/2019 based on inspection conducted on 24/09/2019.
191.	M/s Sante Pvt Ltd A-97 SITE Super Highway Karachi.	Sanphos 250mg tablet	Each Tablet Contains: Chloroquine Phosphate…250mg	Dy.No. 9447 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Good compliance of GMP, inspection date 07/07/2019.
192.	M/s Zephyr Pharmatec Pvt Ltd. Plot No. A-39, S.I.T.E II, Super Highway, Karachi.	Chlorzep 250mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…250mg	Dy.No.9422 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Last inspection report conducted on 18-07-2017 concluding good level of GMP compliance.
193.	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate,	Fh-Chlor 250mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…250mg	Dy.No.9319 29/04/2020 Rs.20,000/- 29-04-2020	As per SRO	GMP inspection dated 03-10-2018, the firm is maintaining satisfactory level of cGMP.

	Haripur.			Form 5		
194.	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi	Archin 250mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate …250mg	Dy.No.9303 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP certificate issued on 11/03/2019 on the basis of inspection conducted on 05/03/2019.
195.	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi	Quintel 250mg tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…250mg	Dy.No. 9222 28/04/2020 Rs. 20,000/- 28-04-2020 Form 5	As per SRO	Inspection date 31-01-2018 the firm is operating at fair level of cGMP compliance as of today.
196.	M/s Faas Pharmaceuticals (Pvt.) Ltd. F-748/L, S.I.T.E Karachi, Pakistan	Chlorofaas 250mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…250mg	Dy.No.9005 dated 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	Routine GMP inspection conducted on 14-07-2017 concluded that the current level of compliance is rated satisfactory
197.	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore	Koved 250mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…250mg	Dy.No.8989 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	Last GMP inspection was conducted on 16-01-2018 and GMP certificate was granted.
198.	Aneeb Pharmaceuticals Pvt Ltd, 24-Km, Badian Road, Lahore Cantt.	AIQ 250mg tablet	Each film coated tablet contains: Chloroquine phosphate …….. 250mg	Dy. No.8111 dated 20/04/2020 Rs. 20,000/- Form 5	Rs8.5 per tab, 3 x 10's.	Panel inspection dated 29-10-2018 recommended renewal of DML
199.	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.	Arquen 250mg tablet	Each film coated tablet contains: Chloroquine phosphate …….. 250mg	Dy. No. 9014 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 28-02-2019 recommended renewal of DML.
200.	M/s Trigon Pharmaceuticals (pvt) Limited 8th KM Thokar Raiwind Road, Lahore	Quinlor-p 250mg tablet	Each film coated tablet contains: Chloroquine phosphate …….. 250mg	Dy. No. 6203 dated 08/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 25/03/2019, satisfactory level of GMP complianc. Liquid injectable (vial & Ampoule) section available.
201.	M/s Nenza Pharmaceuticals Pvt Ltd. 33-A, Industrial Estate, Hayatabad, Peshawar.	Quinen 250mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…250mg	Dy.No. 9310 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 26-09-2018, overall GMP compliance of the firm is satisfactory
Decision: Registration Board approved registration of above applications from Serial No. 123 to 201. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
202.	Applicatn: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore MFG By: M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Cloro 250mg Tablets	Each film coated Tablet Contains: Chloroquine Phosphate …250mg	Dy.No. 9314 dated 29/04/2020 Rs. 50,000/- 29-04-2020 Form 5	As per SRO	GMP certificate issued to M/s Medisave pharmaceuticals on 22/01/2020 on the basis of inspection conducted on 02/10/2019.	**Deferred for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Updated status of GMP from QA & LT Division for inspection of M/s CSH Pharma on priority.**
203.	M/s Biorex Pharmaceuticasl plot No. 251-A, Industrial Triangle Kahuta Road, Islamabad.	Chlorrex 250mg tablet	Each Tablet contains: Chloroquine phosphate……250mg	Dy. No.7619 dated 15/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report is older than 3 years.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
204.	M/s Novae Pharmaceuticals. 123, Phase 5, Industrial Estate, Hattar, Pakistan	Novaquin Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…250 mg	Dy.No. 6223 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Inspection report not provided.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
205.	M/s Synchro Pharmaceuticals. 77-Industrial Estate, Kot Lakhpat, Lahore	Qusyn 250mg Tablet	Each Tablet Contains: Chloroquine Phosphate…250 mg	Dy.No. 9424 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Inspection report is not provided.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
206.	M/s Obsons Pharmceuticals 209-S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore	Obschlor Tablet 250mg	Each film coated tablet contains: Chloroquine phospate…250 mg	Dy.No. 7172 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection date 18/02/2020 Due to area constraint, the firm was unable to expand or rectify certain manufacturing areas related to installation of machinery/equipments, emergency	**Registration Board referred the case to QA & LT Division for updated status of GMP.**

						exits, However; other shortcomings were rectified.	
207.	Applicatn: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore MFG By: M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Cloro 250mg Tablets	Each film coated Tablet Contains: Chloroquine Phosphate…250 mg	Dy.No. 9314 dated 29/04/2020 Rs. 50,000/- 29-04-2020 Form 5	As per SRO	GMP certificate issued to M/s Medisave pharmaceuticals on 22/01/2020 on the basis of inspection conducted on 02/10/2019.	**Deferred for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Updated status of GMP from QA & LT Division for inspection of M/s CSH Pharma on priority.**
208.	M/s Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industral Estate, Hattar	Quin Gen Tablet 250mg	Each film coated tablet contains: Chloroquine phospate…250 mg	Dy.No. 7161 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	**Inspection report** dated 14/11/2017, 15 recommendations were made regarding QC, production, microbiological lab, cleaning validation, stability chambers etc.	Referred to QA Division for updated GMP

3. Chloroquine Phosphate 500mg Tablet:

Composition:

Each Film Coated Tablet contains:
Chloroquine phosphate……..500mg

International Availability:

Chloroquine phosphate (250mg & 500mg) film coated tablet by M/s Hima Pharma, USFDA Approved. However, the product approved in MHRA is uncoated.

Me too: **N**ot registered

Specifications: USP Specification

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
209.	M/s Macter International Limited, F-216, S.I.T.E, Karachi	Macvid 500mg tablet	Each Film Coated Tablet contains: Chloroquine phosphate…..500mg	Dy.No. 5897 dated 07/04/2020 Rs. 20,000/- + 30,000/- 20/04/2020 Form 5D	As per SRO	Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP.
210.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Quinco 500mg Tablet	Each tablet contains: Chloroquine phospate…500mg	Dy.No. 6777 10/04/2020 Rs. 20,000/- 09-04-2020 Rs. 30,000/- (vide challan # 2032235) 29/04/2020 Form 5D	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance.
211.	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan	Arquin Tablet 500mg	Each film coated tablet contains: Chloroquine phospate….500mg	Dy.No. 7766 16/04/2020 Rs. 50,000/-. 09-04-2020 Form 5D	As per SRO	Inspection date 03/01/2019, Good level of GMP compliance.
212.	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi	Ephaquine P Tablet 500mg	Each film coated tablet contains: Chloroquine phospate….500mg	Dy.No. 8919 24/04/2020 Rs. 50,000/-. 23-04-2020 Form 5D	As per SRO	Inspection date 02/10/2018, Good GMP.
213.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	N-CQ Tablets 500mg	Each film coated tablet contains: Chloroquine phospate…500mg	Dy.No. 8324 20/04/2020 Rs. 50,000/- 20-04-2020 Form 5D	As per SRO	Inspection date 31/12/2018 & 28/02/2019, fair level of GP compliance.
214.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Clor Q Tablet 500mg	Each film coated tablet contains: Chloroquine phospate….500mg	Dy.No. 8348 dated 20/04/2020 Rs. 50,000/- 20-04-2020 Form 5D	As per SRO	GMP certificate issued on 11/07/2019 on the basis of inspection conducted on 31/07/2019.
215.	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1,	Quivid Tablet 500mg	Each film coated tablet contains: Chloroquine phospate….500mg	Dy.No. 8463 21/04/2020 Rs. 20,000/- Rs. 30,000/-	As per SRO	Inspection date 24/12/2019, the panel recommended renewal of DML.

	PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Karachi			(vide challan # 1920044) 29/04/2020 Form 5D		
216.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Amaquin 500mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…500mg	Dy.No. 9455 30/04/2020 Rs. 50,000/- 30-04-2020 Form 5D	As per SRO	Good GMP compliance, inspection date 24/07/2018.
217.	M/s Sante Pvt Ltd. A-97, S.I.T.E Super Highway, Karachi, Pakistan	Sanphos 500mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…500mg	Dy.No. 9448 30/04/2020 Rs. 50,000/- 30-04-2020 Form 5D	As per SRO	Good compliance of GMP, inspection date 07/07/2019.
218.	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	MHQ 500mg tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…500mg	Dy.No. 9217 28/04/2020 Rs. 50,000/- 28-04-2020 Form 5D	As per SRO	The firm was granted New Drug Manufacturing License based on inspection dated 5-12-2017.
219.	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Quiclor 500mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…500mg	Dy.No. 9217 dated 27/04/2020 Rs. 50,000/- 27-04-2020 Form 5D	As per SRO	The firm was operating at good level of compliance with GMP as per inspection report dated 06/12/2018.
220.	M/s Bio-Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore	CLOKIT 500mg Tablet	Each tablet contains: Chloroquine phosphate….500mg	Dy.No. 9123 28/04/2020 Rs. 20,000/- 30,000/- 30-04-2020 (Deposit slip # 2032460) Form 5D	As per PRC	The firm is granted GMP certificate based on inspection dated 16-08-2018.
221.	M/s Hamaz Pharmaceuticals (pvt) ltd 13-KM Bosan Road, Lutfabad, Multan.	Phosoquin Tablet 500mg	Each Film Coated Tablet contains: Chloroquine phosphate …. 500mg	Dy. No.5915 07/04/2020 dated 07/04/2020 Rs. 20,000/- + Rs.30,000/- vide challan No.2041195 dated 5/06/2020. Form 5D	As per SRO	GMP certificate issued on 06/11/2019.
Decision: Registration Board approved registration of above applications from Serial No. 209 to 221. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
222.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dyclor 500mg Tablet	Each film coated tablet contains: Chloroquine phosphate …500mg	Dy.No.7280 dated 14/04/2020Rs. 20,000/- 13-04-2020 Form 5	As per SRO	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Form 5D and differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
223.	M/s Simz Pharmaceuticals Pvt Ltd Plot No.574-575, Sundar Industrial Estate, Raiwind Lahore	Chlorosim 500mg Tablet	Each film coated tablet contains: Chloroquine phosphate …500mg	Dy.No.7631 dated 15/04/2020Rs. 20,000/- 15-04-2020 Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017. Form 5D along with differential fee of 30,000/0 is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
224.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Quenta Tablet 500mg	Each film coated tablet contains: Chloroquine phosphate ….500mg	Dy.No.8928 dated 24/04/2020Rs. 20,000/- 24-04-2020 Form 5	As per SRO	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tabklet General, Capsule General, Liquid Syrup General). Form 5D along with differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
225.	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi	Chloquine Tablet 500mg	Each film coated tablet contains: Chloroquine phosphate …….….500mg	Dy.No.7779 dated 16/04/2020Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 06/08/2019. The panel recommended resumption of production Form 5D along with differential fee of Rs. 30,000/- is required..	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
226.	M/s The Searle Company Ltd.F-319, S.I.T.E, Karachi	Qoroze Tablet 500mg	Each film coated tablet contains: Chloroquine phosphate ….500mg	Dy.No.8845 dated 23/04/2020Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Last inspection report dated 30-01-2019 confirms that firm is operating at a Good level of GMP compliance. Form 5D along with differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**

227.	M/s Obsons Pharmceuticals 209-S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore	Obschlor DS Tablet 500mg	Each film coated tablet contains: Chloroquine phosphate ….500mg	Dy.No. 7168 dated 13/04/2020Rs. 20,000/- Form 5	As per SRO	Inspection date 18/02/2020 Due to area constraint, the firm was **unable to expand or rectify** certain manufacturing areas related to installation of machinery/equipments, emergency exits, However \other shortcomings were rectified. Form 5D along with the differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/- and GMP status**
228.	M/s BJ Pharmaceutic als. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore	Chloroquir e tablet	Each tablet contains: Chloroquine as phosphate …500mg	Dy.No.7265 dated 14/04/2020Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Firm has required equipment/machinery, HVAC system and qualified staff, fir showed good intention to further improvements in future. Overall hygienic condition of the firm is satisfactory at the time of inspection. Inspection date 15/01/2020. Form 5D along with differential fee is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/-**
229.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	N-QC tablet	Each tablet contains: Chloroquine phosphate…500 mg	Dy.No.7082 dated 13/04/2020Rs. 20,000/- 13-04-2020 Form 5		Last inspection report dated 18/07/2017, fair level of GMP compliance. Form 5D along with differential fee is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/**
230.	M/s Curatech Pharma Pvt Ltd. 35-Km Multan Road, Lahore.	Caraquine 500mg Tablet	Each Tablet Contains: Chloroquine Phosphate …500mg	Dy.No.8376 21/04/2020Rs. 20,000/- 21-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 16/03/2018. Form 5D along with the differential fee is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/**
231.	M/s Pharmevo Pvt Ltd. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Evoquin Tablet 500mg	Each Film Coated Tablet Contains: Chloroquine Phosphate …500mg	Dy.No.5874 dated 07/04/2020Rs. 20,000/- 06-04-2020 Form 5	As per SRO		**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/**

232.	M/s Harmann Pharmaceutical Laboratories (Pvt.) Ltd, 16-Km Multan Road, Lahore	Citaquine DS Tablet	Each Film Coated Tablet contains: Chloroquine phosphate……..500mg	Dy.No. 9126 dated 28/04/2020 Rs. 20,000/- Form 5	As per PRC	30,000/- fee alongwith Fom-5D is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/**
233.	M/s Harmann Pharmaceutical Laboratories (Pvt.) Ltd, 16-Km Multan Road, Lahore	Citaquine DS Tablet	Each Film Coated Tablet contains: Chloroquine phosphate……..500mg	Dy.No.9126 dated 28/04/2020 Rs. 20,000/- Form 5	As per PRC	30,000/- fee alongwith Fom-5D is required.	**Deferred for submission of Form 5D along with the submission of Differential fee of Rs. 30,000/**

4. Chloroquine Phosphate Syrup:

Composition:

Each 5ml contains:

Chloroquine Phosphate eq. to Chloroquine …… 50mg

International Availability: Malarivon Syrup 50mg /5ml approved by MHRA of UK

Me too: Malaquin syrup of M/s Rakaposhi Pharmaceutical Ltd., Peshawar having registration no. 034687

Specifications: USP

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
234.	M/s Pliva Pakistan (pvt) ltd. B-77, H.I.T.E, Balochistan.	Chloroquine Syrup 50mg/5ml	Each 5ml contains: Chloroquine Phosphate eq. to Chloroquine… 50mg	Dy.No. 7137 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Renewal of DML was granted vide letter No.F.4-1/89-Lic(Vol-V) dated 7th Nov., 2019.
235.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore	N-CQ syrup	Each 5ml contains: Chloroquine as phosphate …50mg	Dy.No. 7078 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance.
236.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi.	CLQ syrup	Each 5ml contains: Chloroquine as phosphate …50mg	Dy.No. 7117 13/04/2020. Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection report 26/02/2019.
237.	M/s British Pharmaceuticals Pvt Ltd, 23-KM, Shekhupura Road, lahore	Brichlor syrup	Each 5ml contains: Chloroquine as phosphate …50mg	Dy.No. 7132 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The panel recommended grant of DML, inspection date 19/8/2019 & 27/12/2019
238.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Eniqor Syrup 50mg/5ml	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine Base…50mg	Dy.No. 6787 10/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/04/2019.
239.	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir	Lorquine-50 Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 7304 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	As of today the firm's facility is suitable to carry out manufacturing & testing of pharmaceuticals. Inspection date 22/2/2019

240.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Quenta 50mg/5ml Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 8926 dated 24/04/2020 Rs. 20,000/- 24-04-2020 Form 5	As per SRO	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tabklet General, Capsule General, Liquid Syrup General).
241.	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad	Medquin 50mg/5ml Syrup	Each 5ml Contains: Chloroquine Phosphate…50mg	Dy.No. 7941 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 16/10/2018, the panel recommended renewal of DML.
242.	M/s Heal Pharmaceuticals Pvt Ltd. W-33, Industrial Area, Hayatabad Peshawar	Healquine-P 50mg/5ml Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 7926 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Satisfactory level of GMP, inspection date 08/11/2019.
243.	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi	Chloquine Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 7780 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 06/08/2019. The panel recommended resumption of production.
244.	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Winquine Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 7795 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017.
245.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan	Qoroze 50mg/5ml Syrup	Each 5ml Contains: Chloroquine as Phosphate…50mg	Dy.No. 8846 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	GMP certificate issued on 22/06/2019 on the basis of inspection 11/07/2019.
246.	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore	Macquine 50mg/5ml Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 8770 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	GMP Certificate issued on 15-03-2018.
247.	M/s Lawrence Pharma Pvt Ltd. 10.5 Km, Sheikhupura Road, Lahore	Larquine Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine Base…50mg	Dy.No. 9950 05/05/2020 Rs. 20,000/- 04-05-2020 Form 5	Rs. 35/- per 60ml & Rs.115/- per 450ml	The panel observed that most of the shortcomings which were pointed out during last inspection had been addressed and found compliant, however, production of the steroidal injectable products will remain stopped. Inspection date 23/02/2018.
248.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway,	Chlorowin 50mg/5ml Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 9720 dated 04/05/2020 Rs. 20,000/-	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-

	Phase-II, Karachi, Pakistan			04-05-2020 Form 5		2018.
249.	M/s Fedro Pharmaceuticals Lab Pvt Ltd. 149-Industrial Estate, Hayatabad, Peshawar	Fequin-cp 50mg/5ml Syrup	Each 5ml Contains: Chloroquine as Chloroquine Phosphate…50mg	Dy.No. 9577 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Inspection date 26/06/2018. Satisfactory level of GMP compliance.
250.	M/s Mediceena Pharma Pvt Ltd. 27 Km, Main Raiwind Road, Lahore, Pakistan	M.Quin Syrup 50mg/5ml	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine Base…50mg	Dy.No. 9568 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP certificate issued on 27/09/2019 based on the inspection conducted on 24/09/2019
251.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Amaquin 50mg/5ml Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 9454 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Good GMP compliance, inspection date 24/07/2018.
252.	M/s Zephyr Pharmatec Pvt Ltd. Plot No. A-39, S.I.T.E II, Super Highway, Karachi.	Chlorzep 50mg/5ml Syrup	Each 5ml Contains: Chloroquine Phosphate Eq. to Chloroquine…50mg	Dy.No. 9421 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Last inspection report conducted on 18-07-2017 concluding good level of GMP compliance.
253.	M/s Ali Industries. 239-C Sundar Industrial Estate, Raiwind Road, Lahore	Aliquine 50mg/5ml Syrup	Each 5ml Contains: Chloroquine as Phosphate… 50mg	Dy.No. 9949 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	Inspection date 02/07/2018, the firm has maintained conformance to GMP compliance.
254.	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.	Arquen 50mg/5ml Syrup	Each 5ml contains: Chloroquine phosphate eq. Chloroquine ….. 50mg	Dy.No. 9013 27-04-2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 28-02-2019 recommended renewal of DML.
255.	M/s Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd, TBIC Building - 1, PCSIR Laboratories complex, Shahrah-e-Dr. salim-uz-Zaman Siddique, off university Road, Karachi	QUIVID 50mg/5ml Syrup	Each 5ml contains: Chloroquine Phosphate eq. to Chloroquine…50mg	Dy.No. 8460 dated 21/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel dated 04-10-2019 recommends for renewal of DML.
256.	M/s EPHARM Laboratories, A-40, Road No, SITE Super Highway Industrial area, North Karachi	EPHAQUIN E-P 50mg/5ml Syrup	Each 5ml contains: Chloroquine Phosphate eq. to Chloroquine …… 50mg	Dy.No.8454 dated 21/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted o 12-09-2019, GMP is rated as Good.
257.	M/s Radiant Pharma (Pvt.) Ltd, 43-E Sundar Industrial Estate, Lahore	Clor-Q 50mg/5ml Syrup	Each 5ml contains: Chloroquine Phosphate eq. to Chloroquine …… 50mg	Dy.No.8344 dated 21/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm was granted GMP certificate based on inspection dated 31-07-2018.

258.	M/s S.J.G. Fazul Ellahi (Pvt) Ltd., E-46, SITE, Karachi	Rexachlor 50mg/5ml Syrup	Each 5ml contains: Chloroquine Phosphate eq. to Chloroquine … 50mg	Dy.No.9143 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 15-01-2020 The firm is recommended grant of GMP certificate.
259.	M/s Pearl Pharmaceuticals, Plot # 204, Street 1, I-10/13, Islamabad	PLASOCHIN 50mg/5ml Syrup	Each 5ml contains: Chloroquine Phosphate eq. to Chloroquine … 50mg	Dy.No.8598 22/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 23-07-2018 firm is found satisfactory compliance with GMP guidelines.
260.	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Hivaquin Syrup 50mg/5ml	Each 5ml contains: Chloroquine phospate….50mg	Dy.No.8127 20/04/2020 Rs. 20,000/- 15/04/2020 Form 5	As per SRO	The firm has been granted GMP certificate based upon evaluation conducted on 06-7-2017.

Decision: Registration Board approved registration of above applications from Serial No. 234 to 260. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
261.	M/s BJ Pharmaceuticals. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore	Chloroquine suspension	Each 5ml suspension contains: Chloroquine as phosphate …50mg	Dy.No. 7264 dated 14/04/2020Rs. 20,000/- dated 14-04-2020 Form 5	As per SRO	Firm has required equipment/ machinery, HVAC system and qualified staff, fir showed good intention to further improvements in future. Overall hygienic condition of the firm is satisfactory at the time of inspection. Inspection date 15/01/2020. The reference is syrup.	**Deferred for submission of evidence of approval of applied formulation as "suspension" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**

5. Chloroquine Phosphate 250mg/5ml ampoule:

Composition:

Each 5ml ampoule contains:

Chloroquine Phosphate eq. to Chloroquine …… 250mg

International Availability: Germany Approved.

Me too: could not be confirmed/not registered

Specifications: Innovator's

Applications for local manufacturing:

262.	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore	Amquine 250mg/5ml Injection	Each 5ml Contains: Chloroquine Phosphate…250mg	Dy.No. 9415 30/04/2020 Rs. 50,000/- 30-04-2020 Form 5D	As per SRO	Inspection date 19/03/2020. Satisfactory level of GMP compliance.

Registration Board approved registration of above application at Serial No. 262. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its

general decision recorded above.

6. Lopinavir/Ritonavir (200mg/50mg) Tablet:

Composition:

Each film Coated Tablet contains:
Lopinavir……..200mg
Ritonavir……..50mg

International Availability:

Kaletra (200mg/50mg & 100mg/25mg) Film coated tablet by M/s Abbvie, USFDA Approved.

Me too:

1. Lopinavir/Ritonavir Tablets 200mg/50mg By M/S Scitech Health (Private) LIMITED, Reg No. 62250

Specifications: USP Specification

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
263.	M/s Trigon Pharmaceuticals (pvt) Limited 8th KM Thokar Raiwind Road, Lahore	Loprit 200mg/50mg tablet	Each film Coated Tablet contains: Lopinavir……200mg Ritonavir…….50mg	Dy. No.6205 dated 08/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 25/03/2019, satisfactory level of GMP complianc.
264.	M/s Wellborne pharmacchem and biological, Plot # 51/1-52/1 Phase II, Industrial Estate Hattar.	Lopiwell 200mg/50mg tablet	Each film Coated Tablet contains: Lopinavir……200mg Ritonavir…….50mg	Dy. No. 6521 Dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 07/11/2018, Satisfactory level of cGMP compliance.
265.	M/s. Wilson's Pharmaceuticals, 387-388, I-9, Sector, Industrial Area, Islamabad.	Divir tablets 200mg/50mg	Each film Coated Tablet contains: Lopinavir……200mg Ritonavir…….50mg	Dy. No. 6526 09/04/2020 Rs. 20,000/- Form 5	As per SRO	24-01-2018 Good level of CGMP Compliance.
266.	M/s Mafins Pharma, A-5, SITE Super highway Industrial Area, Karachi.	Telera 200mg/50mg tablet	Each film Coated Tablet contains: Lopinavir……200mg Ritonavir…….50mg	Dy. No.7283 14/04/2020 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection conducted on 24/07/2019, appropriate GMP compliance.
267.	M/s Amarant Pharmaceuticals Private Limited, 158, D. Tore, Gadap road Super Highway, Karachi.	Ampivir 200mg/50mg tablet	Each film Coated Tablet contains: Lopinavir……200mg Ritonavir…….50mg	Dy. No.7155 13/04/2020 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Good GMP compliance, inspection date 24/07/2018.
268.	M/s Genetics Pharmacetuicasl pvt limited, 539-A, Sundar Industrial Estate, Raiwind, Lahore.	Dualvir 200mg/50mg tablet	Each film Coated Tablet contains: Lopinavir……200mg Ritonavir…….50mg	Dy.No. 6304 dated 08/04/2020 Rs. 50,000/- Form 5D	As per SRO	Last inspection report dated 29/03/2019, firm was operation at satisfactory level of GMP compliance.
269.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.	Scotra tablet 200mg/50mg	Each film Coated Tablet contains: Lopinavir……200mg Ritonavir…….50mg	Dy. No.6558 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel recommended grant of GMP certificate, inspection date 10/10/2018 & 17/10/2018.

270.	M/s Vega Pharmaceuticals (Pvt.) Ltd., Plot No.4, Pharma city Sundar, 30 Km Multan Road Lahore.	LORITOVIR FORTE 200/50 Tablet	Each film Coated Tablet contains: Lopinavir…..200mg Ritonavir…..50mg	Dy.No. 9130 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection dated 21-03-2019 the firm is considered to be operating at fair level of GMP compliance.
271.	M/s Getz Pharma (Pvt) Ltd, 29-30/27, Korangi Industrial Area, Karachi	LONAVIR Tablet 200mg + 50mg	Each film Coated Tablet contains: Lopinavir…..200mg Ritonavir…..50mg	Dy.No. 9003 27/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm is granted GMP certificate based on inspection conducted on 07-01-2019.
272.	M/s LINZ Pharmaceuticals (Pvt.) Ltd, Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area, Karachi	LOPIR 200mg /50mg Tablet	Each film Coated Tablet contains: Lopinavir…..200mg Ritonavir……50mg	Dy.No. 9132 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection dated 09-01-2020, the GMP of the firm is rated GOOD.
273.	M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221,222 and 223 Sector 23, Korangi Industrial Area, Karachi	LORIP 200mg /50mg Tablet	Each film Coated Tablet contains: Lopinavir…..200mg Ritonavir…..50mg	Dy.No. 9137 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 17-09-2019 The firm is operating at acceptable level of compliance with GMP.
274.	M/s ATCO Laboratories Ltd., B-18, SITE, Karachi	ATCOVIR Tablet 200mg + 50mg	Each film Coated Tablet contains: Lopinavir….200mg Ritonavir…..50mg	Dy.No. 9121 28/04/2020 Rs. 50,000/- Form 5	As per SRO	Inspection dated 09-07-2019 Overall GMP of the firm is rated as Good.
275.	M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Lipovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8124 20/04/2020 Rs. 20,000/-. 20-04-2020 Form 5	As per SRO	GMP inspection dated 26-12-2019 concludes that the current GMP compliance level of the firm is rated as Good.
276.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan	Ritovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8119 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018.
277.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan	Biolor Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 6764 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Inspection date 25/11/2019 & 12/12/2019, the panel recommended renewal of DML.
278.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Lopirid Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7294 14/04/2020 Rs. 50,000/- 14-04-2020 Form 5D	As per SRO	Inspection date 11/02/2019, the panel recommended issuance of GMP ceritifcate.
279.	M/s Global Pharmaceuticals Pvt Ltd, Plot#204-205, Industrial Triangle, Kahuta Road, Islamabad	Lopirit Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7297 14/04/2020 Rs. 50,000/- 13-04-2020 Form 5D	As per SRO	Inspection date 26/12/2018, panel recommended renewal of DML.
280.	M/s Fynk Pharmaceuticals, 19km G.T. Road Kalashah Kaku, Lahore, Pakistan	LoritTablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7162 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 21/11/2017, fair level of GMP compliance.

281.	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir	L-lonavir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7302 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	As of today the firm's facility is suitable to carry out manufacturing & testing of pharmaceuticals. Inspection date 22/2/2019
282.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Lopir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 6771 dated 10/04/2020 Rs. 50,000/- 09-04-2020 Form 5D	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance. Form 5D and differential fee Rs. 30,000/- is required.
283.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi	Rilovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7312 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 10-07-2018 GMP compliance level is rated as GOOD
284.	M/s Venus Pharma. 23 km, Multan Road, Lahore	Venovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7275 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 28/11/2019 on the basis of inspection conducted on 05/09/2019.
285.	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad	Rilovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7573 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Satisfactory GMP compliance, inspection date 23/07/2018.
286.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan	Rotavir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7484 14/04/2020 Rs. 50,000/- 14-04-2020 Form 5D	As per SRO	GMP certificate issued in 25/04/2019 on the basis on inspection conducted on 07/03/2019.
287.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi	Ritovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7113 13/04/2020 Rs. 20,000/-. 13-04-2020 Form 5	As per SRO	25-9-2019 Panel recommended the renewal of DML.
288.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Rilotop Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7282 14/04/2020 Rs. 20,000/-. 13-04-2020 Form 5	As per SRO	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to firm.
289.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan	Lorgen Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 10/04/2020 Rs. 20,000/-. 10-04-2020 Form 5	As per SRO	Inspection date 25/11/2019 & 12/12/2019, the panel recommended renewal of DML.
290.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Reetovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7626 15/04/2020 Rs. 20,000/-. 14-04-2020 Form 5	As per SRO	Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
291.	M/s Simz Pharmaceuticals Pvt Ltd., Plot No.574-575, Sundar Industrial Estate, Raiwind Lahore	Kalet DS Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7633 15/04/2020 Rs. 20,000/-. 15-04-2020 Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017.

292.	M/s Curatech Pharma Pvt Ltd., 35-Km, Multan Road, lahore	Kalet DS Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7066 13/04/2020 Rs. 20,000/-. 13-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 16/03/2018.
293.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Lopi-Rito Tablet 200/50mg	Each tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7077 13/04/2020 Rs. 50,000/-. 13-04-2020 Form 5D	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance.
294.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Ritopin Tablet 200/50mg	Each tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 6786 10/04/2020 Rs. 50,000/-. 08-04-2020 Form 5D	As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/04/2019.
295.	M/s PharmaWise Labs pvt Ltd 25-M.Q-A Industrial Estate, Kot Lakhpat, Lahore	Lopinawise plus Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7063 13/04/2020 Rs. 20,000/-. 13-04-2020 Form 5	As per SRO	Last inspection report dated 16/10/2019, firm is GMP compliant.
296.	M/s Himont Pharmaceuticals Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan	Lopivir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7786 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued based upon evaluation conducted on 04-10-2018 & 05-10-2018.
297.	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan	Astevir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7787 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 13/11/2018, Good GMP compliance.
298.	M/s Nimrall Laboratories Plot 24, Street SS-3, Rawat, Industrial Area, Islamabad	Lopivir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7791 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	The panel recommended resumption of production, inspection date17/07/2019 & 24/07/2019.
299.	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Ritomed Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7771 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 02/10/2019.
300.	M/s Palpex Pharmaceuticals Pvt Ltd.FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi	Paletra Capsule 200/50mg	Each capsule contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7773 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 08-05-2018."
301.	M/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi	Protogood Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7939 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on the basis of inspection conducted on 08/08/2018.
302.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Noletra Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8923 24/04/2020 Rs. 20,000/-. 24-04-2020 Form 5	As per SRO	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tablet General, Capsule General, Liquid

						Syrup General).
303.	M/s Epharm Laboratories.A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi	Lorivir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8917 24/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection conducted o 12-09-2019, GMP is rated as Good.
304.	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Hiletra Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8533 22/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	GMP certificate based upon evaluation conducted on 6-7-2017.
305.	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Coronil Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7918 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 27/07/2018 on the basis of inspection conducted on 11/07/2018.
306.	M/s Shawan Pharmaceuticals, Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi	Lopirit Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8553 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	Inspection date 04/03/2020, Good GMP compliance.
307.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Tulip Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8343 20/04/2020 Rs. 50,000/- 20-04-2020 Form 5D	As per SRO	GMP ceritificate issued on 11/07/2019 on the basis of inspection conducted on 31/07/2018.
308.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan	Lonvir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No.8117 20/04/2020 Rs.20,000/- 20-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection report 26/02/2019.
309.	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi	Lonavir Plus Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8842 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Good level of GMP compliance, inspection date 21/02/2019.
310.	M/s Legacy Pharmaceuticals pvt Ltd, 111-A, Industrial Estate Hayatabad Peshawar	Crovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8775 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection date 18/07/2019. The Panel recommended renewal of DML.
311.	M/s Winlet Pharmaceuticals, 30-km, Lahore Sargodha Road, Lahore	Loprit Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7797 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017.
312.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore.	Normavir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7916 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	The firm has maintained conformance to GMP compliance as per inspection report dated 01/04/2019.
313.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km	Schazovir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7088 dated 13/04/2020 Rs. 50,000/-.	As per SRO	Inspection date 30/05/2019, good level of GMP compliance.

	Lahore-Jaranwala Road, Distt Sheikhupura			13-04-2020 Form 5D		
314.	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-industrial triangle kahuta road Islamabad.	Lopritavir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7479 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 18/03/2019.
315.	M/s Amson Vaccines & Pharma Pvt Ltd. 115, Industrial Triangle, Kahuta Road, Islamabad,	Loptir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7291 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 04/02/2020, the panel recommended renewal of DML.
316.	M/s Medera Pharmaceuticals Pvt Ltd., Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad	Lopinarit Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8779 dated 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 07-11-2018 and report concludes that overall GMP compliance is found Good of today.
317.	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore	Advir Tablet 200/50mg	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 7488 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 21/02/2020 on the basis on inspection conducted on 07/11/2019
318.	M/s Mass Pharma Pvt Ltd.17-km, Ferozepur Road, Lahore, Pakistan	Lopi-Mass 200/50 mg Tablet	Each film coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9513 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
319.	M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi, Pakistan-75700	Ritvir 200mg/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9974 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	Inspection date 16/07/2019, good level of GMP compliance
320.	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi	Ropix 200mg/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9435 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	24-04-2018 Conclusion: firm is currently working under satisfactory level of cGMP compliance.
321.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	Lotinavir 200/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9981 05/05/2020 Rs. 20,000/- 04-05-2020 Form 5D	As per SRO	Inspection date 20/02/2019, the panel recommended issuance of GMP certificate.
322.	M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi	Rinovir 200mg/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9731 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	GMP certificate issued on 31/01/2020 on the basis of inspection conducted on 30/01/2020.
323.	M/s Popular Chemical Works Pvt Ltd. 9km, Lahore-Sheikhupura Road, P.O.Box No.527, Lahore.	Ritopin Tablet	Each Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9725 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	Rs. 135/- per tablet	Inspection date 29/05/2019, the panel recommended renewal of DML.
324.	M/s Hygeia Pharmaceuticals.	Hylop-R 200mg/50	Each Film Coated Tablet Contains:	Dy.No. 9717 04/05/2020	As per	Date of Inspection: 21-09-2017

	Plot No 295, Industrial Triangle, Kahuta Road, Islamabad	mg Tablet	Lopinavir…200mg Ritonavir…50mg	Rs. 20,000/- 04-05-2020 Form 5	SRO	Conclusion: Satisfactory
325.	M/s Mediceena Pharma Pvt Ltd. 27 Km, Main Raiwind Road, Lahore, Pakistan	Mediver Tablet 200/50 mg	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9574 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP certificate issued on 27/09/2019 based on the inspection conducted on 24/09/2019.
326.	M/s Sante Pvt Ltd. A-97, S.I.T.E Super Highway, Karachi, Pakistan	Emunvir Tablet 200/50 mg	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9446 30/04/2020 Rs. 50,000/- 30-04-2020 Form 5D	As per SRO	Good compliance of GMP, inspection date 07/07/2019.
327.	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700	Lopivir 200mg/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9417 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Last inspection report dated 02/05/18 concluding as under: ―The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process.
328.	M/s Zephyr Pharmatec Pvt Ltd. Plot No. A-39, S.I.T.E II, Super Highway, Karachi.	Zepnavir 200mg/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9306 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Last inspection report conducted on 18-07-2017 concluding good level of GMP compliance.
329.	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur, Kpk	Ft-Vir 200mg/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9323 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 03-10-2018, the firm is maintaining satisfactory level of cGMP.
330.	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi	Raletra 200mg/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9224 28/04/2020 Rs. 20,000/- 28-04-2020 Form 5	As per SRO	Inspection date 31-01-2018 the firm is operating at fair level of cGMP compliance as of today.
331.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad	Larinza 200mg/50 mg Tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9216 28/04/2020 Rs. 20,000/- 28-04-2020 Form 5	Rs. 12,000/- per 60's & Rs. 6000/- per 30's	Inspection date 21/05/2019, The panel recommended renewal of DML.
332.	M/s Faas Pharmaceuticals (Pvt.) Ltd. F-748/L, S.I.T.E Karachi, Pakistan	Covinavir 200mg/50 mg tablet	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9004 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	Routine GMP inspection conducted on 14-7-2017 concluded that the current level of compliance is rated satisfactory

333.	M/s High-Q Pharmaceuticals. Plot No.224/23, Korangi Industrial Area, Karachi	Covir Tablet 200/50 mg	Each Film Coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8999 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
334.	M/s Fredmann Pharmaceuticals. Plot No. 82-83 B, Old Industrial Area Mirpur, Azad Kashmir	Lovir Plus Tablets	Each film coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 8993 dated 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	Inspection date 10/01/2020. The panel is of the opinion that the report may be forwarded to the competent authority for resumption of production.
335.	M/s Synchro Pharmaceuticals. 77-Industrial Estate, Kot Lakhpat, Lahore	Flysyn 200mg/50 mg Tablet	Each film coated Tablet Contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 9426 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Inspection report is not provided.
336.	M/s Aneeb Pharmaceuticals Pvt Ltd, 24-Km, Badian Road, Lahore Cantt.	Lopravir DS tablet	Each film coated tablet contains: Lopinavir……200mg Ritonavir……50mg	Dy. No. 8113 20/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 29-10-2018 recommended renewal of DML
337.	M/s Relizon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore	Lotril 50mg/200 mg tablet	Each film coated tablet contains: Lopinavir……200mg Ritonavir……50mg	Dy. No. 7983 17/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm was inspected on 05.12.2017, wherein the panel recommended the grant of DML.
338.	M/s Gulf Pharmaceuticals, Rawat, Rawalpindi.	Loritovir 200mg/50 mg tablet	Each film coated tablet contains: Lopinavir……200mg Ritonavir……50mg	Dy. No. 7991 17/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 07-12-2019 recommended resumption of production.
339.	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.	Aletra 200mg/50 mg tablet	Each film coated tablet contains: Lopinavir……200mg Ritonavir……50mg	Dy. No. 9016 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 28-02-2019 recommended renewal of DML.
340.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	Arriva 200/50mg Tablet	Each film coated tablet contains: Lopinavir…200mg Ritonavir…50mg	Dy.No. 12806 05/06/2020 Rs. 20,000/- 02-06-2020 Form 5	As per SRO	Panel inspection dated 09-01-2019 recommends grant of GMP certificate

Decision: Registration Board approved registration of above applications from Serial No. 263 to 340. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.

****Following applications are incomplete:**

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
341.	M/s Harmann Pharmaceutical Laboratories (Pvt.) Ltd, 16-Km Multan Road, Lahore	NAVIR 200/50 Tablet	Each tablet contains: Lopinavir…… …..200mg Ritonavir…… …..50mg	Dy.No. 9124 dated 28/04/2020 Rs. 20,000/- Form 5	As per PRC	GMP Not confirmed Applied formulation is uncoated while the reference product is film coated.	**Deferred for the following:** • **submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory**

							authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee. • **Referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
342.	M/s Sayyed Pharmaceuticals Industries Pvt Ltd Plant No.67/2, Phase-3, Industrial Estate, Hattar	Lopovir Plus Tablet 200/50mg	Each tablet contains: Lopinavir …200mg Ritonavir …50mg	Dy.No. 7119 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5		Inspection conducted on 04-09-2019 the firm operates at satisfactory level of GMP guidelines. The firm has applied for uncoated while the reference product is film coated.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
343.	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi	Lepicvar Tablet 200/50mg	Each tablet contains: Lopinavir ……..200mg Ritonavir …50mg	Dy.No. 6748 dated 10/04/2020 Rs. 20,000/-. 09-04-2020 Form 5	As per SRO	Last inspection report 16-8-2017 firm was considered to be operating at an acceptable level of compliance with GMP.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**

344.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan	Lopinavir Tablet 200/50mg	Each tablet contains: Lopinavir …….200mg Ritonavir ……..…50mg	Dy.No. 7949 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	16,000/- -per 120's & 8,000/- per 60's	Inspection date 19/07/2019, GMP compliance level is rated as good. The firm has applied for uncoatd tablet while reference product is film coated.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
345.	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore	Macovir Tablet 200/50mg	Each tablet contains: Lopinavir ……200mg Ritonavir ……50mg	Dy.No. 8771 dated 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	GMP Certificate issued on 15-03-2018. The firm has applied for uncoatd tablet while reference product is film coated.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
346.	Applicant: M/S CSH Pharmaceuticals Pvt Ltd. 32-km, Ferozepur Road, Lahore Mfg by: Medisave Pharmaceuticals Plot no. 578-579, sundar industrial estate, Sundar raiwind road, Lahore.	Lopvir 200mg/50 mg Tablet	Each Tablet Contains: Lopinavir …200mg Ritonavir …50mg	Dy.No. 9318 dated 29/04/2020 Rs. 50,000/- 29-04-2020 Form 5D		GMP certificate issued to M/s Medisave pharmaceuticals on 22/01/2020 on the basis of inspection conducted on 02/10/2019. The firm has revised the formulation from Uncoated to Film coated without submission of	**Deferred for the following:** • **Submission of details of products which are already being manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.**

						fee. Detail of number of products being manufacture on contract and GMP of CSH Pharma.	• **submission of requisite fee for revision of formulation as per the reference product.**
347.	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan	Obinavir Tablet 200/50mg	Each film coated tablet contains: Lopinavir …..…200mg Ritonavir ……..…50mg	Dy.No. 7171 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 18/02/2020 Due to area constraint, the firm was unable to expand or rectify certain manufacturing areas related to installation of machinery/equipments, emergency exits, However \other shortcomings were rectified.	**Registration Board referred the case to QA & LT division for updated status of GMP.**
348.	M/s Fassgen Pharmaceuticals Plot No. 67/1-A, Phase-III, Industral Estate, Hattar	LopiritTablet 200/50mg	Each film coated tablet contains: Lopinavir …200mg Ritonavir …50mg	Dy.No. 7160 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection report dated 14/11/2017, 15 recommendations were made regarding QC, production, microbiological lab, cleaning validation, stability chambers etc.	**Registration Board referred the case to QA & LT division for updated status of GMP.**
349.	M/s Orta Laboratories Pvt Ltd. 24 Km, Multan Road, Off Defence Road Mohlanwal Near Bahria Town Bridge Lahore	Lopirito Tablet	Each Film Coated Tablet Contains: Lopinavir ……200mg Ritonavir ……..…50mg	Dy.No. 9969 dated 05/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	GMP inspection report is not provided.	**Registration Board referred the case to QA & LT division for updated status of GMP.**

7. Lopinavir/Ritonavir (100mg/25mg) Tablet:

Composition:

Each film Coated Tablet contains:
Lopinavir……..100mg
Ritonavir……..25mg

International Availability: Kaletra (100mg/25mg) Film coated tablet by M/s Abbvie, USFDA Approved

Me too: not registered

Specifications: USP Specification

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
350.	M/s PharmEvo (Pvt). Limited Plot # A-29, North Western Industrial Zone Port Qasim Karachi	EVOKAL Tablet 100mg/25mg	Each film coated tablet contains: Lopinavir…100mg Ritonavir……25mg	Dy.No. 5891 dated 07/04/2020 Rs. 50,000/- Form 5D	As per SRO	GMP inspection dated 23-02-2018, the firm was operating at an acceptable level of compliance with GMP standards.
351.	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62- Industrial Estate, Kot Lakhpat, Lahore	Vorovir 25/100 tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir……25mg	Form 5 Dy.No. 5939 07/04/2020 Rs.50,000/ Form 5D	As per SRO	The firm was granted GMP certificate based on inspection dated 24-04-2018.
352.	M/s Macter International Limited, F-216, S.I.T.E, Karachi	Macletra 100mg/25mg tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir……25mg	Dy.#5904-A 07/04/2020 Rs. 20,000/- + 30,000/- 20/04/2020 Form 5D	As per SRO	Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP.
353.	M/s Sami Pharmaceuticals (pvt) limited, F-95,) off Hub River Road SITE Karachi.	Opna 100mg/25mg tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir……25mg	Dy.No. 6254 dated 8//04/2020 Rs. 50,000/- Form 5D	As per SRO	Last inspection report dated 7th & 14th Feb, 2019, Good level of cGMP compliance.
354.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Lorita 100md/25mg tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir……25mg	Dy.No.6240 dated 08-04-2020 Rs. 50,000/- Form 5D	As per SRO	Last GMP inspection conducted on 01-01-2020 and report concludes GMP compliance.
355.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.	Scotra tablet 100mg/25mg	Each film coated tablet contains: Lopinavir…100mg Ritonavir……25mg	Dy. No.6558 09/04/2020 Rs. 50,000/- Form 5D	As per SRO	The panel recommended grant of GMP certificate, inspection date 10/10/2018 & 17/10/2018.
356.	M/s Next pharmaceutical products private limited, plot no. 44 A-B, Sundar industrial estate, Lahore.	Loritanext 100mg/25mg tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir……25mg	Dy. No.6155 08/04/2020 Rs. 20,000/- + Rs.30,000/ 29/04/2020 challan # 1905809) Form 5D	As per SRO	GMP certificate issued on 08/07/2019.
357.	M/s Ployfine chempharma, 51-industrial estate, Hayatabad Peshawar.	Petala 100mg/25mg tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir……25mg	Dy. No.6296 08/04/2020 Rs. 20,000/- + 30,000/- (dated 20th May, 2020 Dy. No.	As per SRO	Inspection date 24/04/2019, satisfactory level of GMP compliance.

				11598. Form 5D		
358.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Tulip 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 8342 20/04/2020 Rs. 50,000/-. 20-04-2020 Form 5D	As per SRO	GMP ceritificate issued on 11/07/2019 on the basis of inspection conducted on 31/07/2018.
359.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan	Ritohi 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 8844 23/04/2020 Rs. 50,000/- 23-04-2020 Form 5D	As per SRO	GMP certificate issued on 22/06/2019 on the basis of inspection 11/07/2019.
360.	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Hiletra 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No.8532 22/04/2020 (Rs.20,000/- 15-04-2020 +Rs.30,000/- 14/05/2020 vide Challan # 2022413) Form 5D	As per SRO	The firm has been granted GMP certificate based upon evaluation conducted on 06-7-2017.
361.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi	Rilovir 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 7313 14/04/2020 Rs. 50,000/- 14-04-2020 Form 5D	As per SRO	Inspection date 10-07-2018 GMP compliance level is rated as GOOD
362.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Lopir 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 6770 10/04/2020 Rs. 50,000/-. 09-04-2020 Form 5D	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance.
363.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Lopi-Rito 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 7076 13/04/2020 Rs. 50,000/- 13-04-2020 Form 5D	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance.
364.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Ritopin 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 6785 10/04/2020 Rs. 50,000/- 08-04-2020 Form 5D	As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/04/2019.
365.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Lopirid 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 7293 14/04/2020 Rs. 50,000/- 13-04-2020 Form 5D	As per SRO	Inspection date 11/02/2019, the panel recommended issuance of GMP ceritifcate.
366.	M/s Global Pharmaceuticals Pvt Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	Lopirit 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 7298 dated 14/04/2020 Rs. 50,000/-. 13-04-2020 Form 5D	As per SRO	Inspection date 26/12/2018, panel recommended renewal of DML.
367.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Ampivir Tablet 100/25 mg	Each Film Coated Tablet Contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 9452 30/04/2020 Rs. 50,000/- 30-04-2020 Form 5D	As per SRO	Good GMP compliance, inspection date 24/07/2018.

368.	M/s Sante Pvt Ltd. A-97, S.I.T.E Super Highway, Karachi, Pakistan	Emunvir Tablet 100/25 mg	Each Film Coated Tablet Contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 9445 30/04/2020 Rs. 50,000/- 30-04-2020 Form 5D	As per SRO	Good compliance of GMP, inspection date 07/07/2019.
369.	M/s High-Q Pharmaceuticals. Plot No.224/23, Korangi Industrial Area, Karachi	Covir Tablet 100/25 mg	Each Film Coated Tablet Contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 8998 dated 27/04/2020 Rs. 50,000/- 27-04-2020 Form 5D	As per SRO	inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
370.	M/s Getz Pharma (Pvt) Ltd, 29-30/27, Korangi Industrial Area, Karachi	LONAVIR Tablet 100mg + 25mg	Each film Coated Tablet contains: Lopinavir…100mg Ritonavir…..25mg	Dy.No. 9002 27/04/2020 Rs. 50,000/- Form 5D	As per SRO	The firm is granted GMP certificate based on inspection conducted on 07-1-2019.
371.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Reetovir 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 7625 15/04/2020 (Rs.20,000/- 14-04-2020 +Rs.30,000/- 1st june 2020, dy.no.12026 1/6/2020) Form 5D	As per SRO	Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
Decision: Registration Board approved registration of above applications from Serial No. 350 to 371. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
372.	M/s Hamaz Pharmaceuticals (pvt) ltd 13-KM Bosan Road, Lutfabad, Multan.	Novapir tablet 200mg	Each film coated tablet contains: Lopinavir ……100mg Ritonavir …..…25mg	Dy. No.5917 07/04/2020 dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP certificate issued on 06/11/2019. differential fee along with form 5D.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**
373.	M/s Quaper pvt. Ltd. 26-A Samll industrial estate Lahore road Sargodha.	Qlatra tablet 100mg/25mg	Each film coated tablet contains: Lopinavir ……100mg Ritonavir ……25mg	Dy.No. 5887 dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 28/01/2019, the panel recommends the renewal of DML. Application should be on form 5D along with differential fee Rs. 30,000/-.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**
374.	M/s Convell Laboratories Saidu Sharif Swat KPK.	Virovel tablet 100mg/25mg	Each film coated tablet contains: Lopinavir ……100mg Ritonavir ……25mg	Dy.No. 6395 dated 08/04/2020Rs. 20,000/- dated 13-04-2020 Form 5	As per SRO	Inspection date 02/03/2019, the panel recommended renewal of DML. Form 5D along with the differential fee is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**

375.	M/s Iceberg Pharmaceuticals Pvt Ltd Plot No.144, Nowshera Industrial Estate, Rislapur.	Icevir 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir …..…100mg Ritonavir ……25mg	Dy.No. 7929 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per sRO	Inspection date 27/03/2019, The panel resumption of production. Form 5D along with the differential fee is required	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**
376.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan	Rilop 100mg/25mg Tablet	Each tablet contains: Lopinavir …….…100mg Ritonavir ……25mg	Dy.No. 7948 dated 16/04/2020 Rs. 20,000/-. 16-04-2020 Form 5	As per SRO	GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 02/10/2019. Form 5D along with differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**
377.	M/s Paramount Pharmaceuticals. Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad	Loritavir 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir ……100mg Ritonavir ……25mg	Dy.No. 8766 dated 23/04/2020 Rs. 20,000/-. 23-04-2020 Form 5	As per SRO	Last inspection dated 08-02-2019 concluded keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. Form 5D along with the differential fee Rs. 30,000/- required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**
378.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Noletra 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 8922 dated 24/04/2020 Rs. 20,000/-. 24-04-2020 Form 5	As per SRO	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tabklet General, Capsule General, Liquid Syrup General). Form 5D along with differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**
379.	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad	Lopinarit Tablet 100/25mg	Each film coated tablet contains: Lopinavir…100mg Ritonavir…25mg	Dy.No. 8779 dated 23/04/2020 Rs. 20,000/-. 23-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 07-11-2018 and report concludes that overall GMP compliance is found Good of today. Form 5D along with differential fee of	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**

						Rs. 30,000/- is required.	
380.	M/s Aulton Pharmaceuticals, plot no. 84/1, block A, Phase V, Indutrial Estate Hattar.	Kalaulta 100mg/25mg tablet	Each film coated tablet contains: Lopinavir ……100mg Ritonavir ..…25mg	Dy.No. 5944 dated 07/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	Inspection date 13.02.2018, Good level of GMP compliance Form 5D along with differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**
381.	M/s Simz Pharmaceuticals Pvt Ltd, Plot No.574-575, Sundar Industrial Estate, Raiwind Lahore	Kalet 100mg/25mg Tablet	Each film coated tablet contains: Lopinavir …100mg Ritonavir …25mg	Dy.No. 7632 dated 15/04/2020 Rs. 20,000/-. 15-04-2020 Form 5	As per SRO	Form 5D along with differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**
382.	M/s Aneeb Pharmaceuticals Pvt Ltd, 24-Km, Badian Road, Lahore Cantt.	Lopravir tablet	Each film coated tablet contains: Lopinavir ……100mg Ritonavir ……25mg	Dy.No. 8112 dated 20/04/2020 Rs. 20,000/- Form 5	350/tablet	Panel inspection dated 29-10-2018 recommended renewal of DML Differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**
383.	M/s Gulf Pharmaceuticals, Rawat, Rawalpindi.	Loritovir 100/25 tablet	Each film coated tablet contains: Lopinavir ……100mg Ritonavir ……25mg	Dy.No. 7990 dated 17/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 07-12-2019 recommended resumption of production. Differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**
384.	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Niaz Baig, Raiwind Road, Lahore	Loprit 100/25 mg tablet	Each Film Coated Tablet Contains: Lopinavir ……100mg Ritonavir …… 25mg	Dy. No. 6204 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Panel inspection dated 25-03-2019 satisfactory level of GMP compliance Differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/-.**
385.	M/s Wilson's Parmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Divir 100/25 mg Tablet	Each Film Coated Tablet Contains: Lopinavir …100mg Ritonavir …25mg	Dy.No. 6527 dated 09/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	The firm was inspected on 24-01-2018 concluding good level of GMP compliance.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**
386.	M/s Popular Chemical Works Pvt Ltd. 9km, Lahore-Sheikhupura Road, P.O.Box No.527, Lahore.	Ritopin Tablet 100/25 mg	Each Tablet Contains: Lopinavir …100mg Ritonavir …25mg	Dy.No. 9724 dated 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Inspection date 29/05/2019, the panel recommended renewal of DML. Form 5D along with the differential fee is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**
387.	M/s Mediceena Pharma Pvt Ltd. 27 Km, Main Raiwind Road,	Mediver Tablet 100/25 mg	Each Film Coated Tablet Contains: Lopinavir	Dy.No. 9573 dated 30/04/2020 Rs. 20,000/-	As per SRO	GMP certificate issued on 27/09/2019 based on the inspection	**Deferred for submission of Form 5D along with the**

	Lahore, Pakistan		…100mg Ritonavir …25mg	30-04-2020 Form 5		conducted on 24/09/2019 Form 5D along with the differential fee is required.	**submission of differential fee Rs. 30,000/**
388.	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur, Kpk	Ft-Vir Tablet 100/25 mg	Each Film Coated Tablet Contains: Lopinavir …100mg Ritonavir …25mg	Dy.No. 9322 dated 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Form 5D along with the differential fee is required. GMP inspection dated 03-10-2018, firm is maintaining satisfactory level of cGMP.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**
389.	M/s Athan Pharmaceuticals, plot # 84/1, Block B, Phase V, Industrial Estate, Hattar.	Kalath 100mg/25mg tablet	Each Film Coated Tablet Contains: Lopinavir …100mg Ritonavir …25mg	Dy. No.5950 dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	DML issued on 5th March , 2019. Application should be on form 5D along with differential fee Rs. 30,000/-.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**
390.	M/s Vega Pharmaceuticals (Pvt.) Ltd., Plot No.4, Pharma city Sundar, 30 Km Multan Road Lahore.	LORITOVIR 100/25 Tablet	Each film Coated Tablet contains: Lopinavir… ……..100mg Ritonavir… ……..25mg	Dy.No. 9129 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection dated 21-03-2019 the firm is considered to be operating at fair level of GMP compliance. 30,000/- fee alongwith Fom-5D is required.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**
391.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	Arriva 100/25mg Tablet	Each film coated tablet contains: Lopinavir… ……100mg Ritonavir… ……25mg	Dy.No. 12805 dated 05/06/2020 Rs. 20,000/- dated 02-06-2020 Form 5	As per SRO	Panel inspection dated 09-01-2019 recommends grant of GMP certificate.	**Deferred for submission of Form 5D along with the submission of differential fee Rs. 30,000/**

7. Lopinavir/Ritonavir Oral Solution:
Composition:
Each ml contains:
Lopinavir……..80mg
Ritonavir……..20mg
International Availability: Kaletra Oral Solution 80mg/20mg by M/s Abbvie, USFDA Approved.
Me too: Kaletra Oral Solution 80mg/20mg By M/S Abbott, Reg No. 28427
Specifications: USP Specification
Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
392.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi	Ritovir Oral Solution 80/20mg	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 7112 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 25-9-2019 Panel recommended the renewal of DML.

393.	M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Lipovir Oral Solution	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.8123 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	GMP inspection dated 26-12-2019 concludes that the current GMP compliance level of firm is rated as Good.
394.	M/s S.J.G. Fazul Ellahi (Pvt) Ltd., E-46, SITE, Karachi	Lopivir Oral Solution	Each ml contains: Lopinavir…..80mg Ritonavir….20mg	Dy.No. 9140 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 15-01-2020 The firm is recommended grant of GMP certificate.
395.	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar.	Petala Oral Solution 80/20mg	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 7109 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 07-02-2018 firm was considered to be operated at acceptable level of compliance with GMP guideline
396.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	Lopir Oral Solution 80/20mg	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.6769 10/04/2020 Rs. 50,000/- 09-04-2020 Form 5D	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance.
397.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Reetovir Oral Solution 80/20mg	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.7627 15/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
398.	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Loprit Oral Solution 80/20mg	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.6755 10/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	Last inspection report, 16th jan, 2019, panel recommended issuance of GMP certificate.
399.	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir	L-Ronavir oral solution 80/20mg	Each **5ml** contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.7303 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	As of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. Inspection date 22/2/2019. The firm has revised the formulation from Syrup to Oral suspension as per the reference product and submitted Rs. 5000/- dated 18th May, 2020 Dy. No. 11264.
400.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Lorita Oral Solution 80/20mg	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.7917 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 01-01-2020 and report concludes GMP compliance.
401.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Tulip Oral Solution 80/20mg	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 8340 dated 20/04/2020 Rs. 50,000/- 20-04-2020 Form 5D	As per SRO	GMP ceritificate issued on 11/07/2019 on the basis of inspection conducted on 31/07/2018.

402.	M/s Paramount Pharmaceuticals. Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad	Loritavir Oral Solution 80/20mg	Each oral solution contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 8767 dated 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Last inspection dated 08-02-2019 concluded keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines
403.	M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi.	Ritvir Oral Solution 80mg/20 mg	Each Oral Solution Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.9973 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	Inspection date 16/07/2019, good level of GMP compliance
404.	M/s Pharmawise Labs Pvt Ltd. 25-M, Q.A. Industrial Estate, Kot Lakhpat Lahore, Pakistan	Lopina wise Plus Oral Solution	Each Oral Solution Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 9413 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Last inspection report dated 16/10/2019, firm is GMP compliant.
405.	M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi	Rinovir Syrup 80mg+20mg /ml	Each ml Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 9730 dated 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	GMP certificate issued on 31/01/2020 on the basis of inspection conducted on 30/01/2020.
406.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi.	Ritlor Oral Solution 120ml	Each ml Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 9718 dated 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018.
407.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road, Lahore	Lopi-Rito Oral Solution	Each ml Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.7074 13/04/2020 Rs. 50,000/- 13-04-2020 Form 5D	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance.
408.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Ritopin Oral Solution	Each ml Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.6784 10/04/2020 Rs. 50,000/- 08-04-2020 Form 5D	As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/04/2019.
409.	M/s Mediceena Pharma Pvt Ltd. 27 Km, Main Raiwind Road, Lahore, Pakistan	Mediver Oral Liquid Solution	Each ml Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.9572 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP certificate issued on 27/09/2019 based on the inspection conducted on 24/09/2019
410.	M/s Zephyr Pharmatec Pvt Ltd. Plot No. A-39, S.I.T.E II, Super Highway, Karachi.	Zepnavir Oral Solution 80mg+20mg /ml	Each ml Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No.9305 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Last inspection report conducted on 18-07-2017 concluding good level of GMP compliance.
411.	M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi	Covir Oral Solution	Each ml Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 8997 dated 27/04/2020 Rs. 20,000/-		inspection report conducted on 10/04/18 concluding that firm is operating at an

	Industrial Area, Karachi			27-04-2020 Form 5		acceptable level of compliance.
412.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Ampivir Oral Solution 80mg+20mg /ml	Each ml Contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 9456 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5		Good GMP compliance, inspection date 24/07/2018.
413.	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.	Aletra oral Solution 80mg/20mg	Each ml contains: Lopinavir…..80mg Ritonavir…..20mg	Dy.No. 9015 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 28-02-2019 recommended renewal of DML.
Decision: Registration Board approved registration of above applications from Serial No. 392 to 413. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
414.	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	Lopir syrup 80/20mg	Each ml contains: Lopinavir…80mg Ritonavir…20mg	Dy.No. 7299 dated 14/04/2020 Rs. 50,000/-. 13-04-2020 Form 5	As per SRO	Inspection date 26/12/2018, panel recommended renewal of DML. The firm has applied for syrup while reference product is oral solution.	**Deferred for submission of evidence of approval of applied formulation as "Syrup" in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
415.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan	Lonvir syrup 80/20mg	Each ml contains: Lopinavir ……80mg Ritonavir …….20mg	Dy.No. 8116 dated 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection report 26/02/2019. The firm has applied for syrup while reference product is oral solution.	**Deferred for submission of evidence of approval of applied formulation as "Syrup" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with**

							submission of requisite fee.

8. Oseltamivir Phosphate capsule 75mg:

Composition:

Each capsule conatins:

Oseltamivir as phosphate…….75mg

International availability:

Tamiflu 75mg capsule (oseltamivir as phosphate) by M/s Roche, USFDA Approved.

Me too status: Tamiflu 75mg capsule by M/s Roche.

Specifications: USP

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	Composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
416.	M/s Don valley Pharmaceuticasl (Pvt) Ltd. 31-kilometer main ferozpur road Lahore.	Viramir 75mg Capsule	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…75mg	Dy.No. 17061 08-05-2018 Rs. 20,000/- Form 5	As per SRO	Good compliance of GMP, inspection date 13/02/2020.
417.	M/s Wellborne pharmacchem and biological, Plot # 51/1-52/1 Phase II, Industrial Estate Hattar.	Osteiwell Capsules 75mg	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…75mg	Dy. No. 6520 Dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 07/11/2018, Satisfactory level of cGMP compliance.
418.	M/s Arsons Pharmaceutical Industries (pvt) Ltd. 2.5km defence road, off Multan road, Lahore.	Ostavir 75mg capsule	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…75mg	Dy.No. 6534 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection dated 18/09/2019, satisfactory GMP compliance for; ➢ Tablet (General & Psychotropic) ➢ Capsule General ➢ Cream/ointment/Gel (general)
419.	M/s Mafins Pharma, A-5, SITE Super highway Industrial Area, Karachi.	Taflu 75mg capsule	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…75mg	Dy. No.7285 14/04/2020 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection conducted on 24/07/2019, appropriate GMP compliance.
420.	M/s Amarant Pharmaceuticals Private Limited, 158, D. Tore, Gadap road Super Highway, Karachi.	Osvir 75mg capsule	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…75mg	Dy. No.7156 13/04/2020 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Good GMP compliance, inspection date 24/07/2018.
421.	M/s MBL Pharma, B-77-A, HITE, HUB, Balochistan.	MB Vir capsule 75mg	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…75mg	Dy. No.7931 dated 16/04/2020 Rs. 20,000/- Form 5	As per SRO	Good GMP compliance, inspection date 28/02/2018.
422.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.	Flumat Capsules 75mg	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir…75mg	Dy. No.6561 dated 09/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel recommended grant of GMP certificate, inspection date 10/10/2018 & 17/10/2018.

423.	M/s Simz Pharmaceuticals Pvt Ltd Plot No.574-575, Sundar Industrial Estate, Raiwind Lahore	Fluvir Capsule 75mg	Each capsule contains: Oseltamivir as phosphate…75mg	Dy.No. 7637 dated 15/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017.
424.	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Fluvir 75mg capsule	Each capsule contains: Oseltamivir as phosphate…75mg	Dy.No. 7919 dated 16/04/2020 Rs. 20,000/- dated. 16-04-2020 Form 5	As per SRO	GMP certificate issued on 27/07/2018 on the basis of inspection conducted on 11/07/2018.
425.	M/s Vega Pharmaceuticals (Pvt.) Ltd., Plot No.4, Pharma city Sundar, 30 Km Multan Road Lahore.	MYVIR 75mg Capsule	Each capsule conatins: Oseltamivir as phosphate….75mg	Dy.No. 9128 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection dated 21-03-2019 the firm is considered to be operating at fair level of GMP compliance.
426.	M/s Liven pharmaceuticals (Pvt.) Ltd, 49, Km Lahore Multan Road	OSTIM 75mg Capsule	Each capsule conatins: Oseltamivir as phosphate….75mg	Dy.No. 8544 dated 22/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm is granted GMP certificate based on inspection conducted on 03-07-2019.
427.	M/s Jaskan Pharmaceuticals (Pvt.) Ltd, Plot No. 50, SUndart Industrial estate, Lahore	OSVIR 75mg Capsule	Each capsule conatins: Oseltamivir as phosphate...75mg	Dy.No. 8550 dated 22/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm is granted resumption of production on 13-03-2018.
428.	M/s Standpharm Pakistan (Pvt) Ltd, 20Km, Ferozpur Road , Lahore	SELTIUM 75mg Capsule	Each capsule conatins: Oseltamivir as phosphate….75mg	Dy.No.8556 22/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection date d19-10-2017 satisfactory level of compliance.
429.	M/s EPHARM Laboratories, A-40, Road No, SITE Super Highway Industrial area, North Karachi	EPHAVIR 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 8452 dated 21/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted o 12-09-2019, GMP is rated as Good.
430.	M/s Shawan Pharmaceuticals (Pvt.) Ltd. Plot No. 37, Road NS-01, National industrial Zone, Rawat	Osmelt 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 8551 dated 22/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection dated 04-03-2020 overall GMP compliance found Good.
431.	M/s Getz Pharma (Private) Limited, 29-30/27, Korangi Industrial Area, Karachi	OSELTA 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9000 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm is granted GMP certificate based on inspection conducted on 07-01-2019.
432.	M/s LINZ Pharmaceuticals (Pvt.) Ltd, Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area, Karachi	LINVIR 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9133 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection dated 09-01-2020, the GMP of the firm is rated GOOD.
433.	M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221,222 and 223 Sector 23, Korangi	OSTELFLU 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9139 dated 27/04/2020 Rs. 20,000/-	As per SRO	Inspection conducted on 17-09-2019 The firm is operating at acceptable level of

	Industrial Area, Karachi			Form 5		compliance with GMP.
434.	M/s S.J.G. Fazul Ellahi (Pvt) Ltd., E-46, SITE, Karachi	Oseltam 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9142 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 15-01-2020 The firm is recommended grant of GMP certificate.
435.	M/s Lisko Pakistan (Pvt.) Ltd. L-10-D, Block -21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi	Osvir 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9436 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	Last GMP inspection is conducted on 24-04- 2018, overall firm has satisfactory level of GMP compliance.
436.	M/s Mass Pharma (Pvt) Ltd. 17-Km, Ferozpur Road, Lahore	Mass-Flu 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9947 dated 05/05/2020 Rs. 20,000/- Form 5	As per SRO	Inspection dated 04-09-2018 the firm has good compliance of GMP.
437.	M/s Weather Folds Pharmaceuticals, Plot No. 62/2 Phase-II Industrial Estate Hattar.	OsiFold 75MG CAPSULE	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9982 dated 05/05/2020 Rs. 20,000/- Form 5	As per SRO	Last GMP inspection was conducted on 15-09-2017 & the report concludes the firm to be GMP compliant.
438.	M/s Aventek Pharmaceuticals, Plot No. 44-C Sunder Industrial Estate Lahore.	AVIR 75MG CAPSULE	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9441 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection report dated 01-01-2019, the firm maintained satisfactory conformance to cGMP compliance in the manufacturing and quality control operations.
439.	M/s Karachi Chemical Industries (Pvt) Ltd. F-25 Estate Avenue, SITE, Karachi.	Osmir 75MG CAPSULE	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9726 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 30th January, 2020.
440.	M/s Hygeia Pharmaceuticals, Plot No. 295 Industrial Triangle Kahuta Road Islamabad.	Hytamivir 75mg CAPSULE	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9716 dated 04/05/2020 Rs. 20,000/- Form 5	As per SRO	Copy of GMP inspection conduted on 21-09-2017, the firm is considered to be operating at satisfactory level of compliance.
441.	M/s Mediceena Pharma (Pvt) Ltd. 27 Km Raiwind Road Lahore	OSMED 75mg CAPSULE	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9571 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 24-09-2019.
442.	M/s Medipak Ltd., 132 Industrial Estate, Kot Lakhpat, Lahore	Medivir-O 75mg CAPSULE	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9959 dated 05/05/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 11-07-2019, the firm had rectified most of the deficiencies pointed out in last inspection.

443.	M/s GT Pharma (Pvt) Ltd., 713 Sundar Industrial Estate Lahore.	FLUVIR 75MG CAPSULE	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9470 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 31-1-19.
444.	M/s Paramount Pharmaceuticals, 36 Industrial Triangle, Kahuta Road Islamabad.	OSAL-P 75MG CAPSULE	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9464 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm has submitted copy of certificate based on inspection dated 20-11-2018.
445.	M/s Sante (Pvt) Ltd. A/97 S.I.T.E Super Highway Karachi	SANTOSE L 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9451 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection conducted on 02-07-2019, overall compliance level for the said dosage forms is rated as Good.
446.	M/s Baxter Pharmaceuticals, A-1/A Scheme No. 33 Phase-I S.I.T.E. Super Highway Karachi.	Selavir 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9428 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 21-09-2019, the compliance level is rated as satisfactory.
447.	M/s Nenza Pharmaceuticals (Pvt) Ltd. 33-A Hayatabad Industrial Estate Peshawar.	Oseltanen 75mg Capsule	Each capsule contains: Oseltamivir as phosphate.75mg	Dy.No. 9312 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 26-09-2018, overall GMP compliance of the firm is satisfactory
448.	M/s Zephyr Pharmatec (Pvt) Ltd. A-39 S.I.T.E. II Super Highway Karachi.	Zephtam 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9304 dated 29/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 25-09-2019 overall GMP compliance is rated as GOOD.
449.	M/s Farm Aid Group, Plot No. 3/2 Hattar Industrial Estate Haripur.	Famivir 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 9321 dated 29/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 03-10-2018, firm is maintaining satisfactory level of cGMP.
450.	M/s Jupiter Pharma, Plot No. 25, St No. S-6, Rawat, Rawalpindi	OMIVIR 75mg Capsule	Each capsule contains: Oseltamivir as phosphate…75mg	Dy.No. 9223 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 19-09-2019.
451.	M/s Faas Pharmaceuticals (Pvt) Ltd, Plot No. F-748-L SITE Karachi	OMIVIR 75mg Capsule	Each capsule contains: Oseltamivir as phosphate…75mg	Dy.No. 9006 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 13-11-2019 the firm is operating at good level of GMP compliance.
452.	M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore	Osvir 75mg Capsule	Each capsule contains: Oseltamivir as phosphate…75mg	Dy.No.8539 22/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 01-03-2019 and 13-05-2019 recommends renewal of DML.
453.	"M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad"	Turvera 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 8534 dated 22/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm was granted renewal of DML dated 21-05-2019 for only two sections Syrups (General) Plasters

454.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi	Osmivir 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 8114 dated 20/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm has granted renewal of DML from CLB w.e.f 19-07-2019.
455.	M/s Fredmann, plot no 82-83 B, Old industrial Area Mirpur, Azad Kashmir	Osvir 75mg Capsule	Each capsule contains: Oseltamivir as phosphate….75mg	Dy.No. 8994 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection date 10/01/2020. The panel is of the opinion that the report may be forwarded to the competent authority for resumption of production.
456.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan	Oslovir Capsule 75mg	Each capsule contains: Oseltamivir as phosphate…..…… 75mg	Dy.No. 8120 dated 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018.
457.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Flukill capsule 500mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No. 7270 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP Certificate issued on the basis of GMP inspection conducted on 1-03-2019
458.	M/s Amson Vaccines & Pharma Pvt Ltd. 114, Industrial Triangle, Kahuta Road, Islamabad, Pakistan	Asmovir Capslule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7289 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 04/02/2020, the panel recommended renewal of DML.
459.	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore	Adflu Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7487 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 21/02/2020 on the basis on inspection conducted on 07/11/2019
460.	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad	Eltamivir Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7480 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 18/03/2019.
461.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura, Pakistan	Oselta capsule 75mg	Each Capsule contains: Oseltamivir as Phosphate …75mg	Dy.No.7087 dated 13/04/2020 Rs. 20,000/- 13 -04-2020 Form 5	As per SRO	Inspection date 30/05/2019, good level of GMP compliance.
462.	M/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi	Ostagood Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7938 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on the basis of inspection conducted on 08/08/2018.

463.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Palmivir Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No. 7774 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 08-05-2018."
464.	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Osvir capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7768 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 02/10/2019.
465.	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan	Asteflu Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7790 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	13/11/2018, Good GMP compliance.
466.	M/s Himont Pharmaceuticals Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan	Osmi Capsule 75mg	Each Capsule contains: Oseltamivir as phosphtae…75mg	Dy.No. 7784 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued based upon evaluation conducted on 04-10-2018 & 05-10-2018. The firm has revised the formulation from Oseltamivir….75mg to Oseltamivir as phosphate…..75mg and submitted fee **Rs. 5,000/-** vide challan number 1981365 dated 07/05/2020.
467.	M/s Jawa Pharmaceuticals Pvt Ltd, 112/10, Quaid e Azam Industrial Area, Kot Lakhpat, Lahore	Flucap Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No. 8380 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Date of inspection 21/02/2020 & 04/03/2020, satisfactory level of GMP compliance
468.	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi.	M-Flu Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No. 7794 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 04/03/2020, Acceptable level of GMP compliance.
469.	M/s MKB Pharmaceuticals Pvt Ltd.66-Hayatabad Industrial Estate, Peshawar, Kpk, Pakistan	Tamflu 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No. 8773 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection dated 24-01-2019 concludes that the firm is operating at satisfactory level of GMP compliance.
470.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan	Oseltasure-Flu 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7945 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	Rs. 2000/- per 10's	Inspection date 19/07/2019, GMP compliance level is rated as good.

471.	M/s Curatech Pharma Pvt Ltd 35-Km, Multan Road, lahore	Flunavir Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Eq. to Oseltamivir…75mg	Dy.No.7065 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 16/03/2018.
472.	M/s BJ Pharmaceuticals. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore	Osevir 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate …75mg	Dy.No.6759 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	**Firm has required** equipment/machinery , HVAC system and qualified staff, fir showed good intention to further improvements in future. Overall hygienic condition of the firm is satisfactory at the time of inspection. Inspection date 15/01/2020.
473.	M/s British Pharmaceuticals Pvt Ltd 23-KM, Shekhupura Road, lahore	Brisevir Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7131 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The panel recommended grant of DML, inspection date 19/08/2019 & 27/12/2019.
474.	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan	Selvir 75mg capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7128 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	DML was issued on 13/06/2018.
475.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Oselvir Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.6781 dated 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	GMP certificate issued on 21/05/2019 on the basisi of inspection conducted on 23/04/2019.
476.	M/s Biogen Pharmaceuticals. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan	Oseltagen Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate …75mg	Dy.No.7142 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspetion date 12/12/2019, the panel recommended grant of DML.
477.	M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Isalamabad	Oseflu 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7262 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on the basis of inspection conducted on 01-10-2019
478.	M/s Sayyed Pharmaceuticals Industries Pvt Ltd Plant No.67/2, Phase-3, Industrial Estate, Hattar	Sydovir 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7120 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection conducted on 04-09-2019 the firm operates at satisfactory level of GMP guidelines.

479.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Fluvent 75mg capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7296 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 11/02/2019, the panel recommended issuance of GMP ceritifcate.
480.	M/s Global Pharmaceuticals Pvt Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	Fluvir 75mg Capsule	Each Capsule contains: Oseltamivir as phosphate…75mg	Dy.No.7300 dated 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 26/12/2018, panel recommended renewal of DML.
481.	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir	Tamivir 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7305 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	As of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. Inspection date 22/02/2019.
482.	M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad.	Taminas 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7616 dated 15/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines.
483.	M/s Pacific Pharmaceuticals Limited.30 km, Multan Road, Lahore, Pakistan	Oselt 75mg capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7483 dated 14/04/2020 Rs. 50,000/- 14-04-2020 Form 5D	As per SRO	GMP certificate issued in 25/04/2019 on the basis on inspection conducted on 07/03/2019.
484.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	Oselvir Capsule 75mg	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.6775 dated 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance.
485.	M/s PharmaWise Labs pvt Ltd, 25-M.Q-A Industrial Estate, Kot Lakhpat, Lahore	Oseltawise 75mg capsule	Each Capsule contains: Oseltamivir Phosphate Eq.to Oseltamivir…75mg	Dy.No.7061 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 16/10/2019, firm is GMP compliant.
486.	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan	Selvir 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7165 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 21/11/2017, fair level of GMP compliance.
487.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Jenflu 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7272 dated 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 15/02/2019, satisfactory level of GMP compliance.

488.	M/s Venus Pharma. 23 km, Multan Road, Lahore	Oseltavin 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7276 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP ceritifcate issed on 28/11/2019 on the basis of inspection conducted on 05/09/2019.
489.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi	Fluvir 75mg Capsule	Each Capsule contains: Oseltamivir …75mg	Dy.No.7215 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 10-07-2018 GMP compliance level is rated as GOOD
490.	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Fluvir 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No.7918 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 27/07/2018 on the basis of inspection conducted on 11/07/2018.
491.	M/ Pliva Pakistan Ltd, Plot NO.B-77 Hub Industrial Estate, Lasbela, Balochistan.	Plantan Capsule 75mg	Each capsule: Oseltamivir as phosphate ….. 75mg	Dy. No. 8104 dated 20/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 27-02-2018 concluded overall GMP as good.
492.	M/s Aneeb Pharmaceuticals Pvt Ltd, 24-Km, Badian Road, Lahore Cantt.	OSE-FLU Capsule 75mg	Each capsule: Oseltamivir as phosphate ….. 75mg	Dy.No.8108 20/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 29-10-2018 recommended renewal of DML.
493.	M/s Radiant Pharma Pvt Ltd, 43-E Sunder Industrial Estate, Lahore.	SETA-V 75mg Capsule	Each capsule: Oseltamivir as phosphate ….. 75mg	Dy. No. 8335 dated 20/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 31-07-2018 concluding satisfactory GMP compliance
494.	M/s Gulf Pharmaceuticals, Rawat, Rawalpindi.	IN-Osvir 75mg Capsule	Each capsule: Oseltamivir as phosphate ….. 75mg	Dy. No. 7986 dated 17/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 07-12-2019 recommended resumption of production.
495.	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.	Osiflu 75mg Capsule	Each capsule: Oseltamivir as phosphate ….. 75mg	Dy. No. 9010 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 28-02-2019 recommended renewal of DML.
Registration Board approved registration of above applications from Serial No. 416 to 495. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
496.	M/s Hassan Pharmaceuticals (pvt) Ltd. 99-A Industrial Estate, Hayatabad, Peshawar.	Ostam-H 75mg capsule	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir …75mg	Dy.No. 7621 dated 15/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP compliance is NOT satisfactory, Inspection date 01/02/2018.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**

497.	M/s Hassan Pharmaceuticals (pvt) Ltd. 99-A Industrial Estate, Hayatabad, Peshawar.	Ostam-H 75mg capsule	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir ……75mg	Dy.No. 7621 dated 15/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP compliance is NOT satisfactory, Inspection date 01/02/2018.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
498.	M/s Unimark Pharmaceuticals, Plot No. 7-A St. No. S-7 National Industrial Zone Rawat.	FluMark 75MG CAPSULE	Each capsule contains: Oseltamivir as phosphate……….75mg	Dy.No. 9441 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	Not confirmed	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
499.	M/s CSH Pharmaceuticals (Pvt) Ltd., 32-Km Ferozepur Road Lahore Contract manufacturing from M/s Medisave Pharmaceuticals, Plot No.578-579 Sundar Industrial Estate Lahore.	Ostar 75mg Capsule	Each capsule contains: Oseltamivir as phosphate……….75mg	Dy.No. 9316 dated 29/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, Plot No. 578, 579, Sundar Industrial Estate, Lahore GMP of CSH Pharma is required. List of products already approved on contract manufacturing. Number of sections approved for CSH Pharmaceuticals	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
500.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Fluvir 75mg Capsule	Each Capsule contains: Oseltamivir…75mg	Dy.No. 7279 dated 14/04/2020Rs. 20,000/- dated 13-04-2020 Form 5		Inspection date 15/02/2019, satisfactory level of GMP compliance. Salt form is not as per reference product.	**Deferred for correction in salt form of applied formulation.**
501.	M/s Orta Laboratories (Pvt) Ltd., 24-Km Multan Road Off. Defence Road Mohalanwal (Near Bahria Town Bridge) Lahore.	ORTAVIR 75MG CAPSULE	Each capsule contains: Oseltamivir as phosphate……….75mg	Dy.No. 9965 dated 05/05/2020 Rs. 20,000/- Form 5	As per SRO	Not Confirmed	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
502.	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan	Obsel 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No. 7169 dated 13/04/2020Rs. 20,000/- dated 13-04-2020 Form 5	As per SRO	Due to area constraint, the firm was unable to expand or rectify certain manufacturing areas related to installation of machinery/equipments,	**Registration Board referred the case to QA & LT Division for updated status of GMP.**

						emergency exits, However \other shortcomings were rectified.	
503.	M/s Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industral Estate, Hattar	Oseltape 75mg Capsule	Each Capsule contains: Oseltamivir Phosphate Equivalent to Oseltamivir…75mg	Dy.No. 7159 dated 13/04/2020Rs. 20,000/- dated 13-04-2020 Form 5	As per SRO	Inspection report dated 14/11/2017, 15 recommendations were made regarding QC, production, microbiological lab, cleaning validation, stability chambers etc.	**Registration Board referred the case to QA & LT Division for updated status of GMP.**

9. Oseltamivir Phosphate capsule 45mg:

Composition:

Each capsule conatins:

Oseltamivir as phosphate…….45mg

International availability:

Tamiflu 45mg capsule (oseltamivir as phosphate) by M/s Roche, USFDA Approved.

Me too status:

Not registered

Specifications: USP

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status
504.	M/s PharmEvo (Pvt). Limited Plot # A-29, North Western Industrial Zone Port Qasim Karachi	Avenflu Capsule 45mg	Each capsule conatins: Oseltamivir as phosphate…….45mg	Dy.No. 5876 dated 07/04/2020 Rs. 50,000/- Form 5D	As per SRO	GMP inspection dated 23-2-2018 the firm was operating at an acceptable level of compliance with GMP standards.
505.	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore	Temevir 45mg Capsule	Each capsule Contains: Oseltamivir as phosphate ….. 45mg	Form 5 Dy. No. 5940 dated 07/04/2020 Rs.50,000/Form 5D	As per SRO	The firm was granted GMP certificate based on inspection dated 24-04-2018.
506.	M/s Macter International Limited, F-216, S.I.T.E, Karachi	Macflu 45mg capsule	Each capsule Contains: Oseltamivir as phosphate ….. 45mg	Dy.No.5900 07/04/2020 Rs. 20,000/- + 30,000/- 20/04/2020 Form 5D	As per SRO	Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP.
507.	M/s Sami Pharmaceuticals (pvt) limited, F-95, off Hub River Road SITE Karachi.	Flunar 45mg Capsule	Each capsule Contains: Oseltamivir as phosphate ….. 45mg	Dy.No. 6256 dated 8//04/2020 Rs. 50,000/- Form 5D	As per SRO	Last inspection report dated 7th & 14th Feb, 2019, Good level of cGMP compliance.

508.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.	Flumat Capsules 45mg	Each capsule Contains: Oseltamivir as phosphate ….. 45mg	Dy. No.6560 09/04/2020 Rs. 50,000/- Form 5D	As per SRO	The panel recommended grant of GMP certificate, inspection date 10/10/2018 & 17/10/2018.
509.	M/s Next pharmaceutical products private limited, plot no. 44 A-B, Sundar industrial estate, Lahore.	Oseltanext 45mg capsule	Each capsule Contains: Oseltamivir as phosphate ….. 45mg	Dy.No.6158 08/04/2020 Rs. 20,000/- + Rs.30,000/- 29/04/2020 challan # 2009179) Form 5D	As per SRO	GMP certificate issued on 08/07/2019.
510.	M/s Polyfine chempharma, 51-industrial estate, Hayatabad Peshawar.	Ozelta 45mg Capsule	Each capsule Contains: Oseltamivir as phosphate ….. 45mg	Dy.No.6299 dated 08/04/2020 Rs. 20,000/- + 30,000 (dated 20th May, 2020 Dy. NO. 11597. Form 5D	As per SRO	Inspection date 24/04/2019, satisfactory level of GMP compliance.
511.	M/s PharmaWise Labs (Pvt). Ltd.,25-M. QA. Industrial Estate, Kot Lakhpat Lahore Pakistan	Osvir 45mg Capsule	Each capsule contains: Oseltamivir as phosphate……45mg	Dy.No.9962 05/05/2020 Rs. 50,000/- Form 5D	As per SRO	Last inspection report dated 16/10/2019, firm is GMP compliant.
512.	M/s Bio-Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore	CELTA 45mg Capsule	Each capsule contains: Oseltamivir as phosphate……45mg	Dy.No. 9437 dated 30/04/2020 Rs. 50,000/- Form 5D	As per SRO	The firm is granted GMP certificate based on inspection dated 16-08-2018.
513.	M/s Sante (Pvt) Ltd. A/97 S.I.T.E Super Highway Karachi	Santosel 45mg Capsule	Each capsule contains: Oseltamivir as phosphate……45mg	Dy.No. 9450 dated 30/04/2020 Rs. 50,000/- Form 5D	As per SRO	GMP inspection conducted on 02-07-2019, overall compliance level for the said dosage forms is rated as Good.
Decision: Registration Board approved registration of above applications on Form-5D from Serial No. 504 to 513. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
514.	M/s Amson Vaccines & Pharma Pvt Ltd 110-111. 152-156, Industrial Triangle, Kahuta Road, Islamabad	ASMOVIR 45mg Capsule	Each capsule contains: Oseltamivir as phosphate……45mg	Dy.No. 7288 dated 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Not Confirmed Remaining fee of 30,000/-is required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/-.**

515.	M/s Linear Pharma, plot NO. 18, street #S-4, National Industrial Zone (RCCI) Rawat Islamabad.	Oslivir 45mg capsule	Each capsule conatins: Oseltamivir as phosphate…….45mg	Dy.No. 6186 dated 08/04/2019 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 30/01/2019, satisfactory level of GMP compliance. Form 5D along with the differential fee, required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/-.**
516.	M/s Hamaz Pharmaceuticals (pvt) ltd 13-KM Bosan Road, Lutfabad, Multan.	Oselta Capsule 45mg	Each Capsule Contains: Oseltamivir Phosphate Eq. to Oseltamivir …45mg	Dy. No.5922 07/04/2020 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP certificate issued on 06/11/2019. differential fee along with form 5D. The firm has revised the formulation fro Oseltamivir to Oseltamivir phosphate as per reference product.	**Deferred for following:** • **submission of Form 5D alongwith the submission of differential fee Rs. 30,000/-** • **Submission of Requisite fee for revision of formulation as per reference product.**
517.	M/s Simz Pharmaceuticals Pvt Ltd Plot No.574-575, Sundar Industrial Estate, Raiwind Lahore	Fluvir Capsule 45mg	Each capsule contains: Oseltamivir as phosphate…45mg	Dy.No. 7636 dated 15/04/2020 Rs. 20,000/- dated. 15-04-2020 Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017. Form 5D along with differential fee is required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/-.**
518.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	Oselvir capsule 45mg	Each Capsule contains: Oseltamivir Phosphate equivalent to 45mg Oseltamivir	Dy.No. 6774 dated 09/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Form 5D along with the differential fee is required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**
519.	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad	Oslivir Capsule 45mg	Each Capsule Contains: Oseltamivir ……45mg	Dy. No. 6186 dated 08/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	• GMP inspection dated 30-01-2019 concluded satisfactory level of compliance with GMP standards. • Form 5–D shall be submitted. • Differential fee of Rs. 30,000/- shall be submitted.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**

520.	M/s Aulton Pharmaceuticals , plot no. 84/1, block A, Phase V, Indutrial Estate Hattar.	Aultaqflu 45mg capsule	Each Capsule Contains: Oseltamivir ……45mg	Dy.No. 5947 dated 07/04/2020 Rs. 20,000/- dated. 15-04-2020 Form 5	As per SRO	Inspection date 13.02.2018, Good level of GMP compliance. Form 5D along with differential fee of Rs. 30,000/- is required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**
521.	M/s Athan Pharmaceuticals , plot # 84/1, Block B, Phase V, Industrial Estate, Hattar.	Athflu 45mg capsule	Each capsule Contains: Oseltamivir as phosphate ….. 45mg	Dy. No.5953 dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	DML issued on 5th March , 2019. Application should be on form 5D along with differential fee Rs. 30,000/-.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**

10. Oseltamivir Phosphate capsule 30mg:

Composition:

Each capsule conatins:

Oseltamivir as phosphate…….30mg

International availability:

Tamiflu 30mg capsule (oseltamivir as phosphate) by M/s Roche, USFDA Approved.

Me too status: Not registered

Specifications: USP

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status
522.	M/s PharmEvo (Pvt). Limited Plot # A-29, North Western Industrial Zone Port Qasim Karachi	Avenflu Capsule 30mg	Each capsule conatins: Oseltamivir as phosphate….30mg	Dy.No. 5875 dated 07/04/2020 Rs. 50,000/- Form 5D	As per SRO	GMP inspection dated 23-02-2018 firm was operating at an acceptable level of compliance with GMP standards.
523.	M/s Macter International Limited, F-216, S.I.T.E, Karachi	Macflu 30mg capsule	Each capsule Contains: Oseltamivir as phosphate ….. 30mg	Dy.No. 5899 dated 07/04/2020 Rs. 20,000/- + 30,000/- 20/04/2020 Form 5D	As per SRO	Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP.
524.	M/s CCL Pharmaceuticals (Pvt.) Ltd., 62-Industrial Estate, Kot Lakhpat, Lahore	Temevir Capsule 30mg	Each capsule Contains: Oseltamivir as phosphate ….. 30mg	Dy. No. 5933 dated 07/04/2020 Rs.50,000/- Form 5D	As per SRO	The firm was granted GMP certificate based on inspection dated 24-04-2018.
525.	M/s Sami Pharmaceuticals (pvt) limited, F-95, off Hub River Road SITE Karachi.	Flunar 30mg capsule	Each capsule Contains: Oseltamivir as phosphate ….. 30mg	Dy.No. 6255 dated 8//04/2020 Rs. 50,000/- Form 5D	As per SRO	Last inspection report dated 7th & 14th Feb, 2019, Good level of cGMP compliance.
526.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate,	Ostavir 30mg capsule	Each capsule Contains: Oseltamivir as phosphate ….. 30mg	Dy. No. 6238 dated 08-04-2020 Rs. 50,000/-	As per SRO	Last GMP inspection conducted on 01-01-2020 and report concludes GMP

	Lahore, Pakistan			Form 5D		compliance.
527.	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.	Flumat Capsules 30mg	Each capsule Contains: Oseltamivir as phosphate ….. 30mg	Dy. No.6559 dated 09/04/2020 Rs. 50,000/- Form 5D	As per SRO	The panel recommended grant of GMP certificate, inspection date 10/10/2018 & 17/10/2018.
528.	M/s Next pharmaceutical products private limited, plot no. 44 A-B, Sundar industrial estate, Lahore.	Oseltanext 30mg capsule	Each capsule Contains: Oseltamivir as phosphate ….. 30mg	Dy.No.6157 08/04/2020 Rs. 20,000/- + Rs.30,000/- 29/04/2020 challan # 1905810) Form 5D	As per SRO	GMP certificate issued on 08/07/2019.
529.	M/s Pharma Wise Labs (Pvt). Ltd.,25-M. QA. Industrial Estate, Kot Lakhpat Lahore Pakistan	Oseltawise 30mg Capsule	Each capsule contains: Oseltamivir as phosphate…30mg	Dy.No.9961 05/05/2020 Rs. 50,000/- Form 5D	As per SRO	Last inspection report dated 16/10/2019, firm is GMP compliant.
530.	M/s Bio-Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore	CELTA 30mg Capsule	Each capsule contains: Oseltamivir as phosphate…30mg	Dy.No.9438 9438 dated 30/04/2020 Rs. 50,000/- Form 5D	As per SRO	The firm is granted GMP certificate based on inspection dated 16-08-2018.
531.	M/s Sante (Pvt) Ltd. A/97 S.I.T.E Super Highway Karachi	Santosel 30mg Capsule	Each capsule contains: Oseltamivir as phosphate……30mg	Dy.No.9449 9450 dated 30/04/2020 Rs. 50,000/- Form 5D	As per SRO	GMP inspection conducted on 02-07-2019, overall compliance level for the said dosage forms is rated as Good.
Decision: Registration Board approved registration of above applications from Serial No. 522 to 531. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
532.	M/s Linear Pharma, plot NO. 18, street #S-4, National Industrial Zone (RCCI) Rawat Islamabad.	Oslivir 30mg capsule	Each capsule conatins: Oseltamivir as phosphate…….30mg	Dy.No. 6185 dated 08/04/2019 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 30/01/2019, satisfactory level of GMP compliance. Form 5D along with the differential fee, required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**
533.	M/s Hamaz Pharmaceuticals (pvt) ltd 13-KM	Oselta Capsule 30mg	Each Capsule Contains:	Dy. No.5921 07/04/2020	As per SRO	GMP certificate issued on 06/11/2019.	**Deferred for following:** • **submission of**

	Bosan Road, Lutfabad, Multan.		Oseltamivir Phosphate Eq. to Oseltamivir …30mg	dated 13/04/2020 **Rs. 20,000/- Form 5**		differential fee along with form 5D. The firm has revised the formulation fro Oseltamivir to Oseltamivir phosphate as per reference product.	**Form 5D alongwith the submission of differential fee Rs. 30,000/-** • **Submission of Requisite fee for trevision of formulation as per reference product.**
534.	M/s Athan Pharmaceuticals, plot # 84/1, Block B, Phase V, Industrial Estate, Hattar.	Athflu 30mg capsule	Each capsule Contains: Oseltamivir as phosphate ….. 30mg	Dy. No.5952 dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	DML issued on 5th March, 2019. Application should be on form 5D along with differential fee Rs. 30,000/-	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**
535.	M/s Ployfine chempharma, 51-industrial estate, Hayatabad Peshawar.	Ozelta 30mg Capsule	Each capsule Contains: Oseltamivir as phosphate ….. 30mg	Dy. No.6298 dated 08/04/2020 Rs. 20,000/- + 30,000 (dated 20th May, 2020 Dy.No.11599. Form 5D	As per SRO	Inspection date 24/04/2019, satisfactory level of GMP compliance. Application should be on form 5D along with differential fee Rs. 30,000/-	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**
536.	M/s Simz Pharmaceuticals Pvt Ltd Plot No.574-575, Sundar Industrial Estate, Raiwind Lahore	Fluvir Capsule 30mg	Each capsule contains: Oseltamivir as phosphate… 30mg	Dy.No. 7635 dated 15/04/2020Rs. 20,000/- dated. 15-04-2020 Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017. Form 5D along with the differential fee is required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**
537.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Oselvir capsule 30mg	Each Capsule contains: Oseltamivir Phosphate equivalent to 30mg Oseltamivir	Dy.No. 6773 dated 09/04/2020 Rs. 20,000/- dated 08-04-2020 Form 5	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance. Form 5D along with the differential fee is required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**
538.	M/s Aulton Pharmaceuticals, plot no. 84/1, block A, Phase V, Indutrial Estate Hattar.	Aultaqflu 30mg capsule	Each Capsule contains: Oseltamivir Phosphate equivalent to 30mg Oseltamivir	Dy.No. 5946 dated 07/04/2020 Rs. 20,000/- dated. 15-04-2020 Form 5	As per SRO	Inspection date 13.02.2018, Good level of GMP compliance. Form 5D along with differential fee of Rs.30,000/- is required.	**Deferred for submission of Form 5D alongwith the submission of differential fee Rs. 30,000/**

539.	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad	Oslivir Capsule 30mg	Each Capsule Contains: Oseltamivir …30mg	Dy. No. 6185 dated 08/04/2020 Rs. 20,000/- dated 07-04-2020 Form 5	As per SRO	• GMP inspection dated 30-1-2019 concluded satisfactory level of compliance with GMP standards. • Form 5 –d shall be submitted. • Differential fee of Rs. 30,000/- shall be submitted. • Salt form is not as per Reference.	**Deferred for the following:** • **submission of Form 5D alongwith the submission of differential fee Rs. 30,000/.** • **submission of evidence of approval of applied formulation containing "Oseltamivir (base only)" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**

11. Oseltamivir Phosphate Dry Suspension :

Composition:

Each ml of reconstituted suspension contains:
Oseltamivir as phosphate……..12mg

International availability:

Tamiflu 12mg/ml for Suspension (oseltamivir as phosphate) by M/s Roche, Italy AIFA Approved.

Me too status: Ozenta 12mg Dry Suspensin by M/s Hilton, reg. No. 42219

Specifications: Innovator's

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status
540.	M/s Sami Pharmaceuticals (pvt) limited, F-95, off Hub River Road SITE Karachi.	FLunar 12mg/ml powder for suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…..12mg	Dy.No. 7153 dated 13/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 7th & 14th Feb, 2019, Good level of cGMP compliance.
541.	M/s Simz Pharmaceuticals Pvt Ltd Plot No.574-575, Sundar Industrial Estate, Raiwind Lahore	Fluvir Dry Suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…12mg	Dy.No. 7634 dated 15/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017.

542.	M/s Getz Pharma (Private) Limited, 29-30/27, Korangi Industrial Area, Karachi	OSELTA Dry Powder suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…...12mg	Dy.No. 9001 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm is granted GMP certificate based on inspection conducted on 07-01-2019.
543.	M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221,222 and 223 Sector 23, Korangi Industrial Area, Karachi	OSTELFLU Dry Powder suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…12mg	Dy.No. 9138 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 17-09-2019 firm is operating at acceptable level of compliance with GMP.
544.	M/s S.J.G. Fazul Ellahi (Pvt) Ltd., E-46, SITE, Karachi	Oseltam Dry Powder suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate….12mg	Dy.No. 9141 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 15-01-2020 The firm is recommended grant of GMP certificate.
545.	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan"	Onzir oral suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…..12mg	Dy.No. 7624 dated 15/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection dated 02-08-2018 concludes that firm is considered to be operating at an acceptable level of cGMP.
546.	M/s MKB Pharmaceuticals Pvt Ltd. 66-Hayatabad Industrial Estate, Peshawar, Kpk	Tamflu dry suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…..12mg	Dy.No. 8774 dated 23/04/2020 Rs. 60,000/- Form 5	As per SRO	Inspection dated 24-01-2019 concludes that the firm is operating at satisfactory level of GMP compliance.
547.	M/s EPHARM Laboratories, A-40, Road No, SITE Super Highway Industrial area, North Karachi	EPHARVIR Dry suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…..12mg	Dy.No. 8920 dated 23/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted o 12-09-2019, GMP is rated as Good.
548.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi,	Oslovir Dry suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…...12mg	Dy.No. 9721 dated 05/05/2020 Rs. 20,000/- Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018.
549.	M/s Hygeia Pharmaceuticals, Plot No. 295 Industrial Triangle Kahuta Road Islamabad.	Hytamivir Dry suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…...12mg	Dy.No. 9715 dated 04/05/2020 Rs. 20,000/- Form 5	As per SRO	Copy of GMP inspection conducted on 21-09-2017, the firm is considered to be operating at satisfactory level of compliance.
550.	M/s Mediceena Pharma (Pvt) Ltd. 27 Km Raiwind Road Lahore	Osmed Dry suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…...12mg	Dy.No. 9570 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 24-9-2019.
551.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-	Osmivir Dry suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate..…..12mg	Dy.No. 8115 dated 20/04/2020 Rs. 20,000/- Form 5	As per SRO	The firm has granted renewal of DML from CLB w.e.f 19-07-2019.

552.	M/s Zephyr Pharmatec (Pvt) Ltd. A-39 S.I.T.E. II Super Highway Karachi.	Zephtam Dry suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate..…..12mg	Dy.No. 9418 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 25-09-2019 overall GMP compliance is rated as GOOD.
553.	M/s Hamaz Pharmaceuticals Pvt Ltd. Business City Plaza, Hall # 1, 2nd Floor, Bosan Road, Multan, Pakistan	Oselta 12mg/ml Suspension	Each ml Contains: Oseltamivir as phosphate…12mg	Dy.No. 5920 dated 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	GMP certificate issued on 06-11-2019. The firm has revised the formulation to Oseltamivir as poshphate and submitted fee Rs. 5000/- vide challan number 2941196 dated 05/06/2020.

Decision: Registration Board approved registration of above applications from Serial No. 540 to 553. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
554.	"M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi"	Osvir dry suspension 12mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate….. …..12mg	Dy.No. 9453 dated 30/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 24-07-2018, current GMP compliance is rated as Good. The formulation mentioned in fee challan is Amaquin (50mg/5ml) syrup different from that applied formulation. Clarification is required.	**Deferred for the following:** • **Clarification since the attached fee challan is for Amaquin (50mg/5ml).** • **Submission of evidence of approval of applied formulation as "Syrup" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**

12. Oseltamivir Phosphate dry suspension:

Composition:

Each ml of reconstituted suspension contains:
Oseltamivir as phosphate……..6mg

International availability:

Tamiflu 6mg/ml for Suspension (oseltamivir as phosphate) by M/s Roche, USFDA Approved.

Me too status:

Osemvir Powder for Oral Suspension (60mg/5ml) by M/s Brookes Pharmaceutical, reg. No. 42290

Specifications: Innovator's

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status
555.	M/s Ipram International Pharmaceuticals plot # 26, street # S.S-3 national industrial zone, (RCCI) Rawat, Islamabad.	Covi-flu powder for oral suspension 6gm/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No. 6393 dated 08/04/2020 Rs. 20,000/- Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 20th December, 2018.
556.	M/s Macter International Limited, F-216, S.I.T.E, Karachi	Macflu 6mg/ml For oral suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No. 5897 dated 07/04/2020 Rs. 20,000/- + 30,000/- 20/04/2020 Form 5D	As per SRO	Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP.
557.	M/s Sami Pharmaceuticals (pvt) limited, F-95,) off Hub River Road SITE Karachi.	Flunar 6mg/ml Powder for suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No. 6257 dated 8//04/2020 Rs. 50,000/- Form 5D	As per SRO	Last inspection report dated 7th & 14th Feb, 2019, Good level of cGMP compliance.
558.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Ozwir 6mg/ml dry suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No. 6292 dated 08/04/2020 Rs. 50,000/- Form 5D	As per SRO	Last GMP inspection conducted on 13/01/20020, the panel recommended renewal of DML.
559.	M/s Wnsfield Pharmaceuticals, Plot # 122, block-A, Phase-V Hattar industrial estate, Hattar.	Oseltamivir 6mg/ml for suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No. 6287 dated 08/04/2020 Rs. 50,000/- Form 5D	As per SRO	Inspection date 18/01/2018, the panel recommended renewal of DML.
560.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan contract manufacturing by Wenvo Pharmaceutical, plot#31,32 punjab small industries estate taxila Rawalpindi.	Flukill Dry powder suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No. 7269 dated 14/04/2020 Rs. 50,000/- 14-04-2020 Form 5D	As per SRO	Last inspection report of M/s Wenovo Pharmaceuticals, dated 13/01/2020. The panel recommended renewal of DML. Agreement is attached.

561.	M/s Global Pharmaceuticals Pvt Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	Fluvir Dry suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No.7301 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 26/12/2018, panel recommended renewal of DML.
562.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Fluvent 6mg/ml dry suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No.7295 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 11/02/2019, the panel recommended issuance of GMP ceritifcate.
563.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi	Fluvir Dry suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No.7314 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 10-07-2018 GMP compliance level is rated as GOOD
564.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Oselvir powder for suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No.6772 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance.
565.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Oselvir for oral suspension	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No.7301 08/04/2020 Rs. 50,000/- 08-04-2020 Form 5D	As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/04/2019.
566.	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan	Asteflu Dry Powder suspension 6mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate……..6mg	Dy.No. 7789 dated 27/04/2020 Rs. 50,000/- Form 5D	As per SRO	GMP inspection dated 13-11-2018, overall GMP compliance of the firm is Good.
567.	M/s GT Pharma (Pvt) Ltd., 713 Sundar Industrial Estate Lahore.	Fluvir suspension 6mg/ml	Each ml of reconstituted suspension contains: Oseltamivir as phosphate…...6mg	Dy.No.9469 30/04/2020 Rs. 50,000/- Form 5D	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 31-01-2019.
568.	M/s Pharma Wise Labs (Pvt). Ltd.,25-M. QA. Industrial Estate, Kot Lakhpat Lahore Pakistan	Oseltawise 6mg/ml Oral suspension	Each ml contains: Oseltamivir base…..…..6mg	Dy.No.6414 30/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP certificate issued on the basis of inspection conducted on 16-10-2019.

Decision: Registration Board approved registration of above applications from Serial No. 555 to 568. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.

Following applicatrions are not complete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
569.	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Niaz Baig, Raiwind Road,	Ost-p 6mg/ml Oral Solution	Each ml Contains: Oseltamivir as Phosphate…6 mg	Dy.No. 6201 dated 08/04/2020 Rs. 20,000/- 08-4-2020 Form 5	As per SRO	Last inspection report dated 25/03/2019, satisfactory level of GMP compliance.	**Deferred for submission of evidence of approval of applied formulation as "Liquid oral**

	Lahore					Liquid injectable (vial & Ampoule) section available. The firm has applied for liquid oral suspension while it is dry powder for suspension in reference countries.	**suspension" in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**

13. Ascorbic acid chewable tablet 500mg:
Composition:
Each chewable tablet contains:
Ascorbic acid……..500mg
International availability:
Ascorbic acid chewable tablet (50mg, 100mg, 200mg, 500mg) by M/s Ennogen Pharma ltd, MHRA Approved
Me too status: Cecon 500mg tablet by M/s Abbott.
Specifications: USP
Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status
570.	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir	Vitabic Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7308 dated 14/04/2020 Rs.20,000/- 14-04-2020 Form 5	As per SRO	As of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. Inspection date 22/02/2019. The firm has revised the formulation from uncoated to Chewable tablet and submitted Rs. 5000/- dated 18th May, 2020, dy. No. 11265..
571.	M/s Zanctok Pharmaceuticals Laboratories F-5 Site Hyderabad	Zeta-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8991 dated 27/04/2020 Rs.20,000/- 27-04-2020 Form 5	As per SRO	GMP inspection dated 21-03-2019, current GMP compliance level is rated as Good.
572.	M/s Nenza Pharmaceuticals Pvt Ltd, 33-A, Industrial Estate Hayatabad Peshawar	Ascoban Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.9313 29/04/2020 Rs.20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 26-09-2018, overall GMP compliance of the firm is satisfactory

573.	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur	C-Mune Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9325 dated 29/04/2020 Rs.50,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 03-10-2018, the firm is maintaining satisfactory level of cGMP.
574.	M/s Citi pharmaceuticals Pvt Ltd 3-KM, Head Balloki Road, Phool Nagar District Kasur	Ascon Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9218 dated 28/04/2020 Rs.20,000/- 28-04-2020 Form 5	As per SRO	The firm has copy of GMP certificate based on inspection dated 19-03-2019.
575.	M/s Wellborne pharmacchem and biological, Plot # 51/1-52/1 Phase II, Industrial Estate Hattar.	Ascowell 500mg tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy. No. 7612 15/04/2020 Rs.20,000/- Form 5	As per SRO	Last inspection report dated 07/11/2018, Satisfactory level of cGMP compliance.
576.	M/s Arsons Pharmaceutical Industries (pvt) Ltd. 2.5km defence road, off Multan road, Lahore.	Vitasol-C 500mg Chewable tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 6540 dated 09/04/2020 Rs.20,000/- Form 5	As per SRO	Last inspection dated 18/09/2019, satisfactory GMP compliance for; ➢ Tablet (General & Psychotropic) ➢ Capsule General ➢ Cream/ointment/Gel (general)
577.	M/s LINZ Pharmaceuticals (Pvt.) Ltd, Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area, Karachi	ACE-C 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 9131 dated 28/04/2020 Rs.20,000/- Form 5	As per PRC	Inspection dated 09-01-2020, the GMP of the firm is rated GOOD.
578.	M/s Vega Pharmaceuticals (Pvt.) Ltd., Plot No.4, Pharma city Sundar, 30 Km Multan Road Lahore.	VC 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 9127 dated 28/04/2020 Rs.20,000/- Form 5	As per SRO	Inspection dated 21-03-2019 the firm is considered to be operating at fair level of GMP compliance.
579.	M/s Standpharm Pakistan (Pvt) Ltd, 20Km, Ferozpur Road , Lahore	CEEVIT 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid..500mg	Dy.No. 8557 dated 22/04/2020 Rs.20,000/- Form 5	As per SRO	GMP inspection date d19-10-2017 satisfactory level of compliance.
580.	M/s Reign Pharmaceuticals PCSIR-KLC (Pvt) Ltd, TBIC Building -1, PCSIR Laboratories complex, Shahrah-e-Dr. salim-uz-Zaman Siddique, off university Road, Karachi	Reigncon 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 8457 dated 21/04/2020 Rs. 20,000/- Form 5	As per SRO	The panel dated 04-10-2019 recommends for renewal of DML.

581.	M/s EPHARM Laboratories, A-40, Road No, SITE Super Highway Industrial area, North Karachi	EPHABIC 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 8453 dated 21/04/2020 Rs.20,000/- Form 5	As per SRO	Inspection conducted o 12-09-2019, GMP is rated as Good.
582.	M/s Shawan Pharmaceuticals (Pvt.) Ltd. Plot No. 37, Road NS-01, National industrial Zone, Rawat	Vit. C 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 8552 dated 22/04/2020 Rs.20,000/- Form 5	As per SRO	Inspection dated 04-03-2020 overall GMP compliance found Good.
583.	M/s Radiant Pharma (Pvt.) Ltd, 43-E Sundar Industrial Estate, Lahore	C-CHEW 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No.8339 20/04/2020 Rs.20,000/- Form 5	As per SRO	The firm was granted GMP certificate based on inspection dated 31-07-2018.
584.	M/s Medisure Laboratories Pakistan (Pvt) Ltd., A-115, SITE, Super Highway, Karachi	Medi-Vit C 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 7951 dated 16/04/2020 Rs.20,000/- Form 5	As per SRO	Inspection conducted on 19-07-2019 current GMP compliance level is rated as GOOD.
585.	M/s Bosch Pharmaceuticals (Pvt.) Ltd., 221,222 and 223 Sector 23, Korangi Industrial Area, Karachi	WIN-C 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No.9135 28/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 17-09-2019 The firm is operating at acceptable level of compliance with GMP.
586.	M/s S.J.&G. Fazul Ellahi (Pvt) Ltd., E-46, SITE, Karachi	Rexcor 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No.9145 28/04/2020 Rs.20,000/- Form 5	As per SRO	Inspection conducted on 15-01-2020 The firm is recommended grant of GMP certificate.
587.	M/s Panacea Pharmaceuticals. Plot.no.4, Street.no.S-6, National Industrial zone Rawat, Islamabad	Carbox Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8537 dated 22/04/2020 Rs.20,000/- 22-04-2020 Form 5	As per SRO	QA division vide letter No.F.4-5/2007-QA stated that the current GMP status of the firm shall be considered as compliant.
588.	M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore	3Con Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8541 22/04/2020 Rs.20,000/- 22-04-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate granted based on inspection dated 08-1-2020.
589.	M/s Fredmann Pharmaceuticals Plot No.82-83, B, Old Industrial Area Mirpur	Ascor Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8995 dated 27/04/2020 Rs.20,000/- 27-04-2020 Form 5	As per SRO	Inspection date 10/01/2020. The panel is of the opinion that the report may be forwarded to the competent authority for resumption of production.
590.	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi	Ascar Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9225 dated 28/04/2020 Rs.20,000/- 28-04-2020 Form 5	As per SRO	Inspection report dated 19-09-2019, the firm has been recommended grant of GMP certificate.

591.	M/s Citi pharmaceuticals Pvt Ltd 3-KM, Head Balloki Road, Phool Nagar District Kasur	ASCON Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9218 dated 28/04/2020 Rs.20,000/- 28-04-2020 Form 5	As per SRO	The firm has copy of GMP certificate based on inspection dated 19-03-2019.
592.	M/s Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate, Hattar, KPK	Wel-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8321 dated 20/04/2020 Rs.20,000/- 20-04-2020 Form 5	As per SRO	Panel Inspection dated 04-09-2018 & 26-09-2018 recommends renewal of DML.
593.	M/s Faas Pharmaceuticals (Pvt.) Ltd. F-748/L, S.I.T.E Karachi, Pakistan	Faascon chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9008 dated 27/04/2020 Rs.20,000/- 27-04-2020 Form 5	As per SRO	GMP inspection dated 13-11-2019, the firm is operating at good level of GMP compliance.
594.	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan	Ascorbic acid chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8105 dated 20/04/2020 Rs.20,000/- 20-04-2020 Form 5	As per SRO	GMP inspection dated 27th Feb, 2018, overall GMP of the firm is rated as good.
595.	M/s Zephyr Pharmatec Pvt Ltd. Plot No. A-39, S.I.T.E II, Super Highway, Karachi.	Zevit-C Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9420 dated 30/04/2020 Rs.20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 25-09-2019, overall GMP compliance is rated as GOOD.
596.	M/s Regent Laboratories C-20, SITE Super Highway, Karachi	REGOVIT-C Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.9302 29/04/2020 Rs.20,000/- 29-04-2020 Form 5	As per SRO	Panel inspection dated 09th October, 2019 recommends renewal of DML.
597.	M/s Variant Pharmaceuticals Pvt Ltd, Plot No05, M2-Pharmazone, 26KM, Main Sharaqpur Road, Shaikhupura.	V-CALCE 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9442 dated 30/04/2020 Rs.20,000/- 30-04-2020 Form 5	As per SRO	Inspection report dated 09-12-2019 & 20-12-2019, the firm is granted DML by way of formulation.
598.	M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi	Mac-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9948 dated 05/05/2020 Rs.20,000/- 05-05-2020 Form 5	As per SRO	GMP inspection dated 07-11-2019, the firm is operating at a satisfactory level of GMP compliance.
599.	M/s Mediceena Pharma Pvt Ltd 27-km, Raiwind Lahore	MC-500 chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.9566 dated 30/04/2020 Rs.20,000/- 30-04-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate granted based on inspection dated 24-9-2019.
600.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh,	URGEN-C Chewable Tablet	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9460 dated 30/04/2020 Rs.20,000/-	As per SRO	Panel inspection dated 09-01-2019 recommends grant of GMP certificate

	Nowshera-Khyber Pakhtunkhwa	500mg		29-04-2020 Form 5		
601.	M/s Lowitt Pharma Pvt Ltd. 24-Industrial Estate, Hayatabad, Peshawar	Hi-C Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.9963 05/05/2020 Rs.20,000/- 05-05-2020 Form 5	As per SRO	Panel inspection dated 12-05-2020 recommends grant of GMP certificate.
602.	M/s Medipak Limited 132, Industrial Estate, Kot Lakhpat Lahore	Medivit-C Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9960 dated 05/05/2020 Rs.20,000/- 05-05-2020 Form 5	As per SRO	GMP inspection dated 11-07-2019, the firm had rectified most of the deficiencies pointed out in last inspection.
603.	M/s. Munawar Pharma (Pvt) Ltd 31-KM, Ferozepur Road Lahore	C-Chew Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.9951 05/05/2020 Rs.20,000/- 05-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate granted based on inspection dated 07-11-2017.
604.	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi	VC Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9431 dated 30/04/2020 Rs.20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 21-09-2019, the compliance level is rated as satisfactory.
605.	M/s Epoch Pharmaceuticals. Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi	Ascorbid Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9814 dated 04/05/2020 Rs.20,000/- 04-05-2020 Form 5	As per SRO	GMP inspection dated 26th July, 2019, the firm is considered to be operating at satisfactory level of GMP compliance.
606.	M/s Aventek Pharmaceuticals. 44-C, Sundar Industrial Estate, Lahore	Avecid Chewable Tablet 500mg	Each Chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9732 dated 04/05/2020 Rs.20,000/- 04-05-2020 Form 5	As per SRO	GMP inspection report dated 01-01-2019, the firm maintained satisfactory conformance to GMP compliance in the manufacturing and quality control operations.
607.	M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi	Vita-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9729 dated 04/05/2020 Rs.20,000/- 04-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 30th January, 2020.
608.	M/s Zanctok Pharmaceuticals Laboratories F-5 Site Hyderabad	Zeta-C Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8991 dated 27/04/2020 Rs.20,000/- 27-04-2020 Form 5	As per SRO	GMP inspection dated 21-03-2019, current GMP compliance level is rated as Good.
609.	M/s Nenza Pharmaceuticals Pvt Ltd 33-A, Industrial Estate Hayatabad Peshawar	Ascoban Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9313 dated 29/04/2020 Rs.20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 26-09-2018, overall GMP compliance of the firm is satisfactory

610.	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur	C-Mune Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9325 dated 29/04/2020 Rs.20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 03-10-2018, the firm is maintaining satisfactory level of cGMP.
611.	M/s Citi pharmaceuticals Pvt Ltd., 3-KM, Head Balloki Road, Phool Nagar District Kasur	Ascon Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9218 dated 28/04/2020 Rs.20,000/- 28-04-2020 Form 5	As per SRO	The firm has copy of GMP certificate based on inspection dated 19-03-2019.
612.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan	Abacod Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8121 dated 20/04/2020 Rs.20,000/- 20-04-2020 Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018.
613.	M/s Eros Pharmaceuticals (pvt) ltd, 94/23, Korangi industrial Area, Karachi.	Ero C 500 tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 7266 dated 14/04/2020 Rs.20,000/- Form 5	As per SRO	Last inspection report dated 26/03/2018, the panel recommended resumption of production.
614.	M/s Sami Pharmaceuticals (pvt) limited, F-95,) off Hub River Road SITE Karachi.	Vitcee 500mg chewable tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 7151 dated 13/04/2020 Rs.20,000/- Form 5	As per SRO	Last inspection report dated 7th & 14th Feb, 2019, Good level of cGMP compliance.
615.	M/s Jinnah Pharmaceuticals (pvt) ltd. 13km Lahore Road, Multan.	J-C500 Chewable tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No.7111 13/04/2020 Rs.20,000/- Form 5	As per SRO	The panel recommended renewal of DML, inspection date 03/05/2019.
616.	M/s Mafins Pharma, A-5, SITE Super highway Industrial Area, Karachi.	Vitamin-C 500mg tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No.7286 14/04/2020 14/04/2020 Rs.20,000/- Form 5	As per SRO	Last inspection conducted on 24/07/2019, appropriate GMP compliance.
617.	M/s Simz Pharmaceuticals (Pvt) ltd. Plot # 5740575 Sundar industrial Estate, Raiwind Road, Lahore.	Simcon Tablet 500mg	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No.7628 dated 15/04/2020 Rs.20,000/- Form 5	As per SRO	GMP certificate issued on 03/10/2017 on the basis of inspection conducted on 19/08/2017.
618.	M/s Pearl Pharmaceuticals, plot # 204, street 1, I-10/3, Islamabad.	C-Pearl 500mg tablet	Each chewable tablet contains: Ascorbic acid..500mg	Dy.No.6570 dated 09/04/2020 Rs.20,000/- Form 5	As per SRO	Satisfactory GMP compliance, inspection date 23/07/2018.
619.	M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad.	Cor-C 500 tablet	Each chewable tablet contains: Ascorbic acid ……..500mg	Dy.No. 6528 dated 09/04/2020 Rs.20,000/- Form 5	As per SRO	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines.

620.	M/s Evolution Pharmaceuticals (pvt) ltd Plot # 25&26, street S-3, RCCI, National Industrial zone, Rawat, Islamabad.	C-Vit 500mg tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 6531 dated 09/04/2020 Rs.20,000/- Form 5	As per SRO	Inspection date 25/10/2018, As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals.
621.	M/s Convell Laboratories Saidu Sharif Swat KPK.	Vell-C Chewable tablet	Each chewable tablet contains: Ascorbic acid……..500mg	Dy.No. 6397 dated 08/04/2020 Rs.20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 02/03/2019, the panel recommended renewal of DML.
622.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Cechew Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7623 dated 15/04/2020 Rs.20,000/- 14-04-2020 Form 5	As per SRO	Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
623.	M/s Noa Hemis Pharmaceuticals, Plot No.Sector 23, Korangi Industrial Area, Karachi.	Covit-C Chewable tablet 500mg	Each chewable tablet contains: Ascorbic acid ……. 500mg	Dy. No. 9612 dated 27/04//2020 Rs.20,000/- Form 5	As per SRO	Panel inspection dated 28-02-2019 recommended renewal of DML.
624.	M/s Valor Pharmaceuticals, 124/Am Kahuta Triangle, Industrial Area Islamabad.	Vitan-C Chewable tablet 500mg	Each chewable tablet contains: Ascorbic acid ……. 500mg	Dy. No. 7981 dated 17/04//2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 20-04-2018 recommended renewal of DML.
625.	M/s Unison Chemical Works Raiwind Road, Lahore.	C IN 500mg Chewable tablet	Each chewable tablet contains: Ascorbic acid ……. 500mg	Dy. No. 8332 dated 20/04//2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 19-11-2019 recommended renewal of DML.
626.	M/s Gulf Pharmaceuticals, Rawat, Rawalpindi.	Asci-C 500mg Chewable tablet	Each chewable tablet contains: Ascorbic acid ……. 500mg	Dy. No. 7989 dated 17/04//2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 07-12-2019 recommended resumption of production.
627.	M/s Relizon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore	ReVit C 500mg Chewable tablet	Each chewable tablet contains: Ascorbic acid ……. 500mg	Dy. No. 7985 dated 17/04//2020 Rs. 20,000/- Form 5	As per SRO	The firm was inspected on 05.12.2017, wherein the panel recommended the grant of DML.

628.	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi	Cee-Max Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7783 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Good level of GMP compliance, inspection date 21/02/2019.
629.	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi	Asicon Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7778 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 06/08/2019. The panel recommended resumption of production.
630.	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Tab-c Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7767 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 22/01/2020 on the basis of inspection conducted on 02/10/2019.
631.	M/s Palpex Pharmaceuticals Pvt Ltd.FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Pal-c Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7775 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on 08-05-2018."
632.	M/s Medifine Laboratories Pvt Ltd Mirpur	Ascorbic Acid Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8379 dated 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Inspection date 09/11/2018, the panel recommended renewal of DML.
633.	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi	Ascorb-C Acid Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8372 dated 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	GMP certificate issued on 11/03/2019 on the basis of inspection conducted on 05/03/2019.
634.	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan	C-white chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8371 dated 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 15-09-2017 the firm has acceptable level of GMP.
635.	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan	Recon C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.8840 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection date 19/09/2018, The panel recommended issuance of GMP certificate.
636.	M/s Legacy Pharmaceuticals pvt Ltd., 111-A, Industrial Estate Hayatabad Peshawar	Ascorbic Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.8776 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection date 18/07/2019. The Panel recommended renewal of DML.

637.	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab	Lor-c Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.8768 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	03/05/2019 inspection dated. The panel recommended renewal of DML.
638.	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad	Vital-c Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.8765 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 20-11-2017 firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today.
639.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	VIXI Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No.7271 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP Certificate issued on the basis of GMP inspection conducted on 1-03-2019
640.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura, Pakistan	Ascor Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7085 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 30/05/2019, good level of GMP compliance.
641.	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad	C-Rulz Tablet 500mg	Each chewable tablet contains: Vitamin C…500mg	Dy.No.7150 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	GMP certificate issued on 18/03/2019.
642.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neu-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7073 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance.
643.	M/s Goodman Laboratories. No.5, Street No. S-5, National Industrial Zone, Rawat, Rawalpindi	Vital-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7937 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued on the basis of inspection conducted on 08/08/2018.
644.	M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan	Mb-Cecon Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7935 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Good GMP compliance, inspection date 28/02/2018.
645.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Novita-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8921 dated 24/04/2020 Rs. 20,000/- 24-04-2020 Form 5	As per SRO	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tabklet General, Capsule General, Liquid Syrup General).
646.	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad	Medi-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7940 dated 24/04/2020 Rs. 20,000/- 24-04-2020	As per SRO	Inspection date 16/10/2018, the panel recommended renewal of DML.

				Form 5		
647.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	C-500 Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8387 dated 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	GMP inspection dated 23-02-2018 the firm was operating at an acceptable level of compliance with GMP standards.
648.	M/s Sayyed Pharmaceuticals Industries Pvt Ltd Plant No.67/2, Phase-3, Industrial Estate, Hattar	Say-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7121 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection conducted on 04-09-2019 the firm operates at satisfactory level of GMP guidelines.
649.	M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar	Scor Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 6750 dated 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	GMP inspection conducted on January 24th, 2019 concluded that firm is operating at satisfactory level of GMP compliance.
650.	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan	Hivit-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7129 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	DML was issued on 13/06/2018.
651.	M/s Miracle Pharmaceuticals Pvt Ltd, Plot.No.08, Street no.S-5, National Industrial Zone, Rawat	Mecon Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7138 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Minimal level of GMP compliance/, inspection date 28/02/2019.
652.	M/s Ambrosia Pharmaceuticals. Plot # 18, Street # 09, National Industrial Zone, Rawat, Pakistan	Vita C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7140 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 08/10/2018, the firm was found working in compliance to GMP.
653.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Corcid Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 6788 10/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	Last inspection report dated 22/01/2019, good level of GMP compliance.
654.	M/s Heal Pharmaceuticals Pvt Ltd. W-33, Industrial Area, Hayatabad Peshawar	C-Vit Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7481 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 09/10/2019, The inspection is conducted and firm's request acceded to complete the work and appoint technical staff as required along with the instrument required.
655.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi	C-500 Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7309 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 10-07-2018 GMP compliance level is rated as GOOD

656.	Life Pharmaceuticals Company 24-III, Industrial Estate, Multan	Volta-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7376 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Inspection date 15/01/2018, satisfactory level of GMP compliance.
657.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Cecor chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7477 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 21/05/2019 on the basisi of inspection conducted on 23/04/2019.
658.	M/s Medicon Pharmaceuticals Pvt Ltd. Industrial Estate, Jamrud Road, Peshawar, Pakistan	Medi-C Tablet 500mg	Each CHEWABLE tablet contains: Ascorbic Acid…500mg	Dy.No. 7925 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 03/10/2017, satisfactory level of GMP.
659.	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad	Sicorb Tablet 500mg Alternate brand names: Sicon Sicorbic Siacid	Each CHEWABLE tablet contains: Ascorbic Acid…500mg	Dy.No. 7762 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Date of inspection 18/02/2020 and 20/02/2020, the panel recommended issuance GMP certificate.
660.	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan	Asco Chewable tablet	Each chewable tablet contains: Ascorbic acid …500mg	Dy.No. 7163 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 21/11/2017, fair level of GMP compliance.
661.	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi	Ascorbi Chewable Tablet	Each chewable Tablet Contains: Ascorbic Acid…500mg	Dy.No. 7058 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	GMP certificate issued on 05/03/2020 on the basis of inspection conducted on 25/02/2020.
662.	M/s MKB Pharmaceuticals Pvt Ltd. 66-Hayatabad Industrial Estate, Peshawar, KPK.	Cecan 500mg tablet	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8772 23/04/2020 Rs. 20,000/- 23-04-2020 Form 5	As per SRO	Inspection dated 24-01-2019 concludes that the firm is operating at satisfactory level of GMP compliance.
663.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad	Immune-C chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8535 22/04/2020 Rs. 20,000/- 22-04-2020 Form 5	As per SRO	The firm was granted renewal of DML dated 21-05-2019 for only two sections Syrups (General) Plasters
Decision: Registration Board approved registration of above applications from Serial No. 570 to 663. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
664.	M/s Biorex Pharmaceuticals Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan	Bio C Tablet 500mg	Each Chewable Tablet Contains: Ascorbic Acid…500mg	Dy. No. 7618 dated 15/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	Last inspection report is older than 3 years.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
665.	M/s Harmann Pharmaceuticals Laboratories Pvt Ltd 16-KM, Multan Road, Lahore	VITAKIT-C Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 8106 dated 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	GMP status not confirmed.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
666.	M/s Perfect Pharma (Pvt) Ltd. 5-Km, Manga Road, Raiwind, Lahore	PERVIT-C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9301 dated 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Panel inspection dated 09-02-2018 recommended the renewal of DML. Reference formulation is chewable tablet while the firm has applied uncoated tablet.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
667.	M/s Advanced Pharmaceuticals Plot No.38, Street No S-4, National Industrial Zone Rawat	Advanced-C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9579 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP status not confirmed. Reference formulation is chewable tablet while applied formulation is plain tablet.	**Decision: Registration Board referred the case to QA & LT Division for updated status of GMP.**
668.	M/s CSH Pharmaceuticals Pvt Ltd 32-Km, Ferozepur Road, Lahore By M/s Medisave Pharmaceuticals.	VC-500 Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9317 dated 29/04/2020 Rs. 50,000/- 29-04-2020 Form 5	As per SRO	GMP inspection of M/s Medisave Pharmaceuticals, dated 02-10-2019, the firm was operating at	**Deferred for the following:** • **Submission of details of products which are already being**

	Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan					satisfactory level of GMP compliance on the day of inspection. GMP of CSH Pharma is required. List of products already approved on contract manufacturing. Number of sections approved for CSH Pharmaceuticals Reference product uis chewable.	**manufactured on contract and detail of number of approved sections.** • **Registration Board referred the case to QA & LT Division to conduct GMP inspection of M/s CSH Pharma on priority.** • **submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
669.	M/s Advanced Pharmaceuticals Plot No.38, Street No S-4, National Industrial Zone Rawat	Advanced-C chewable Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9578 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP status not confirmed. Reference formulation is chewable tablet while applied formulation is plain tablet.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in**

							accordance with reference product along with submission of requisite fee. **The Board also referred the case to QA & LT Division for updated status of GMP.**
670.	M/s ARP (Pvt) Ltd. Plot No 12 & 12A, Street No W-3, National Industrial Zone RCCI, Rawat, Islamabad	Active-C chewable Tablet 500mg	Each uncoated chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9463 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate granted based on inspection dated 06-10-2017. The reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
671.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	URGEN-C TABLET 500MG	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9461 dated 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	The applied formulation is not verified in RRA. Panel inspection dated 09-01-2019 recommends grant of GMP certificate	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**

672.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	C-Fold Tablet 500mg	Each uncoated tablet contains: Ascorbic Acid…500mg	Dy.No. 9984 dated 05/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Reference formulation is chewable tablet while the firm has applied uncoated tablet. Panel inspection dated 20-02-2019 recommends the grant of GMP certificate.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
673.	M/s Orta Labortaories Pvt Ltd 24 KM Multan Road, Off Defence Road Mohlanwal Lahore	Citron Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9968 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	GMP status not confirmed.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
674.	M/s Swat Pharmaceuticals Saidu Sharif, Swat, 19130 Pakistan	Swamin-C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9958 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As Per SRO	The firm has applied plain tablet while reference formulation is chewable tablet. GMP status could not be verified.	**Deferred for following:** • **submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** • **referred the case to QA & LT Division to conduct GMP**

							inspection of Firm on priority.
675.	M/s IPP (Pvt) Ltd Gulkada Saidu Sharif Sawat	IPIMIN-C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9956 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	GMP status not confirmed. Reference formulation is chewable tablet while the firm has applied uncoated tablet.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
676.	M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK	Lecon Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 9952 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	GMP status not confirmed. Reference formulation is chewable tablet while the firm has applied uncoated tablet.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
677.	M/s Unimark Pharmaceuticals Plot No.7-A, Street No.S-7, National Industrial Zone Rawat	Univit-C Chewable Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 9440 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP status Not confirmed.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
678.	M/s AAA Health Pharmaceutical Laboratories, Plot No: 9-A, Street N-5, National	VITA-C 500mg Chewable Tablet	Each chewable tablet contains: Ascorbic acid…….500mg	Dy.No. 9122 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP status Not confimed	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm**

	Industrial Zone, RCCI, Rawat						**on priority.**
679.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Ascogen Tablet 50mg	Each Tablet Contains: Ascorbic Acid …….. 500mg	Dy. No. 6242 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm was inspected on 01-01-2020 concluding GMP compliant status. The firm has applied for plain tablet while the reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
680.	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan	Obvit-C Tablet 500mg	Each chewable tablet contains: Ascorbic Acid…500mg	Dy.No. 7170 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 18/02/2020 Due to area constraint, the firm was unable to expand or rectify certain manufacturing areas related to installation of machinery/equipments, emergency exits, However \other shortcomings were rectified.	**Registration Board referred the case to QA & LT Division for updated status of GMP.**

13. Ascorbic acid chewable tablet 100mg:

Composition:

Each chewable tablet contains:
Ascorbic acid……..100mg

International availability:

Ascorbic acid chewable tablet (50mg, 100mg, 200mg, 500mg) by M/s Ennogen Pharma ltd, MHRA Approved.

Me too status: acid tablet 100mg by M/s Pfizer, Reg. No. 2794.

Specifications: USP

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status
681.	M/s Eros Pharmaceuticals (pvt) ltd, 94/23, Korangi industrial Area, Karachi.	Ero C 100 tablet	Each chewable tablet contains: Ascorbic acid……..100mg	Dy.No. 7267 14/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 26/03/2018, panel recommended resumption of production.
682.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neo-C chewable 100mg tablet	Each chewable tablet contains: Ascorbic acid …100mg	Dy.No. 7072 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance.
683.	M/s Gulf Pharmaceuticals, Plot No. 49, Street S-5, National Industrial Zone, Rawat, Islamabad	Asic-C Tablet 100mg	Each Chewable Tablet Contains: Ascorbic Acid…100mg	Dy. No. 7988 17/04/2020 Rs. 20,000/- 17-04-2020 Form 5	As per SRO	Panel inspection dated 07-12-2019 recommended resumption of production.
684.	M/s Quaper pvt. Ltd. 26-A Samll industrial estate Lahore road Sargodha.	Vitamin C tablet 100mg	Each Chewable Tablet Contains: Ascorbic Acid…100mg	Dy.No. 5886 07/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 28/01/2019, the panel recommends the renewal of DML.
685.	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur	C-mune Chewable Tablet 100mg	Each chewable Tablet contains: Ascorbic Acid…100mg	Dy.No. 9324 29/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 03-10-2018, the firm is maintaining satisfactory level of GMP.
686.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	C-chew Chewable Tablet 100mg	Each chewable Tablet contains: Ascorbic Acid…100mg	Dy.No. 8338 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	The firm was granted GMP certificate based on inspection dated 31-07-2018.
687.	M/s Arsons Pharmaceutical Industries Pvt Ltd. 2.5km Defence Road, Off Multan Road, Lahore, Pakistan	Vitasol Chewable Tablets 100mg	Each chewable Tablet Contains: Ascorbic Acid…..100mg	Dy. No. 6539 09/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Panel inspection dated 18-09-2019 concluded satisfactory level of GMP compliance

Decision: Registration Board approved registration of above applications from Serial No. 681 to 687. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
688.	M/s Fresh Pharmaceuticals, Plot # 07, Street S-6 National Industrial Zone Rawat, Islamabad	Ascor tablet 100mg	Each Tablet Contains: Ascorbic Acid…100mg	Dy.No. 5909 dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection report dated 02-10-2019 is complying satisfactory level of cGMP as of today. The firm has applied for plain tablet while reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
689.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan	Bio-C 100mg tablet	Each tablet contains: Ascorbic acid …100mg	Dy.No. 7143 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. The reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
690.	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Werrick's Vitamin C 100mg Chewable Tablet	Each Tablet Contains: Vitamic C (Ascorbic Acid) …….100mg	Dy.No. 6160 dated 08/04/2020 Rs. 20,000/- 07-4-2020 Form 5	As per SRO	The firm has applied for plain tablet while the reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
691.	M/s BJ Pharmaceuticals. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore	Vita C 100mg Tablet	Each tablet contains: Ascorbic acid …100mg	Dy.No. 6761 dated 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Firm has required equipment/machinery, HVAC system and qualified staff, fir showed good intention to further improvements in	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or**

						future. Overall hygienic condition of the firm is satisfactory at the time of inspection. Inspection date 15/01/2020. The firm has applied for plain tablet while the reference product is chewable.	**else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
692.	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Vitan-C 100mg tablet	Each tablet contains: Ascorbic acid …100mg	Dy.No. 6753 dated 10/04/2020Rs. 20,000/- dated 10-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 20/04/2018. The firm has applied for plain tablet while the reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
693.	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Vita-C Tablet 100mg	Each Tablet Contains: Ascorbic Acid…100mg	Dy. No. 5880 dated 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	The firm was inspected on 16th January, 2019 and was decided to recommend the issuance of GMP certificate. The firm has applied for plain tablet while the reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**
694.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Ascogen Tablet 100mg	Each Tablet Contains: Ascorbic Acid …….. 100mg	Dy. No. 6243 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm was inspected on 01-01-2020 concluding GMP compliant status. The firm has applied for plain tablet while the reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of**

							requisite fee.
695.	M/s Biogen Pharma. 8Km, Chakbeli Road Rawat, Rawalpindi.	C-Gen tablet 100mg	Each tablet contains: Ascorbic acid …100mg	Dy.No. 6767 dated 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Inspection date 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. The firm has applied for plain tablet while the reference product is chewable.	**Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.**

14. Ascorbic acid chewable tablet 50mg:

Composition:

Each chewable tablet contains:

Ascorbic acid……..50mg

International availability:

Ascorbic acid chewable tablet (50mg, 100mg, 200mg, 500mg) by M/s Ennogen Pharma ltd, MHRA Approved.

Me too status:

Ascorbic acid 50mg tablet by M/s Irza Pharma, Reg. NO. 64818.

Specifications:

USP

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status/Remarks
696.	M/s Gulf Pharmaceuticals. Plot No. 49, Street S-5, National Industrial Zone, Rawat, Islamabad	Asic-C Tablet 50mg	Each Chewable Tablet Contains: Ascorbic Acid…50mg	Dy. No. 7987 dated 17/04/2020 Rs. 20,000/- 17-04-2020 Form 5	As per SRO	Panel inspection dated 07-12-2019 recommended resumption of production.
697.	M/s Arsons Pharmaceutical Industries Pvt Ltd. 2.5km Defence Road, Off Multan Road, Lahore, Pakistan	Vitasol Tablets 50mg	Each chewable Tablet Contains: Ascorbic Acid…50mg	Dy.No. 6538 dated 09/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Panel inspection dated 18-09-2019 concluded satisfactory level of GMP compliance

Decision: Registration Board approved registration of above applications from Serial No. 696 and 697. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.

14. Ascorbic acid Injection 500mg/5ml:

Composition:

Each 5ml contains:

Ascorbic acid……..500mg

International availability:

Ascorbic Acid Injection BPC 500mg/5ml (glass ampoule) by M/s Phoenix Labs, MHRA Approved. (product approved by Italy is in glass vial-Vitamin C Salf 500mg/5ml injectable solution-AIC 008194045)

Me too status: ASCORBIC ACID 500 MG INJ by M/s Schazoo Reg. No. 1629

Specifications: USP

Applications for local manufacturing:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status/Remarks
698.	M/s Friends Pharma (pvt) Limited, 31-km Ferozepur road, Lahore.	Vitafen Injection 500mg//5ml	Each 5ml ampoule contains: Ascorbic acid……..500mg	Dy.No. 6390 dated 08/04/2019 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 08/03/2019, the panel recommended renewal of DML.
699.	M/s. Shaigan Pharma, 14 Km Adyala Road, Rawalpindi.	C-Vit injection 500mg/5ml	Each 5ml ampoule contains: Ascorbic acid……..500mg	Dy. No. 6791 dated 08/04/2020 Rs. 20,000/- Form 5	As per SRO	25-9-2019 Panel recommended the renewal of DML. Liquid injectable section (ampoule & vials) available.
700.	M/s Trigon Pharmaceuticals (pvt) Limited 8th KM Thokar Raiwind Road, Lahore	Ascorbic acid injection 500mg/5ml	Each 5ml ampoule contains: Ascorbic acid……..500mg	Dy. No. 6207 dated 08/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 25/03/2019, satisfactory level of GMP compliance. Liquid injectable (vial & Ampoule) section available.
701.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Ascogen injection 500mg/5ml	Each 5ml ampoule contains: Ascorbic acid……..500mg	Dy. No. 6235 dated 08-04-2020 Rs. 20,000/- Form 5	As per SRO	Last GMP inspection conducted on 01-01-2020 and report concludes GMP compliance. (liquid injectable general Ampoule section vailable).
702.	M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan	MB Cecon-V Injection	Each 5ml contains: Ascorbic acid Bp…500mg	Dy.No. 7934 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Good GMP compliance, inspection date 28/02/2018.
703.	M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad.	Cor C Injection	Each 5ml ampoule contains: Ascorbic acid …500mg	Dy.No. 7474 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines.
704.	M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan	Asco Injection	Each 5ml ampoule contains: Ascorbic acid Bp…500mg	Dy.No. 7164 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 21/11/2017, fair level of GMP compliance.

705.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Cecor Injection 100mg/ml	Each 5ml ampoule contains: Ascorbic acid…500mg	Dy.No. 6782 10/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/04/2019.
706.	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad	Vita-C 500mg Injection	Each 5ml ampoule Contains: Ascorbic Acid…500mg	Dy.No. 6563 dated 09/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	GMP inspection dated 30-01-2019 concluded satisfactory level of compliance with GMP standards.
707.	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Niaz Baig, Raiwind Road, Lahore	Ascel-C 500mg/5ml Oral Solution	Each 5ml ampoule Contains: Ascorbic Acid…500mg	Dy.No. 6206 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Last inspection report dated 25/03/2019, satisfactory level of GMP compliance. Liquid injectable (vial & Ampoule) section available.
708.	M/s Medisure Laboratories Pakistan (Pvt) Ltd., A-115, SITE, Super Highway, Karachi	Medi-Vit C Injection 500mg/5ml	Each 5ml ampoule contains: Ascorbic acid……..500mg	Dy.No. 7950 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Inspection conducted on 19-07-2019 current GMP compliance level is rated as GOOD. The firm has provided liquid Injectable (Ampoule & vial) section.
709.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Corcid Injection 100mg/ml	Each 5ml ampoule contains: Ascorbic Acid……..500mg	Dy.No. 6747 dated 10/04/2020Rs. 20,000/- dated 09-04-2020 Form 5	5ml ×5's; 5ml× 50's; 5ml× 100's; As per SRO	Copy of GMP inspection conducted on 22-01-2020, the firm is considered to be operating at GOOD level of compliance with GMP guidelines.
710.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan	Rosbic Injection 500mg/5ml	Each 5ml ampoule contains: Ascorbic Acid…500mg	Dy.No. 9954 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate granted based on inspection dated 01-04-2019.
711.	M/s Unison Chemical Works Raiwind Road, Lahore.	C IN 500mg/5ml Injection	Each ml contains: Ascorbic acid …... 100mg	Dy. No.8333 dated 20-04-2020 Rs. 20,000/- Form 5	5ml ampoule x 50's: As per SRO	Panel inspection dated 19-11-2019 recommended renewal of DML.
Decision: Registration Board approved registration of above applications from Serial No. 698 to 711. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following applications are incomplete:

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	Decision
712.	M/s Orta Laboratories Pvt Ltd, 24 KM Multan Road, Off Defence Road Mohlanwal Lahore	Citron Injection 500mg/5ml	Each 5ml ampoule contains: Ascorbic Acid…500mg	Dy.No. 9967 dated 05/05/2020 Rs. 20,000/- 05-05-2020 Form 5	As Per SRO	GMP status not confirmed.	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.**
713.	M/s Otsuka Pakistan Limited, F/4-9, Hub Industrial Trading Estate, HITE, Distt. Lasbela, Baloschistan	Ascorvid Injection 500mg/5ml	Each 5ml ampoule contains: Ascorbic acid ……..500mg	Dy.No. 8988 dated 27/04/2020 Rs. 20,000/- Form 5	As per SRO	Routine GMP inspection conducted on 11 & 12 December, 2018 GMP compliance is rated as Good. The firm has applied LDPE ampoule while reference formulation is in glass vial.	**Deferred for following:** • **Evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in LDPE packaging.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in LDPE packaging.**

15. Ascorbic acid Injection 1000mg/5ml:
Composition:
Each 5ml vial contains:
Ascorbic acid……..1000mg
Reference Regulatory Authority status: AIFA ITALY
Generic status: N/A
Specifications: USP

714.	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore	VC-SHOT INJECTION 1000mg/5ml	Each 5ml ampoule contains: Ascorbic Acid…… …....1000mg	Dy.No. 9416 dated 30-04-2020 Rs.50,000/- dated 30-04-2020 Form 5D	1's, 5's, 6's × 5ml ampoule; As per SRO	The panel inspection dated 19-03-2020 recommended the issuance of GMP certificate to the firm. Firm has applied for ampoule while the product approved in reference country is in vial.
Registration Board approved registration of above application at Serial No. 714. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

16. Ascorbic Acid Effervescent tablet 1000mg:

Composition:

Each effervescent tablet contains:
Ascorbic acid……..1000mg

Status in reference regualtroy authority:

1 G EFFERVESCENT TABLETS of M/s Dompe Farmaceutici SPA approved by AIFA of Italy

Me too: C-1000 Efferevscent tablet of M/s Werrick pharmaceutical Reg.# 025425

Specifications: Innovator's specifications

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	GMP status/Remarks
715.	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan	C- White effervescent tablet 1g	Each effervescent tablet contains: Ascorbic acid…1g	Dy.No. 8916 dated 24/04/2020 Rs. 20,000/- 24-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 15-09-2017 the firm has acceptable level of GMP.
716.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura, Pakistan	Ascor effervescent 1g tablet	Each effervescent tablet contains: Ascorbic acid…1g	Dy.No. 7089 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Inspection date 30/05/2019, good level of GMP compliance.
717.	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore	C-Vit Tablet 1000mg	Each Effervescent Tablet Contains: Ascorbic Acid…1000mg	Dy.No. 5935 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	The firm was granted GMP certificate based on inspection dated 24-04-2018.
718.	M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad	Cor C Effervescent Tablet 1000mg	Each effervescent Tablet Contains: Ascorbic Acid…1000mg	Dy. No. 7615 dated 15/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 03-10-2017 concluding satisfactory level of compliance with GMP guidelines
719.	M/s Wilson's Pharmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Wilson's Vitamin C Tablet 1000mg	Each Effervescent Tablet Contains: Vitamin C…1000mg	Dy. No. 6216 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm was inspected on 24-01-2018 concluding good level of GMP compliance.
720.	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK	Ascarb-C Effervescent Tablet 1000mg	Each Effervescent Tablet Contains: Ascorbic Acid…1000mg	Dy.No. 6151 08/04/2020. Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm was inspected on 12/05/18 concluding Good level of cGMP.
721.	M/s Amros Pharmaceuticals. A-96, S.I.T.E, Super Highway Karachi	Vitamin C Effervescent Tablet	Each Effervescent Tablet Contains: Ascorbic Acid…1000mg	Dy.No. 6251 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm was inspected on 12/05/18 concluding Good level of cGMP.
722.	M/s Evolution Pharmaceuticals Pvt Ltd. Plot 25 & 26, Street S-3, RCCI, National Industrial Zone,	C-Vit Effervescent Tablet 1000mg	Each Tablet Contains: Ascorbic Acid…1000mg	Dy. No. 7475 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	Firm was inspected on 25-10-2018 recommending that as the operations have not started as of yet at M/s Evolution

	Rawat, Islamabad					Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
723.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	NEU-C 1000mg Effervescent Tablets	Each effervescent Tablet contains: Ascorbic Acid…1000mg	Dy.No. 8325 dated 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	GMP inspection conducted on 28-02-2019, the firm has maintained fair level of GMP compliance.
724.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Vit-C 1000mg Effervescent Tablets	Each effervescent Tablet contains: Ascorbic Acid…1000mg	Dy.No. 8336 dated 20/05/2020 Rs. 20,000/- 20-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 31-07-2018.
725.	M/s Advanced Pharmaceuticals Plot No.38, Street No S-4, National Industrial Zone Rawat	Advanced-C 1000mg Effervescent Tablets	Each effervescent Tablet contains: Ascorbic Acid…1000mg	Dy.No. 9580 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Not confirmed
726.	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi,	Abacod 1000mg Effervescent Tablets	Each effervescent Tablet contains: Ascorbic Acid…1000mg	Dy.No. 9719 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018.
727.	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33, Phase-1,S.I.T.E, Super Highway, Karachi	VC-1000mg Effervescent Tablets	Each effervescent Tablet contains: Ascorbic Acid…1000mg	Dy.No. 9432 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 21-09-2019, the compliance level is rated as satisfactory.
Decision: Registration Board approved registration of above applications from Serial No. 715 to 727. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Following application is not complete:

728.	M/s Advanced Pharmaceuticals Plot No.38, Street No S-4, National Industrial Zone Rawat	Advanced-C 1000mg Effervescent Tablets	Each effervescent Tablet contains: Ascorbic Acid…1000mg	Dy.No. 9580 dated 30/04/2020Rs. 20,000/- dated 30-04-2020 Form 5	As per SRO	GMP status Not confirmed
Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.						

17. Ascorbic acid drops:
Composition:
Each ml Contains:
Ascorbic Acid…100mg
International Availability:
Approved by AIFA of Italy
Me too: could not be confirmed
Specifications: USP specifications

729.	M/s Wilson's Parmaceuticals. 387-388, I-9/3, Industrial Area, Islamabad	C-Drops 100mg/ml	Each ml Contains: Ascorbic Acid…100mg	Dy.No. 6209 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Me-too could not be confirmed
730.	M/s Hamaz Pharmaceuticals Pvt Ltd. Business City Plaza, Hall # 1, 2nd Floor, Bosan Road, Multan, Pakistan	Vita-C Drops 100mg/ml	Each ml Contains: Ascorbic Acid…100mg	Dy.No. 5912 dated 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	GMP certificate issued on 06-11-2019 Me-too could not be confirmed
731.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	C Drops 100mg/ml	Each ml Contains: Vitamin C (Ascorbic Acid)…100mg	Dy.No. 6306 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 09-11-2018 recommend the Grant of GMP Certificate." Me-too could not be confirmed.
732.	M/s Radiant Pharma (Pvt) Ltd. 43-E, Sundar Industrial Estate, Lahore	C-Drop 100mg/ml drops	Each ml contains: Ascorbic Acid…100mg	Dy.No. 8337 dated 20/04/2020 Rs. 20,000/- 20-04-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 31-07-2018. Me-too status could not be verified.
733.	M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi	Vita-C 100mg/ml drops	Each ml contains: Ascorbic Acid…100mg	Dy.No. 9728 dated 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection conducted on 30th January, 2020. Me-too status could not be verified.
734.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan	Semo-C 100mg/ml drops	Each ml contains: Ascorbic Acid…100mg	Dy.No. 9713 dated 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	The panel inspection of the firm dated 27th August, 2019 recommends renewal of DML. Me-too status could not be verified.
Decision: Registration deferred the cases from serial number 729 to 734 for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else the applications should be submitted on form form 5D along with the differential fee.						

Following product is discontinued are discontinued in all the refence authorities where previously it was registered:

Lopinavir…133.3mg/Ritonavir…33.3mg Capsule:

735.	M/s EG Pharmaceuticals, Industrial Triangle Kahuta road, Islamabad.	Loritavir 133.3mg/33.3 mg capsule	Each Capsule contains: Lopinavir…133.3mg Ritonavir…33.3mg	Dy. No. 5925 dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	Renewal of DML recommended in the inspection dated 13-02-2019
736.	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Valetra Soft Gel capsule	Each Capsule contains: Lopinavir…133.3mg Ritonavir…33.3mg	Dy.No. 7135 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 20/04/2018. Not present in RRAs.
737.	M/s BJ Pharmaceuticals. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore	Caleto capsule	Each Capsule contains: Lopinavir…133.3mg Ritonavir…33.3mg	Dy.No. 6760 dated 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Firm has required equipment/machinery, HVAC system and qualified staff, fir showed good intention to further improvements in future. Overall hygienic condition of the firm is satisfactory at the time of inspection. Inspection date 15/01/2020. Not present in RRAs.
738.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Lopi-rito capsule	Each Capsule contains: Lopinavir…133.3mg Ritonavir…33.3mg	Dy.No. 7075 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance. Not present in RRAs.
739.	M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan	Mb Loprit Capsule	Each Capsule Contains: Lopinavir…133.30mg Ritonavir…33.30mg	Dy.No. 7930 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Not present in RRAs.
740.	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Loprit Capsule	Each Capasule Contains: Lopinavir..133.30mg Ritonavir…33.30mg	Dy.No. 5878 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	Not present in RRAs.
741.	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore	Macovir Capsule	Each Capasule Contains: Lopinavir…133.30mg Ritonavir…33.30mg	Dy.No. 6137 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Not present in RRAs.
742.	M/s Pulse Pharmaceuticals Pvt Ltd. Mozay Badoke, Raiwind Road(Sua Aasil	Coronavir Capsule	Each Capasule Contains: Lopinavir…133.30mg Ritonavir…33.30mg	Dy.No. 6123 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Not present in RRAs.

	Road), Lahore, Pakistan					
743.	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi	Loprito 133.3/33.3 Capsule	Each capsule contains: Lopinavir….133.3mg Ritonavir….33.3mg	Dy.No. 9430 dated 28/04/2020 Rs. 20,000/- Form 5	As per SRO	GMP inspection dated 21-09-2019, the compliance level is rated as satisfactory.
Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.						

Following products could not be verified from Reference Regulatory Authorities:

744.	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan	Semo-C plus Effervescent Tablets	Each effervescent Tablet contains: Ascorbic Acid…1000mg Zinc…10mg	Dy.No. 9714 dated 04/05/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Evidence of approval of applied formulation in reference country is not confirmed. The panel inspection of the firm dated 27th August, 2019 recommends renewal of DML.
745.	M/s Popular chemical works,9-K.m. Lahore, Pakistan	Lopinavir 400/100mg Syrup	Each 5ml contains: Lopinavir…..400mg Ritonavir….100mg	Dy.No. 9723 04/05/2020 Rs. 20,000/- Form 5	As per SRO	Panel inspection dated 29-05-2019 recommends renewal of DML.
746.	M/s Legacy Pharmaceuticals pvt Ltd, 111-A, Industrial Estate Hayatabad Peshawar	Ascorbic Oral Solution 100mg/ml	Each ml contains: Ascorbic Acid…100mg	Dy.No. 9740 dated 04/05/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on inspection dated 18-07-2019.
747.	M/s Curatech Pharma Pvt Ltd 35-Km, Multan Road, lahore	Corbivit Tablet 250mg	Each tablet contains: Ascorbic Acid…250mg	Dy.No. 8374 dated 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	The applied strength of formulation is not verified in RRA. Panel inspection dated dated 16-03-2018 recommends grant of renewal of DML.
748.	M/s The Schazoo Pharmaceutical Laboratories Pvt Ltd. Kalalwala Stop, 20 km Lahore-Jaranwala Road, Distt Sheikhupura,	Aver Effervescent Tablets	Each Effervescent Tablets contains: Calcium lactate gluconate…1000mg Calcium carbonate…327mg Ascorbic Acid…500mg Vitamin D3..400 i.u Vitamin B6…10mg	Dy.No. 9086 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The formulation is not verified in RRA. Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance.
749.	M/s Bio-Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Cecor Effervescent Tablets 1g	Each Effervescent Tablets contains: Ascorbic Acid…1000mg Calcium carbonate…227mg Calcium gluconate…578mg Calcium lactate…422mg	Dy.No. 6783 dated 10/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The formulation is not verified in RRA. The firm has submitted copy of GMP certificate granted based on inspection dated 23-04-2019.

750.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	URGEN-C Sachets 1000mg	Each sachet contains: Ascorbic Acid…1000mg	Dy.No. 9459 dated 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	Panel inspection dated 09-01-2019 recommends grant of GMP certificate
751.	M/s Variant Pharmaceuticals Pvt Ltd Plot No05, M2-Pharmazone, 26KM, Main Sharaqpur Road, Shaikhupura.	V-Calce 1000 Sachet	Each sachet contains: Ascorbic Acid…1000mg Calcium carbonate…600mg Calcium lactate gluconate…1000mg	Dy.No. 9444 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	The applied formulation is not verified in RRA. Inspection report dated 09-12-2019 & 20-12-2019, the firm is granted DML by way of formulation.
752.	M/s Variant Pharmaceuticals Pvt Ltd, Plot No05, M2-Pharmazone, 26KM, Main Sharaqpur Road, Shaikhupura.	V-CALCE 500 Sachet	Each sachet contains: Ascorbic Acid……500mg Calcium carbonate…327mg Calcium lactate gluconate…1000mg	Dy.No. 9443 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	The applied formulation is not verified in RRA. Inspection report dated 09-12-2019 & 20-12-2019, the firm is granted DML by way of formulation.
753.	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore	Mega-C 300mg Tablets	Each tablet contains: Ascorbic Acid…300mg	Dy.No. 8383 dated 21/04/2020 Rs. 20,000/- 21-04-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on evaluation conducted on 19-03-2020. The applied strength of formulation could not be verified in RRA.
754.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	C-500 Effervescent Tablet	Each Tablet Contains: Vitamin C (Ascorbic Acid)…500mg	Dy.No. 6163 08/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 09-11-2018 recommend the Grant of GMP Certificate."
755.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Eniqor 40mg/ml Injection	Each ml Contains: Chloroquine Phosphate 64.5mg Eq. to Chloroquine Base…40mg	Dy.No. 6788 dated 10/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/04/2019. Not present in RAs
756.	M/s Synchro Pharmaceuticals. 77-Industrial Estate, Kot Lakhpat, Lahore	Qusyn Injection	Each 5ml Contains: Chloroquine as Phosphate…200mg	Dy.No. 9427 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Inspection report is not provided. Not present in RRAs.
757.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan	Qlor 200mg Injection	Each 5ml Contains: Chloroquine Phosphate…200mg	Dy.No. 9423 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP certificate issued in 25/04/2019 on the basis on inspection conducted on 07/03/2019. Not present in RRAs
758.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Hydro-q Tablet 400mg	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 5441 dated 01/04/2020 Rs. 20,000/- 31-03-2020 Form 5	As per SRO	The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents

						reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
759.	M/s Global Pharmaceuticals Pvt Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	Quinex DS Tablet 400mg	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 5558 dated 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	24-10-2018 panel unanimously decided to recommend the issuance of GMP certificate.
760.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Cov-HCQ Tablet 400mg	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 5543 dated 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
761.	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Quinglit Tablet 400mg	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 5299 26/03/2020 Rs. 20,000/- 24-03-2020 Form 5	As per SRO	Last inspection report, 16th Jan, 2019, the panel Recommended issuance of GMP certificate.
762.	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad	Foquin Tablet 400mg	Each film coated tablet contains: Hydroxychloroquine sulfate …… 400mg	Dy. No. 5295 dated 26/03/2020 Rs. 20,000/- 26-03-2020 Form 5	As per SRO	Last GMP inspection conducted on 15-01-2019 & 17-01- 2019 and report concludes that "Keeping in view of the above facts on record, the panel unanimously recommends a- renewal of DML by way of formulation to M/s Focus and Rulz Pharma Islamabad.
763.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Visoquine-H Tablet 400mg	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 5592 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 11-2-2019 recommends issuance of GMP certificate.
764.	M/s Pharmevo Pvt Ltd.Plot#A-29, North Western Industrial Zone, Port Qasim, Karachi	Evoquin Plus Tablet 400mg	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 5590 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 07-02-2019 recommends the issuance of GMP certificate
765.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Miniquin-H Tablet 400mg	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 6141 08/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 05-8-2019 Concludes acceptable level of compliance of GMP requirements.

766.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	N-CQ injection 200mg/5ml	Each 5ml contains: Chloroquine phosphate injection …200mg	Dy.No. 7079 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5		Last inspection report dated 18/07/2017, fair level of GMP compliance. Ampule is available in reference
767.	M/s Wilson's Parmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Wilson's Vitamin C 1000mg XR Tablets	Each XR Tablet Contains: Vitamin C…1000mg	Dy.No. 6217 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	GMP inspection Dated 24-01-2018 Concludes very good level of GMP compliance.
768.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Werrick's Vitamin C 100 XR Tablets 1000mg	Each Extended Release Film Coated Tablet Contains: Vitamin C (Ascorbic Acid)…1000mg	Dy.No. 6307 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 09-11-2018 recommend the Grant of GMP Certificate."
769.	M/s Wilson's Parmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Wilson's Vitamin C Tablet 500mg	Each Tablet Contains: Vitamin C…500mg	Dy.No. 6213 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	GMP inspection dated 24-01-2018 Concludes very good level of GMP compliance.
770.	M/s Mafins Pharma. A-5, S.I.T.E, Super Highway Industrial Area, Karachi, Pakistan	Vitamin-C Tablet 1000mg	Each Dispersible Tablet Contains: Ascorbic Acid…1000mg	Dy.No. 7284 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	
771.	M/s Wilson's Pharmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Wilson's Vitamin C Sachets 1000mg	Each Sachet Contains: Vitamin C (Ascorbic Acid)…1000mg	Dy. No. 6214 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm was inspected on 24-01-2018 concluding good level of GMP compliance.
772.	M/s Faas Pharmaceuticals (Pvt.) Ltd. F-748/ L, S.I.T.E Karachi, Pakistan	Faascon Sachet 1000mg	Each Sachet Contains: Ascorbic Acid…1000mg	Dy. No. 9009 27/04/2020 Rs. 20,000/- 27-04-2020 Form 5	As per SRO	GMP certificate issued on 08-05-2018
773.	M/s Evolution Pharmaceuticals Pvt Ltd. Plot 25 & 26, Street S-3, RCCI, National Idustrial Zone, Rawat, Islamabad	C-Vit Sachet 1000mg	Each Sachet Contains: Ascorbic Acid…1000mg	Dy. No. 7476 dated 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	The firm was inspected on 25-10-2018 recommending that as the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
774.	M/s Wilson's Pharmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Wilson's Vitamin C Sachets 500mg	Each Sachet Contains: Vitamin C (Ascorbic Acid)…500mg	Dy. No. 6210 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm was inspected on 24-01-2018 concluding good level of GMP compliance.
775.	M/s Trigon Pharmaceuticals	Vil-Tid Tablet	Each Tablet Contains:	Dy.No. 6208 dated	As per SRO	Last inspection report dated 25/03/2019,

	Pvt Limited. 8 km, Thoker Niaz Baig, Raiwind Road, Lahore	1000mg	Ascorbic Acid…1000mg	08/04/2020 Rs. 20,000/- 08-04-2020 Form 5		satisfactory level of GMP compliance. Liquid injectable (vial & Ampoule) section available.
776.	M/s Saaaf Pharmaceuticals. Plot No.15, Special Industrial Zone, Risalpur, Kpk, Pakistan	Ceta-C Syrup	Each ml Contains: Ascorbic Acid…100mg	Dy.No. 6269 dated 08/04/2020 No challan form is attached Form 5		Inspection date 20/02/2019, The panel recommends the resumption of production.
777.	M/s Hamaz Pharmaceuticals Pvt Ltd. Business City Plaza, Hall # 1, 2nd Floor, Bosan Road, Multan	Phosoquine Tablet 80mg	Each Tablet Contains: Chloroquine Phosphate…80mg	Dy.No. 5914 dated 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	GMP certificate issued on 06-11-2019. Firm has not mentioned salt form of the API.
778.	M/s Gulf Pharmaceuticals. Plot No. 49, Street S-5, National Industrial Zone, Rawat, Islamabad	Chloqin-80 Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…80mg	Dy. No. 7992 17/04/2020 Rs. 20,000/- 17-04-2020 Form 5	As per SRO	Panel inspection dated 07-12-2019 recommended resumption of production.
779.	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad	Chlord Tablet 80mg	Each Film Coated Tablet Contains: Chloroquine Phosphate..…. 80mg	Dy. No. 5907 07/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	Panel inspection dated 02-10-2019 complying satisfactory level cGMP as of today.
780.	M/s Quaper pvt. Ltd. 26-A Samll industrial estate Lahore road Sargodha.	Chloroquine 80mg tablet	Each Tablet Contains: Chloroquine Phosphate..…. 80mg	Dy.No. 5883 dated 07/04/2020 Rs. 20,000/- Form 5	As per SRO	Last inspection report dated 28/01/2019, the panel recommends the renewal of DML.
781.	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi	Oxiquine Tablet 400mg	Each film coated tablet contains: Hydroxychloroquine sulfate…400mg	Dy.No. 9434 dated 30/04/2020 Rs. 20,000/- 29-04-2020 Form 5	As per SRO	GMP inspection dated 21-09-2019, the compliance level is rated as satisfactory.
782.	M/s Mega Pharmaceuticals Ltd, 27-Km Raiwind Road, Lahore	HYROX Tablet 400mg	Each tablet contains: Hydroxychloroquine sulfate……400mg	Dy.No. 8386 21/04/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	The firm has submitted copy of GMP certificate based on evaluation conducted on 19-3-2020.
783.	M/s NovaMed Pharmaceuticals (Pvt) Ltd, 28-Km Ferozpur Road, Lahore	QuinCo-H Tablet 400mg	Each tablet contains: Hydroxychloroquine sulfate……400mg	Dy.No. 6779 10/04/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Copy of GMP inspection conducted on 22-01-2020, firm is considered to be operating at GOOD level of compliance with GMP guidelines.
784.	M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1, S.I.T.E, Super Highway, Karachi	QuinCo-H Tablet 400mg	Each tablet contains: Hydroxychloroquine sulfate……400mg	Dy.No. 9434 10/04/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	GMP inspection dated 21-09-2019, the compliance level is rated as satisfactory.

785.	M/s AJM Pharma (Pvt) Ltd., Plot No.44, Sector No.27, Korangi Industrial Area, Karachi.	Ajquine Tablet 400mg	Each tablet contains: Hydroxychloroquine sulfate……400mg	Dy.No. 7929 dated 10/04/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Panel inspection dated 13-03-2019 recommends grant of renewal of DML.
786.	M/s Novartana Pharmaceuticals (Pvt) Ltd., 87-B Sundar Industrial Estate, Raiwind Road, Lahore	Hiquenta Tablet 400mg	Each tablet contains: Hydroxychloroquine sulfate……400mg	Dy.No. 8925 24/04/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tabklet General, Capsule General, Liquid Syrup General).
787.	M/s Curatech Pharma (Pvt) Ltd. 35-Km Multan Road Lahore	Curacovid Tablet 400mg	Each tablet contains: Hydroxychloroquine sulfate……400mg	Dy.No. 8375 24/04/2020 Rs. 20,000/- 04-05-2020 Form 5	As per SRO	Panel inspection dated dated 16-03-2018 recommends grant of renewal of DML.
788.	M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Plavaquine Tablet 400mg	Each film coated tablet contains: Hydroxychloroquine sulfate……400mg	Dy.No. 8129 20/04/2020 Rs. 20,000/- 15/04/2020 Form 5	As per SRO	The firm has been granted GMP certificate based upon evaluation conducted on 06-7-2017. Applied formulation is not verified in RRA.
789.	M/s Ipram International Pharmaceuticals plot # 26, street # S.S-3 national industrial zone	Viroquin injection 200mg/5ml	Each 5ml Ampoule Contains: Chloroquine Phosphate…200mg	Dy.No. 6391 dated 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	Certificate of cGMP is issued to the firm based on inspection conducted on 20th December, 2018.
790.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Visoquine 40mg/ml Injection	Each ml Contains: Chloroquine Dihydrochloride 50mg Eq. to Chloroquine Base…40mg	Dy.No. 5560 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	Not presen tin RRAs
791.	M/s Global Pharmaceuticals Pvt Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	C-Quin Injection 40mg	Each ml Contains: Chloroquine Dihydrochloride50mg Eq. to Chloroquine Base…40mg	Dy.No. 5555 dated 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	24-10-2018 panel unanimously decided to recommend the issuance of GMP certificate.
792.	M/s Friends Pharma Pvt Ltd. 31-km Ferozpur Road Lahore, Pakistan	Fendoquine Injection 200mg/5ml	Each 5ml Contains: Chloroquine Phosphate…200mg	Dy.No. 6387 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	
793.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Covlor-P 200mg/5ml Injection	Each 5ml Ampoule Contains: Chloroquine Phosphate…200mg	Dy.No. 5540 dated 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	Not presen tin RRAs
794.	M/s Otsuka Pakistan Ltd,	Resoquin Injection	Each 5ml Ampoule (LDPE) Contains:	Dy.No. 9512 30/04/2020	As per SRO	Inspection date 11 & 12 December, 2018. Good

	F/4-9, Hub Industrial Tradin Estate, Distt Lasbell, Balochistan		Chloroquine Phosphate …200mg	Rs. 20,000/- 30-04-2020 Form 5		level of GMP compliance. Not present in RRAs
795.	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore	Clor 200mg/5ml Injection	Each 5ml Contains: Chloroquine Phosphate…200mg	Dy.No. 7489 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5	As per SRO	GMP certificate issued on 21/02/2020 on the basis on inspection conducted on 07/11/2019 Not present in RRAs
796.	M/s Legacy Pharmaceuticals pvt Ltd, 111-A, Industrial Estate Hayatabad Peshawar	Legoquine 81 Syrup	Each 5ml Contains: Chloroquine Phosphate…81mg	Dy.No. 9709 04/05/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	Inspection date 18/07/2019. The Panel recommended renewal of DML. Not present in RRAs
797.	M/s Iceberg Pharmaceuticals Pvt Ltd. Plot No. 144, Nowshera Industrial Estate, Risalpur, Kpk, Pakistan	Icequine 50mg/5ml Dry Suspension	Each 5ml of reconstituted Suspension Contains: Chloroquine Phosphate Eq. to…50mg	Dy.No. 7924 dated 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 27/03/2019, The panel recommended resumption of production. Not present in RRAs.
798.	M/s Arsons Pharmaceutical Industries Pvt Ltd. 2.5km Defence Road, Off Multan Road, Lahore, Pakistan	Chlorisol Tablet 80mg	Each Film Coated Tablet Contains: Chloroquine Phsophate…80mg	Dy.No. 6536 dated 09/04/2020 Rs. 20,000/- 09-04-2020 Form 5		
799.	M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad	Medquin 80mg Tablet	Each Tablet Contains: Chloroquine Phosphate…80mg	Dy.No. 7942 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	Inspection date 16/10/2018, the panel recommended renewal of DML. Not present in RRAs
800.	M/s British Pharmaceuticals Pvt Ltd, 23-KM, Shekhupura Road, Lahore	Brichlor 80mg Tablet	Each Film Coated Tablet Contains: Chloroquine Phosphate…80mg	Dy.No. 7134 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	The panel recommended grant of DML, inspection date 19/08/2019 & 27/12/2019. Not present in RRAs
801.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Eniqor 80mg Tablets	Each Film Coated Tablet Contains: Chloroquine Phosphate…80mg	Dy.No. 6789 10/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	GMP certificate issued on 21/05/2019 on the basis of inspection conducted on 23/4/2019. Not present in RRAs
802.	M/s Linear Pharma, Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad	Malaram-H 200mg Injection	Each 5ml Contains: Chloroquine as Dihydrochloride…200mg	Dy.No. 6565 dated 09/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	GMP inspection dated 30-01-2019 concluded satisfactory level of compliance with GMP standards. Not present in RRAs
803.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road,Sheikhupura	Jenvit-C tablet	Each chewable tablet contains: Ascorbic acid …1000mg	Dy.No. 7274 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5		Inspection date 15/02/2019, satisfactory level of GMP compliance. Not present in RRAs

804.	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Mac-c 1000mg tablet	Each chewable tablet contains: Ascorbic acid …1000mg	Dy.No. 7261 dated 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5		Inspection date 24/10/2019, panel recommended renewal of DML. Not present in RRAs
805.	M/s Wilson's Pharmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Wilson's Vitamin C 1000mg Chewable Tablet	Each Chewable Tablet Contains: Vitamin C…1000mg	Dy. No. 6215 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	The firm was inspected on 24-01-2018 concluding good level of GMP compliance.
806.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore.	N-CQ Tablets 100mg	Each film coated tablet contains: Chloroquine phospate…100mg	Dy.No. 7080 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance. Not present in RRAs.
807.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore.	N-CQ Tablets 100mg	Each film coated tablet contains: Chloroquine phospate…100mg	Dy.No. 7080 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance. Not present in RRAs.
808.	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Vitan C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 6754 dated 10/04/2020 Rs. 20,000/- dated 10-04-2020 Form 5		The panel recommended renewal of DML, inspection date 20/04/2018. The firm has applied for plane tablet while the product approved in reference country is chewable.
809.	M/s Nimrall Laboratories Plot 24, Street SS-3, Rawat, Industrial Area, Islamabad.	Ascoral Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7144 dated 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5		The panel recommended resumption of production, inspection date17/07/2019 & 24/07/2019. Not present in RRAs
810.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Seha Tablet 500mg	Each uncoated tablet Contains: Vitamin C…500mg	Dy. No. 6556 09/04/2020 Rs. 20,000/- 09-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 10-10-2018 & 17-10-2018 recommends the Grant of GMP Certificate."
811.	M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan	Vitcee Tablet 500mg	Each Tablet Contains: Ascorbic Acid…500mg	Dy.No. 7152 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 14-06-2018 recommends the Grant of GMP Certificate."
812.	M/s Linear Pharma, Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad	Vita-C Tablet 500mg	Each Tablet Contains: Ascorbic Acid (Vitamin C) ……500mg	Dy. No. 6184 dated 08/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	GMP inspection dated 30-01-2019 concluded satisfactory level of compliance with GMP standards.
813.	M/s. Shaigan Pharma, 14 Km Adyala Road, Rawalpindi.	Ascomin tablet 500mg	Each Tablet Contains: Ascorbic Acid (Vitamin	Dy. No. 6190 dated 08-04-2020 Rs. 20,000/-	As per SRO	Last GMP dated 30-05-2019 concluding that firm is complying 25-9-2019 Panel

			C)……500mg	Form 5		recommended the renewal of DMLmost of the GMP Guidelines.
814.	M/s Wilson's Parmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Wilson's Vitamin C Tablets 500mg	Each Film Coated Tablet Contains: Vitamin C (Ascorbic Acid)…500mg	Dy.No. 6211 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	GMP inspection conducted on 24-01-2018 concludes that the firm was found to be operating at a very good level of GMP compliance at the time of inspection.
815.	M/s Hassan Pharmaceuticals Pvt Ltd. 99-A Industrial Estate, Hayatabad, Peshawar,	Scor-c Tablet 500mg	Each Tablet Contains: Ascorbic Acid…500mg	Dy.No. 7622 dated 15/04/2020 Rs. 20,000/- 15-04-2020 Form 5	As per SRO	GMP compliance is NOT satisfactory, Inspection date 01/02/2018.
816.	M/s Saibins Pharmaceuticals. Plot # 316, Industrial Triangle, Kahuta Road, Islamabad	Asco Vit 500mg Tablet	Each Film Coated Tablet Contains: Ascorbic Acid…500mg	Dy.No. 6144 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	GMP certificate issued on 17/01/2019 on the basis of inspection conducted on 24/12/2018.
817.	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK	Ascarb-C 500mg Tablet	Each Tablet Contains: Ascorbic Acid…500mg	Dy.No. 6149 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Last inspection report dated 03/05/2019. Firm was operating under good level GMP.
818.	M/s Himont Pharmaceuticals Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan	C-vit Tablet 500mg Effervescent tablet	Each effervescent tablet contains: Ascorbic Acid…500mg	Dy.No. 7785 16/04/2020 Rs. 20,000/- 16-04-2020 Form 5	As per SRO	GMP certificate issued based upon evaluation conducted on 4-10-2018 & 05-10-2018. Not present in RRAs.
819.	M/s Curatech Pharma Pvt Ltd 35-Km, Multan Road, lahore	Corbivit Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7069 dated 15/04/2020 Rs. 20,000/-. 13-04-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 16/3/2018. The firm has applied for plain tablet while it is approved in reference country as chewable.
820.	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi.	C-Gen Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 6765 dated 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Inspection date 25/11/2019 & 12/12/2019, the panel recommended renewal of DML. Plain Tablet
821.	M/s Biogen Pharmaceuticals 8-Km, Chakbeli Road, Rawat, Rawalpindi.	Bio-C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 6763 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Inspetion date 12/12/2019, the panel recommended grant of DML. Plain tablet
822.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road	Cpec Tablet 500mg	Each tablet contains: Vitamin c…500mg	Dy.No. 7281 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the

	Lahore					firm. The firm has applied for plain tablet while it is approved in reference country as chewable
823.	M/s BJ Pharmaceuticals. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore	Vita-C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 6762 dated 10/04/2020 Rs. 20,000/- 10-04-2020 Form 5	As per SRO	Firm has required equipment/machinery, HVAC system and qualified staff, fir showed good intention to further improvements in future. Overall hygienic condition of the firm is satisfactory at the time of inspection. Inspection date 15/01/2020. The firm has applied for plain tablet while it is approved in reference country as chewable
824.	M/s Venus Pharma. 23 km, Multan Road, Lahore	Ascor-V Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7278 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5		GMP ceritifcate issed on 28/11/2019 on the basis of inspection conducted on 05/09/2019.
825.	M/s Maple Pharmaceuticals Pvt Ltd, Plot No.147, Sector 23, Korangi Industrial Area, Karachi	C-Sure Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7258 14/04/2020 Rs. 20,000/- 14-04-2020 Form 5		GMP certificate issued on 22/01/2020 on basis of inspection conducted on 22/12/2020. The firm has applied for plain tablet while it is approved in reference country as chewable
826.	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Mac-C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7260 dated 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5		Inspection date 24/10/2019, panel recommended renewal of DML. Diary number is not written
827.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Jenvit-C Tablet 500mg	Each tablet contains: Ascorbic Acid…500mg	Dy.No. 7273 dated 14/04/2020 Rs. 20,000/- 13-04-2020 Form 5		Inspection date 15/02/2019, satisfactory level of GMP compliance. The firm has applied for plain tablet while it is approved in reference country as chewable
828.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neu-C Oral Drops	Each ml contains: Ascorbic Acid…500mg	Dy.No. 7070 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Last inspection report dated 18/07/2017, fair level of GMP compliance. Not present in RRAs.
829.	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neu-C Injection 500mg/2ml	Each 2ml contains: Ascorbic Acid…500mg	Dy.No. 7071 13/04/2020 Rs. 20,000/- 13-04-2020 Form 5	As per SRO	Not present in RRAs. Last inspection report dated 18/07/2017, fair level of GMP compliance.

830.	M/s Friends Pharma Pvt Ltd. 31-km Ferozpur Road Lahore, Pakistan	Vitafen Injection 500mg/2ml	Each ml Contains: Ascorbic Acid…250mg	Dy.No. 6389 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Not present in RRA.
831.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	C Syrup 100mg/5ml	Each 5ml Contains: Vitamin C (Ascorbic Acid)…100mg	Dy. No. 6305 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 09-11-2018 recommend the Grant of GMP Certificate."
832.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Werrick's Vitamin C Tablets 500mg	Each Film Coated Tablet Contains: Vitamin C (Ascorbic Acid)…500mg	Dy. No. 6162 08/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	Last GMP inspection conducted on 09-11-2018 recommend the Grant of GMP Certificate."
833.	M/s Saaaf Pharmaceuticals, plot NO. 15, special industrial zone (EPZ) Risalpur, KPK.	Ascorbic Acid 500mg tablet	Each Film Coated Tablet Contains: Vitamin C (Ascorbic Acid)…500mg	Dy. No. 6268 08/04/2020 Rs. 20,000/- 07-04-2020 Form 5	As per SRO	Inspection date 20/02/2019, The panel recommends the resumption of production.
834.	M/s Cher Wel Pharmaceuticals Pvt Ltd. Plot # 20, Phase 4, Hattar Industrial Estate, Hattar, Kpk	Quinoline-DS 400mg Tablet	Each Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 5422 dated 01/04/2020 Rs. 20,000/- 31-03-2020 Form 5	As per SRO	Last GMP inspection was conducted on 4-2-2019 and panel recommend the renewal of DML
835.	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind, Lahore	Coviquin-H 400mg Tablet	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…400mg	Dy.No. 5366 30/03/2020 Rs. 20,000/- 30-03-2020 Form 5	As per SRO	Last inspection report dated 29/03/2019, firm was operation at satisfactory level of GMP compliance.
Decision: Registration Board deferred the cases from serial number 744 to 835 for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.						

Priority approval of Azithromycin:

In continuation to Authority's letter NO. F.76-DRAP/2020(PE&R) dated 5th May, 2020, Drug Regulatory Authority of Pakistan in its 77th held on 7th April, 2020 has also approved the formulation of Azithromycin in the list of drugs/formulations for priority approval/registeration during COVID-19 pandemicalong with other drugs.

1. Azithromycin Tablet 500mg:

Composition:

Each Film coated tablet contains:

Azithromycin as dihydrate…….500mg

Availability in RRAs: MHRA Approved

ME too status: "Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd,Plot.No.24 Industrial Estate, Peshawar." Reg. No. 068269

Specifications: USP

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
836.	M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-km, Main Ferozpur Road, Lahore	Azidon Tablet 500mg	Each Film Coated Tablet Contains: Azithromycin as dihydrate…500mg	Dy.No. 5548 06/04/2020 Rs. 20,000/- 02-04-2020 Form 5	As per SRO	Good compliance of GMP, inspection date 13/02/2020.

837.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan	Azitron Tablet 500mg	Each Film Coated Tablet Contains: Azithromycinas dihydrate…500mg	Dy.No. 5576 dated 06/04/2020 Rs. 20,000/- 06-04-2020 Form 5	As per SRO	Last inspection report dated 30-01-2019 confirms that firm is operating at a Good level of GMP compliance.
838.	M/s Ferozsons Laboratories limited. PO Ferozsons, Amangarh, Nowshera, KPK.	Azofer 500mg tablet	Each Film Coated Tablet Contains: Azithromycinas dihydrate…500mg	Dy.No. 5223 23/03/2020 Rs. 20,000/- 24-03-2020 Form 5	As per SRO	Panel inspection dated 09-01-2019 recommends grant of GMP certificate
839.	M/s Honig Pharmaceuticals Laboratories. 14 km-Adyala Road, Rawalpindi	Emzin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 5413 31/03/2020 Rs. 20,000/- 31-03-2020 Form 5	As per SRO	GMP certificate issued on 15th April, 2019.
Decision: Registration Board approved registration of above applications from Serial No. 836 to 839. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

2. Azithromycin Tablet 250mg:

Composition:

Each Film coated tablet contains:

Azithromycin as dihydrate…….250mg

Availability in RRAs: MHRA Approved

ME too status: Azithrolide tablet of M/s Heal Pharma (Reg. # 084233)

Specifications: USP

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
840.	M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-km, Main Ferozpur Road, Lahore	Azidon Tablet 250mg	Each Film Coated Tablet Contains: Azithromycin …250mg	Dy.No. 5547 dated 06/04/2020 Rs. 20,000/- 02-04-2020 Form 5	As per SRO	Good compliance of GMP, inspection date 13/02/2020.
841.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	Azofer 250mg Tablet	Each film coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin ….250mg	Dy.No. 5220 dated 24/03/2020 Rs. 20,000/- 24-03-2020 Form 5	As per SRO	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
Decision: Registration Board approved registration of above application at Serial No. 840 to 841. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

3. Azithromycin for suspension 200mg/5ml:

Composition:

Each 5ml reconstituted suspension Contains:
Azithromycin…200mg

Availability in RRAs: MHRA Approved.

ME too status:

Azithrolide Dry Powder Suspension Heal Pharma Hayatabad Industrial Estate, Peshawar 084236

Specifications: USP

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
842.	M/s Ferozsons Laboratories limited. PO Ferozsons, Amangarh, Nowshera, KPK.	Azofer 200mg/5ml dry suspension	Each 5ml reconstituted suspension Contains: Azithromycin …….200mg	Dy.No. 5224 dated 24/03/2020 Rs. 20,000/- 24-03-2020 Form 5	As per SRO	Panel inspection dated 09-01-2019 recommends grant of GMP certificate
843.	M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-km, Main Ferozpur Road, Lahore	Azidon for oral Suspension 200mg/5ml	Each 5ml reconstituted suspension Contains: Azithromycin..200mg	Dy.No. 6193 dated 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Good compliance of GMP, inspection date 13/02/2020.
Decision: Registration Board approved registration of above application at Serial No. 842 to 843. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

4. Azithromycin for suspension 100mg/5ml:

Composition:

Each 5ml reconstituted suspension Contains:
Azithromycin…100mg

Availability in RRAs: USFDA Approved.

ME too status: Could not be confirmed

Specifications: USP

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status
844.	M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-km, Main Ferozpur Road, Lahore	Azidon for oral Suspension 100mg/5ml	Each 5ml reconstituted suspension Contains: Azithromycin …100mg	Dy.No. 6192 08/04/2020 Rs. 20,000/- 08-04-2020 Form 5	As per SRO	Good compliance of GMP, inspection date 13/02/2020. Me too status could not be confirmed.
Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.						

Applications which were submitted on form 5 for registration of Azithromycin before the decision of Authority:

845.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Azisoft 500mg/vial Injection
	Composition	Each vial of dry substance contains: Azithromycin dihydrate eq to Azithromycin…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3919 dated 29-01-2019 Rs.20,000/- 28-01-2019 (#0004731)
	Pharmacological Group	Antibiotic
	Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	Glass vial/ As per SRO
	Approval status of product in Reference Regulatory Authorities	Zithromax injection by Pfizer (USFDA)
	Me-too status	Zithromax Injection by M/s Biocare Pharmaceutica, Lahore (Reg.#053895)
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	
	Decision: Deferred for confirmation of manufacturing method (lyophiolization or dry powder vial filling).	
846.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Zitomax 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin as Dihydrate eq to Azithromycin..……250mg
	Diary No. Date of R& I & fee	Dy.No 7904 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Zidor Capsule 250mg of M/s Winthrox Karachi. (Reg.# 074943)
	GMP status	Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in USP. • General capsule section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
847.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Kalthro Capsule 250mg
	Composition	Each Capsule Contains: Azithromycin Dihydrate……..250mg
	Diary No. Date of R& I & fee	Dy.No 9245 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 14 100 As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Azithromycin 250mg Capsules of M/s UniPharma (Pvt.) Ltd., Lahore (Reg. # 071421)
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section & grant of additional psychotropic tablet section.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in USP. • General capsule section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	

848.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Kalthro Capsule 500mg
	Composition	Each Capsule Contains: Azithromycin dihydrate…500mg
	Diary No. Date of R& I & fee	Dy.No 9250 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 14 100 & As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Azithromycin 500mg Capsules Unipharma (Pvt) Ltd., Lahore. 071422
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in USP. • General capsule section is available in the firm as mentioned in the submitted GMP inspection report. • Azithromycin "as" dihydrate is approved in me- too. • International reference could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
849.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Alide Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……..500mg
	Diary No. Date of R& I & fee	Dy.No 8252 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3's, 6's, 15's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Zetro 500mg Tablets of M/s Getz Pharma (Pvt) Ltd Karachi (Reg. # 053120)
	GMP status	Last GMP inspection conducted on 31-05-2018 and 01-06-2018 report concludes that "With reference to last inspection the firm has made improvement regarding previous GMP inspection and they have installed a new HPLC (gradient system) and double beam UV spectrophotometer. Firm has also improved their documentation regarding production, quality control and quality assurance."
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
850.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name+Dosage Form + Strength	Zenados tablet 250mg
	Composition	Each film- coated tablet contains: Azithromycin as Dihydrate……250mg
	Diary No. Date of R& I & fee	Dy.No.41038; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	Anti- infective

	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Azithrolide tablet of M/s Heal Pharma (Reg. # 084233)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
851.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name+Dosage Form + Strength	Zithrolide tablet 500mg
	Composition	Each film- coated tablet contains: Azithromycin as dihydrate ……..…..500mg
	Diary No. Date of R& I & fee	Dy.No.39854; 04-12-2018; Rs.20,000 (03-12-2018)
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3's, 6's, 14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Azithrolide tablets of M/s Heal Pharmaceuticals (Pvt.) Ltd, Peshawar (Reg. # 084234)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
852.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name+Dosage Form + Strength	Azimed 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin dihydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 44138 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Azithromycin 250mg Capsules Unipharma (Pvt) Ltd., 071421
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	• Azithromycin "as" dihydrate is approved in MHRA. • Manufacturing facility / section needs to be confirmed.
	Decision: Deferred for evidence of approval of relevant/required manufacturing dacility and revision of formulation as per the innovator / reference product along with submission of fee for revision of formulation.	
853.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name+Dosage Form + Strength	Azimed 200mg/5ml Dry Powder Suspension
	Composition	Each 5ml contains: Azithromycin…200mg
	Diary No. Date of R& I & fee	Dy.No.43948 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018

	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Azithrolide Dry Powder Suspension M/s Heal Pharma, Peshawar (Registration No.084236)
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	• Azithromycin "as monohydrate" is approved in MHRA. • Manufacturing facility / section needs to be confirmed.
	Decision: Deferred for evidence of approval of relevant/required manufacturing dacility and revision of formulation as per the innovator / reference product along with submission of fee for revision of formulation.	

854.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Maxibest Capsules 500mg
	Composition	"Each Capsule Contains: Azithromycin…500mg"
	Diary No. Date of R& I & fee	Dy.No 41724 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Macrolides ATC Code: J01FA10
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	071422; Brand Name: Azithromycin 500mg Capsules Manufacturer Name: Unipharma (Pvt) Ltd.,
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
855.	**Name and address of manufacturer / Applicant**	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Thromocin V Tablet 500mg
	Composition	"Each Film Coated Tablet Contains: Azithromycin as dihydrate…500mg"
	Diary No. Date of R& I & fee	Dy.No 4906 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO./ 1x10's, 1x6's, 1x3's, 1x2's, 1x4's.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	068269; "Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd, Peshawar."
	GMP status	

	Remarks of the Evaluator	Signature of applicant is missing on Form 5.
	Decision: Registration Board deferred the case for submission of signed Form-5.	
856.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Azirom Tablet 500mg
	Composition	"Each Tablet Contains: Azithromycin as Dihydrate…500mg"
	Diary No. Date of R& I & fee	Dy.No 8641 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	068269;"Ery-Pack Tablets " Lowitt Pharmaceutical (Pvt) Ltd, Peshawar."
	GMP status	18th April, 2019 the firm has complied to the previous recommendation with commitment for continuous improvement.Overall the firm is found operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Evidence of international availability as uncoated tablets.
	Decision: Deferred for revision of formulation in accordance with reference product along with submission of requisite fee.	
857.	Name and address of manufacturer / Applicant	"M/s Medicaids Pakistan (pvt) Ltd. Plot No 10, Sector-27 Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Kraze ophthalmic solution 10mg/ml
	Composition	"Each ml of sterile ophthalmic solution contains: Azithromycin…10mg"
	Diary No. Date of R& I & fee	Dy.No 5936 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs 600/5ml plastic dropper bottle
	Approval status of product in Reference Regulatory Authorities.	Azasite® (Azithromycin Ophthalmic Solution) 1% Sterile Topical Ophthalmic Drops/ USFDA Approved.
	Me-too status	Me too could not be confirmed.
	GMP status	GMP certificate of M/s Medicaids issued on basis of inspection conducted on 09/08/2018.
	Remarks of the Evaluator	• According to firm the product is already registered with different pack size 1.e 2.5ml with Reg No. 082125. • Storage and Handling: Store unopened bottle under refrigeration at 2°C to 8°C (36°F to 46°F). Once the bottle is opened, store at 2°C to 25°C (36°F to 77°F) for up to 14 days. Discard after the 14 days.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
858.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Azionce 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin…500mg
	Diary No. Date of R& I & fee	Dy.No. 41524 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antibiotic (Macrolide)
	Type of Form	Form 5
	Finished product Specifications	USP

	Pack size & Demanded Price	3's, 6's, & 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin tablet of (MHRA approved)
	Me-too status	Azic 500mg Tablet by M/s NabiQasim
	GMP status	Last GMP inspection conducted on 19 -09-2018 a And report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good".
	Remarks of the EvaluatorIV	
	Decision: Approved.	
859.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatab
	Brand Name +Dosage Form + Strength	Azlur 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 3355 dated 24-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	6's and 10's/As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin tablet of (MHRA approved)
	Me-too status	Azic 250mg Tablet by M/s NabiQasim
	GMP status	Last GMP inspection of conducted on 26-07-2018, and the report concludes that the firm is operating at good level of GMP compliance**.** panel unanimously recommends the grant of renewal of DML by way of formulation
	Remarks of the EvaluatorIV	
	Decision: Approved.	
860.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatab
	Brand Name +Dosage Form + Strength	Azlur 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg
	Diary No. Date of R& I & fee	Dy.No 3356 dated 24-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	6's and 10's/As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin tablet of (MHRA approved)
	Me-too status	Azic 500mg Tablet by M/s NabiQasim
	GMP status	Last GMP inspection of conducted on 26-07-2018, and the report concludes that the firm is operating at good level of GMP compliance**.** panel unanimously recommends the grant of renewal of DML by way of formulation
	Remarks of the EvaluatorIV	
	Decision: Approved.	
861.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Azaltic Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Azithromycin as Dihydrate..500mg
	Diary No. Date of R& I & fee	Dy.No 3860 dated 28-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Antibiotic (Macrolide)
	Type of Form	Form 5
	Finished product Specifications	USP

	Pack size & Demanded Price	6's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin tablet of (MHRA approved)
	Me-too status	Azic 500mg Tablet by M/s NabiQasim
	GMP status	Last GMP inspection of avant Pharmaceutical conducted on 07-12-17 & the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the EvaluatorIV	
	Decision: Registration Board referred the case to QA & LT division for updated status of GMP.	
862.	Name and address of manufacturer / Applicant	M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Azaltic Suspension 200mg/5ml
	Composition	Each 5ml suspension contains: Azithromycin as Dihydrate..200mg
	Diary No. Date of R& I & fee	Dy.No 3861 dated 28-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	15ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zithromax Powder for Oral Suspension 200mg/5ml of MHRA approved
	Me-too status	Azomax Dry Suspension by M/s Novartis (Reg#022201),
	GMP status	Last GMP inspection of avant Pharmaceutical conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the EvaluatorIV	
	Decision: Registration Board referred the case to QA & LT division for updated status of GMP.	
863.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Macromax 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 1883 dated 15-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin tablet of (MHRA approved)
	Me-too status	Azic 250mg Tablet by M/s NabiQasim
	GMP status	Certificate of current Good Manufacturing practices on the basis of inspection conducted on 19-03-2020
	Remarks of the EvaluatorIV	
	Decision: Approved.	
864.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Macromax 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg
	Diary No. Date of R& I & fee	Dy.No 1884 dated 15-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	Antibiotic (Macrolide)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin tablet of (MHRA approved)

	Me-too status	Azic 500mg Tablet by M/s NabiQasim
	GMP status	Certificate of current Good Manufacturing practices on the basis of inspection conducted on 19-03-2020
	Remarks of the EvaluatorIV	
	Decision: Approved.	
865.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Zorix 500mg Capsule
	Composition	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin…500mg
	Diary No. Date of R & I & fee	Dy. No. 998: 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Cinzit Capsule 500mg. REg. No. 79253
	GMP status	Certificate of GMP issued on 18-10-2019.
	Remarks of the Evaluator[IX]	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • Submit complete finished product specifications.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of complete finished product specifications.**	
866.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Zorix 500mg Injection
	Composition	Each Injection Contains: Azithromycin as Dihydrate…500mg
	Diary No. Date of R & I & fee	Dy. No. 1003 09.01.2019 PKR. 20,000/-; 31.12.2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX for injection 500mg (eq to base) in lyophilized form. USFDA approved
	Me-too status	Macrocap 500mg Dry Powder Injection. Reg. No. 82589
	GMP status	Certificate of GMP issued on 18-10-2019.
	Remarks of the Evaluator[IX]	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by concerned person. • The USP has mentioned amperometric electrochemical detector with dual glassy carbon electrodes for assay /analysis.
	Decision: Deferred for evidence of approval of required manufacturing facility i.e., "Lyophilized vial injectable section."	
867.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	AZICIN 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin as Dihydrate……..250mg
	Diary No. Date of R& I & fee	Dy. No. 39699: 06.12.2018 Rs. 20,000/- : 06.12.2018

	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	3's & 6's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin 250 mg Capsules. MHRA approved
	Me-too status	Azofas 250mg Capsules. Reg. No. 60291
	GMP status	GMP certificate issued on the basis of inspection conducted on 01-03-2019
	Remarks of the Evaluator[IX]	• Form 5 has been signed by the manager regulatory affairs. • The firm has mentioned capsule in the cover letter. The form 5 and all other documents are meant for film-coated tablet. Upon clarification, the firm revised all the documents meant for capsule with submission of Rs. 5000/- fee. • The USP has mentioned amperometric electrochemical detector with dual glassy carbon electrodes for assay/ analysis. The firm was asked to provide proof of availability of the same. The firm has claimed BP specifications. • Dosage form has not been mentioned on fee challan.
	Decision: Deferred for completion of Form 5 as recorded above.	
868.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	AZICIN 500mg Capsule
	Composition	Each Capsule Contains: Azithromycin as Dihydrate……..500mg
	Diary No. Date of R& I & fee	Dy. No. 39700: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Cinzit Capsule 500mg. Reg. No. 79253
	GMP status	GMP certificate issued on the basis of inspection conducted on 01-03-2019
	Remarks of the Evaluator[IX]	• Form 5 has been signed by the manager regulatory affairs. • The firm has mentioned capsule in the cover letter. The form 5 and all other documents are meant for film-coated tablet. Upon clarification, the firm revised all the documents meant for capsule without submission of any fee. • The USP has mentioned amperometric electrochemical detector with dual glassy carbon electrodes for assay/ analysis. Provide proof of availability of the same. The firm has claimed BP specifications. • Dosage form has not been mentioned on fee challan.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
869.	Name and address of manufacturer/ Applicant	M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan
	Brand Name + Dosage Form + Strength	Blozin 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin as Dihydrate…250mg
	Diary No. Date of R & I & fee	Dy. No. 41698; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished product Specification	USP

	Pack size & Demanded Price	6's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 250 mg Capsules. MHRA approved
	Me-too status	Azofas 250mg Capsules. Reg. No. 60291
	GMP status	The firm was inspected on 07.04.2018 with the following conclusion: Overall the firm was operating under good level of CGMP.
	Remarks of the Evaluator[IX]	The USP has specified Amperometric electrochemical detector with Dual glassy carbon Electrode. Provide proof of provision of the same. However, in previous cases, it was claimed that the said electrode is not a requirement in USP 42. The undersigned does not have any access to USP 42. Adjust the weight of API in master formula as per salt factor.
	Decision: Approved.	
870.	Name and address of manufacturer / Applicant	Zafa Pharmaceutical Laboratories (Private) Limited L-1/B Block-22 Federal B Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Azid Capsule 500mg
	Composition	Each capsule contains: Azithromycin…….500mg
	Diary No. Date of R& I & fee	Dy No. 9027: 12.03.2018 PKR 20,000/-: 09.03.2018
	Pharmacological Group	Macrolide
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Cinzit Capsule. Reg. No. 79253
	GMP status	The firm M/s Zafa Pharmaceutical Laboratories (Private) Limited L-1/B Block-22 Federal B Industrial Area, Karachi was issued GMP certificate on the basis of inspection dated 23.05.2018
	Remarks of the Evaluator[IX]	• Provide proof of International availability of same dosage form with same strength and salt form in reference regulatory authority as defined in 275th meeting of the Registration Board. • The USP has specified Amperometric electrochemical detector with Dual glassy carbon Electrode. Provide proof of provision of the same. However, in previous cases, it was claimed that the said electrode is not a requirement in USP 42. The undersigned does not have any access to USP 42.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

871.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Azithroin 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No.66 (01-01-2019) Rs.20,000/- 31-12-2018
	Pharmacological Group	Macrolides
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin 500mg (as monohydrate/dihydrate) Film Coated Tablets MHRA Approved
	Me-too-status	Azithrolide Tablets (Dihydrate) by M/s Heal Pharmaceuticals (Reg#84234)

	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator [XI]	Revise the label claim mentioning the hydrated form of API, along master formulation mentioning the hydrated form and revising the weight of API.
	Decision: Deferred for revision of label claim of the applied product mentioning the hydrated form alongwith the submission of master formulation.	
872.	Name and address of manufacture / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Azal Eye Drops
	Composition	Each ml contains: Azithromycin…..1% (10mg)
	Dairy No. date of R &I fee	Form-5 Dy.No 6348 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Macrolide Antibiotic
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azasite 1% sterile opthalmic solution USFDA approved.
	Me-too-status	Kraze Opthalmic solution 10mg/ml by M/s Meidcaids (Reg#082125)
	GMP Status	Firm was inspected on 20-12-2017 and Conclusion of inspection was: Based on the areas inspected, the people met and considering the findings of inspection M/s Jaens Pharmaceuticals (pvt.) ltd., is operating satisfactory. Overall hygienic condition of the firm was satisfactory at the time of inspection however, they were advised to continue improvements in production and quality control, they agreed."
	Remark of the Evaluator [XI]	Submit revised form 5 as per approved formate (signatory alongwith some text is missing) You have not submit master formulation. Submit complete master formulation
	Decision: Deferred for submission of Form 5 as per approved format along with master formulation.	
873.	Name and address of manufacture / Applicant	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Azopharm 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin (as dihydrate)…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9081 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Macrolide
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin 500mg Film Coated Tablets MHRA Approved
	Me-too-status	Azithrolide Tablets 500mg by M/s Heal Pharma(R#84234)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was:

		Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted **as satisfactory**
	Remark of the Evaluator [XI]	
	Decision: Approved.	
874.	Name and address of manufacture / Applicant	M/s Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Azopharm 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin (as dihydrate).…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9080 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Macrolide
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin 250mg Film Coated Tablets MHRA Approved
	Me-too-status	Azithrolide Tablets 250mg by M/s Heal Pharmaceuticals (Reg#84233)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted **as satisfactory**
	Remark of the Evaluator [XI]	
	Decision: Approved.	
875.	Name and address of manufacture / Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form and Strength	Zatrocin 500mg Tablet
	Composition	Each film coated Tablet Contains: Azithromycin (as Dihydrate)……500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8532 dated 26-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Macrolide
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; 1x6's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin 500mg Film Coated Tablets MHRA Approved
	Me-too-status	Azithrolide Tablets 500mg by M/s Heal Pharma(Reg#84234)
	GMP Status	The firm was inspected on 23.07.2018 and conclusion of inspection was; The firm was found in satisfactory compliance with GMP guidelines, documents including SOPs, log books were found intact and implemented. Although firm was directed to shift all the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act 1976/ DRAPAct 2012 and make available all the requisites including columns and certified reference standards.
	Remark of the Evaluator [XI]	
	Decision: Approved.	
876.	Name and address of manufacture / Applicant	M/s Al Fazal PharmaIndustries (Pvt) Ltd., Plot No.20-22; 16.5 Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form and Strength	Mizicin Capsule 500mg

	Composition	Each capsule contains: Azithromycin as dihydrate……500mg
	Dairy No. date of R &I fee	Dy.No. Duplicate dated 24/08/2017 Rs.20,000/- (Copy attached) dated 24/08/2017 The file was received from section Reg-II vide letter No.F.1-11/2019-Reg-II.
	Pharmacological Group	Antibiotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too-status	Azithromycin 500mg Capsules M/s Unipharma (Pvt) Ltd., Lahore. 071422
	GMP Status	Last GMP inspection conducted on 25-10-2017, wherein overall up gradation condition of firm was satisfactory.
	Remark of the Evaluator	Evidence of approval of applied formulation in reference country is not verified.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

877.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mezethro 500mgcapsule
	Diary No. Date of R& I & fee	Dy. No. 41018 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each capsule contains: Azithromycin as dihydrate……..500mg
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	AZOTINE of M/s Nimral Pharma, Islamabad, Reg. No. 68501
	GMP Status	Last inspection report dated 22/05/2018, the firm is Operating with cGMP as of today.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

Deferred Cases:

878.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Ezocin Capsule 250mg
	Composition	Each capsule contains: Azithromycin as dihydrate…… 250mg
	Diary No. Date of R& I & fee	Dy No. 1734: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 250 mg Capsules. MHRA approved
	Me-too status	Azofas 250mg Capsules. Reg. No. 60291

	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator[IX]	The USP has mentioned amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis. The firm submitted that they will purchase the same.
	Previous decision	The Board in its 289th meeting deferred the case for amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis.
	Evaluation by PEC	The USP has specified Amperometric electrochemical detector with Dual glassy carbon Electrode. Provide proof of provision of the same. However, in previous cases, it was claimed that the said electrode is not a requirement in USP 42. The firm submitted that they have purchased amperometric electrochemical detector with dual glassy carbon electrodes.
	Decision: Approved.	
879.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name+ Dosage Form + Strength	Zito 250mg Capsule
	Composition	Each hard gelatin capsule contains: Azithromycin as Dihydrate……250mg
	Diary No. Date of R & I & Fee	Dy No. 15550: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x6's, 10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Azithromycin 250 mg Capsules. MHRA approved
	Me-too Status	Azofas 250mg Capsules. Reg. No. 60291
	GMP Status	New License
	Remarks of the Evaluator[IX]	The USP has mentioned amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis. The firm submitted that they will purchase the said electrode.
	Previous decision	The board in its 289th meeting deferred the case for provision of amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis.
	Evaluation by PEC	The firm again submitted that they will purchase the said electrode.
	Previous decision	The board in its 290th meeting deferred the case for provision of amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis.
	Evaluation by PEC	The firm requested that they may be granted USP sepcifications or BP specification. The USP has specified Amperometric electrochemical detector with Dual glassy carbon Electrode. Provide proof of provision of the same. However, in previous cases, it was claimed that the said electrode is not a requirement in USP 42. The undersigned does not have any access to USP 42.
	Decision: Approved.	
880.	Name and address of manufacturer / Applicant	M/s Vega Pharmaceuticals (Pvt) Ltd,
	Brand Name +Dosage Form + Strength	Azocin 250mg tablet
	Diary No. Date of R& I & fee	Duplicate dossier Dated 29/04/2013 Rs. 20,000 (8000/- + 12000/-)
	Composition	Each tablet contains: Azithromycin as dehydrate…….250mg
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 280/- per 10's
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Azithrolide tablet of M/s Heal Pharma (Reg. # 084233)
	GMP Status	Date of inspection 9th January, 2019 & 21st March, 2019.Fair level of cGMP compliance at the time of inspection.
	Remarks of the Evaluator.	
	Decision: Deferred in 261st meeting for: • Commitments as per decision of the Board. • Inspection report • Finished product specifications. • Fee Rs. 8000/- and 12000/- are photocopies. • Approval status in reference countries. **Evaluation by PEC:** • Commitments as per decision of the Board are submitted. • Inspection report Submitted. • The product is present in USP. The submitted monograph shows that the firm has applied for Film Coated tablet as per the reference product while the minutes of 261st meeting the composition is mentioned as Each Tablet Contains azithromycin as dihydrate…250mg. • The product is approved in MHRA and me too status is confirmed.	
Decision: Approved. Fee shall be verified as per procedure adopted in 285th meeting.		

Case No. 01 Priority Registration of Remdesivir containing drug products

Keeping in view the current outbreak of Covid-19, the Drug Regulatory Authority of Pakistan in its 84th meeting held on 01st June, 2020 decided as:

1. exercising its power under Rule 26 of Drugs (LRA) Rules amended via SRO 713(I)/2018 dated 8th June, 2018, allowed to submit registration applications on Form 5 / Form 5-A / Form 5-D instead of Form 5F, for Registration of Remdesivir and Tocilizumab in light of approvals granted by the reference regulatory authorities and with the following additional conditions:

a. The applicants can submit their applications till 31-07-2020 and these applications will be considered out of queue.
b. Registration Board shall consider grant of registration under proviso of Rules 29(6) (8) of the Drug (Licensing, Registration & Advertising) Rules, 1976 and shall follow precautions / terms & conditions as adopted by the Reference Regulatory Authorities.
c. The registration holders including those granted registration under Form 5D as a new drug will submit data of product development and 6 months accelerated and 6 months real time stability studies data within one year alongwith other data as may be required by Registration Board. The data will be considered by Registration Board for further decision.

Following applications are presented before the Registration Board for its consideration:

I. Applications for "Lyophilized powder for injection" (applied by way of Lyophilization in the vial)

881.	Name and address of Manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Coriv Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12411; 03-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per PRC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Last inspection dated 05-08-2019 concluded acceptable level of GMP compliance

Remarks of Evaluator:

Observations	Firm's response
• Test for reconstitution has not been included in the finished product specifications.	• The test for reconstitution has been added in the Finished Product Specification. The revised Finished Product Specification is submitted.
• Reference for finished product specifications shall be submitted.	• Firm has declared finished product specification's "As per Innovator's specifications".
• Unlike the formulation ingredients of the reference product of M/s Gilead Pharma, as revealed in literature from US FDA & EMA you have not mentioned any ingredient in the master formulation for pH adjustment. Clarification shall be submitted in this regard.	• The ingredient Sodium Hydroxide has been used for pH adjustment and it was mentioned in the manufacturing procedure but the ingredient was overlooked to mention in the Manufacturing Formulation Ingredient List. The corrected Master Formulation has been submitted.

882.	Name and address of Manufacturer / Applicant	M/s BF Biosciences Ltd. 5-Km,Sundar Raiwind Road, Lahore
	Brand Name+DosageForm+Strength	Remidia Lyophillized Powder for Infusion 100mg/Vial
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.763 (Dir. PE & R); 28-05-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	MRP Rs. 14,600 TP Rs. 12410 ($ 76.98) per Vial
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Last GMP inspection report conducted on 22-08-2019 recommended renewal of DML.

Remarks of Evaluator:

Observations	**Firm's response**
• Submit evidence of approval of required manufacturing facility for Lyophilization from CLB.	• The facility is licensed to manufacture liquid & Lyophilized Vials manufacturing.
• Submit master formulation for per unit dosage form.	• Master formulation for per unit dosage form has been submitted.
• Test for pH of reconstituted solution has not been included in finished product specifications.	• Revised finished product specification with inclusion of test for pH has been submitted.
• Submitted finished product testing method recommends use of UPLC (Ultra Performance Liquid Chromatograph) equipped with Photodiode Array Detector, for the performance of Assay test whereas submitted List of equipment of QC does not include UPLC.	• UHPLC is not in list of existing equipment as UHPLC is on order (Proforma invoice submitted). Ordered equipment is with PDA (Photo Diode array) detector.
• Sample preparation described in the Assay test is for the "Liquid Injection" instead of "Powder for injection".	• Revised finished product testing method has been submitted, wherein description of sample preparation in assay test has been corrected for powder for injection.
• Reference for proposed finished product specifications shall be submitted.	• Firm has referred to "Innovator's specifications

Keeping in view the current outbreak of Covid-19, the Drug Regulatory Authority of Pakistan in its 84th meeting held on 01st June, 2020 decided as:

- Recommended to the Registration Board under Section 7(c) of DRAP Act, 2012 for permitting M/s BF Biosciences, Lahore for manufacturing of Remdesivir in already approved section for biological drugs on campaign manufacturing basis in light of decision of Appellate Board taken in its 151st sitting held on 16th January, 2019.
- Manufacturing of Remdesivir on campaign basis will also be applicable to other applicants on the same analogy.

883.	Name and address of Manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot No. 209, Sector 23, Korangi Indsutrial Area, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Remivir Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12483; 03-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs

	Pack Size & Demanded Price	As Per PRC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Last inspection dated 10-04-2020 concluded acceptable level of GMP compliance

Remarks of Evaluator:

Observations	**Firm's response**
• The dosage form of applied product shall be clearly declared in Form-5D, whether it is "Dry powder for injection" or "Liquid injectable solution."	• Firm has submitted photocopy of revised Form 5D, wherein dosage form has been declared as "Dry powder for injection (Lyophilized powder).
• Master formulation does not include water for injection. Clarification shall be submitted in this regard.	• Firm has submitted revised master formulation wherein "Water for injection" has been added as diluent along with following statement: "Water for injection not present in final formulation (to be evaporated during lyophilization)
• Test for reconstitution, pH of reconstituted solution, water content, uniformity of dosage have not been included in the finished product specifications.	• Firm has submitted revised finished product specifications, wherein tests for Constituted solution, pH, water content, uniformity of dosage have been included. While firm has referred to their specifications "as per innovator". Note: Acceptance criteria for reconstitution time has not been declared in the finished product specifications.
• Submitted finished product specifications declare the limit for Assay test as 90% - 115%. Scientific justification shall be submitted for extending assay limit beyond usual limit of 110%.	• Limits for Assay test have been changed to 90% - 110% in the revised finished product specifications submitted by firm.
• Finished product testing method shall be submitted.	• Finished product testing method has been submitted.
• Justification shall be submitted for proposed storage condition of "Store below 25^{o}C".	• Firm has changed the proposed storage condition to "Store below 30^{o}C" in the revised Form 5D, while referring to innovator's product storage instructions.
• Justification shall be submitted or demanded shelf life of 36 months.	• The shelf life of Besivir 100mg is established as per Innovator Product by Gilead Sciences, Inc. which is 48 months.

884.	Name and address of Manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221-223, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Besivir Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12482; 03-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per PRC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Last inspection dated 17-09-2019 concluded acceptable level of GMP compliance

Remarks of Evaluator:

Observations	Firm's response
• The dosage form of applied product shall be clearly declared in Form-5D, whether it is "Dry powder for injection" of "Liquid injectable solution."	• Firm has submitted photocopy of revised Form 5D, wherein dosage form has been declared as "Dry powder for injection (Lyophilized powder).
• Master formulation does not include water for injection. Clarification shall be submitted in this regard.	• Firm has submitted revised master formulation wherein "Water for injection" has been added as diluent along with following statement: "Water for injection not present in final formulation (to be evaporated during lyophilization)
• Test for reconstitution, pH of reconstituted solution, water content, uniformity of dosage have not been included in the finished product specifications.	• Firm has submitted revised finished product specifications, wherein tests for Constituted solution, pH, water content, uniformity of dosage have been included. While firm has referred to their specifications "as per innovator". Note: Acceptance criteria for reconstitution time has not been declared in the finished product specifications.
• Submitted finished product specifications declare the limit for Assay test as 90% - 115%. Scientific justification shall be submitted for extending assay limit beyond usual limit of 110%.	• Limits for Assay test have been changed to 90% - 110% in the revised finished product specifications submitted by firm.
• Finished product testing method shall be submitted.	• Finished product testing method has been submitted.
• Justification shall be submitted for proposed storage condition of "Store below 25°C".	• Firm has changed the proposed storage condition to "Store below 30°C" in the revised Form 5D, while referring to innovator's product storage instructions.
• Justification shall be submitted or demanded shelf life of 36 months.	• The shelf life of Besivir 100mg is established as per Innovator Product by Gilead Sciences, Inc. which is 48 months.

885.	Name and address of Manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Biovir IV Injection 100mg
	Composition	Each Vial Contains: Remdesivir Lyophillized Powder…100mg
	Diary No. Date of R&I & fee	Dy No.12371; 03-06-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Last inspection dated 18 & 23-04-2019 concluded acceptable level of GMP compliance

Remarks of Evaluator:

Observations	Firm's response
• Form-5D shall be submitted for applied formulation along with differential fee of Rs. 30,000/-	• Firm has submitted differential fee of Rs. 30,000/- vide deposit slip# 1943897 dated 05-06-2020, whereas again Form 5 has been submitted instead of Form 5D.
• Submit manufacturing outline specific to the applied product.	• Firm has submitted outline of method of manufacturing including steps of mixing, solution preparation, filtration, vial filling & Lyophilization.
• The submitted raw material testing method of Remdesivir declares the description as "white to off-white to yellow lyophilized powder". Clarification shall be submitted for use of lyophilized API, while the finished product is itself to be manufactured by way of Lyophilization.	Firm has submitted revised raw material specifications for Remdesivir wherein description has been changed to "off-white to yellow colored powder".
• Test for reconstitution has not been included in the finished product specifications.	• Firm has submitted revised finished product specifications, wherein tests for reconstitution and water content have been included.
• Test for water content has not been included in finished product specifications.	• Note: *Acceptance criteria for reconstitution time has not been declared in the finished product specifications.*
• Reference for finished product specifications shall be submitted.	• While firm has referred to their specifications "as Bio-Lab's specifications".
• Justification for the acceptance limit between 9.0 – 12.0, for the pH test shall be submitted.	• Firm has submitted revised finished product specifications wherein limit for test of pH has been changed to "Between 3.0 & 4.0"

886.	Name and address of Manufacturer / Applicant	M/s The Nextar Pharma Private Limited. Plot No. E-58, North Western Industrial Zone, Port Qasim, Pakistan **Contract manufacturing by:** M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Remency IV Injection 100mg
	Composition	Each 20ml Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12412; 03-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	
	Pack Size & Demanded Price	As Per DPC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Bio-Lab: Last inspection dated 18 & 23-04-2019 concluded acceptable level of GMP compliance

Remarks of Evaluator:

Observations	Firm's response
• Undertaking for resemblance of brand name has been submitted from manufacturer i.e., M/s Bio-Labs, whereas it must be submitted from the applicant.	• Undertaking for resemblance of brand name has been submitted from the applicant.
• Submit manufacturing outline specific to the applied product.	• Firm has submitted outline of method of manufacturing including steps of mixing, solution preparation, filtration, vial filling & Lyophilization.
• The submitted raw material testing	Firm has submitted revised raw material specifications

	method of Remdesivir declares the description as "white to off-white to yellow lyophilized powder". Clarification shall be submitted for use of lyophilized API, while the finished product is itself to be manufactured by way of Lyophilization.	for Remdesivir wherein description has been changed to "off-white to yellow colored powder".
	• Test for reconstitution has not been included in the finished product specifications.	• Firm has submitted revised finished product specifications, wherein tests for reconstitution and water content have been included. • Note: *Acceptance criteria for reconstitution time has not been declared in the finished product specifications.*
	• Test for water content has not been included in finished product specifications.	
	• Reference for finished product specifications shall be submitted.	• While firm has referred to their specifications "as Bio-Lab's specifications".
	• Justification for the acceptance limit between 9.0 – 12.0, for the pH test shall be submitted.	• Firm has submitted revised finished product specifications wherein limit for test of pH has been changed to "Between 3.0 & 4.0"

887.	Name and address of Manufacturer / Applicant	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad **Contract manufacturing by:** M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Desivir Injection 100mg IV
	Composition	Each Vial Contains: Remdesivir…100mg Lyophillized Powder
	Diary No. Date of R&I & fee	Dy No.12579; 04-06-2020 ; Rs.100,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per PRC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Bio-lab: Last inspection dated 18 & 23-04-2019 concluded acceptable level of GMP compliance

Remarks of Evaluator:

Observations	**Firm's response**
• Form-5 has been submitted by the applicant, while Form 5D shall be submitted from the applicant	• The firm has again submitted Form 5, which has been stamped by M/s Bio-labs.
• Submit manufacturing outline specific to the applied product.	• Firm has submitted outline of method of manufacturing including steps of mixing, solution preparation, filtration, vial filling & Lyophilization.
• The submitted raw material testing method of Remdesivir declares the description as "white to off-white to yellow lyophilized powder". Clarification shall be submitted for use of lyophilized API, while the finished product is itself to be manufactured by way of Lyophilization.	Firm has submitted revised raw material specifications for Remdesivir wherein description has been changed to "off-white to yellow colored powder".
• Test for reconstitution has not been included in the finished product	• Firm has submitted revised finished product specifications, wherein tests for reconstitution and

	specifications.	water content have been included.
	• Test for water content has not been included in finished product specifications.	• Note: *Acceptance criteria for reconstitution time has not been declared in the finished product specifications.*
	• Reference for finished product specifications shall be submitted.	• While firm has referred to their specifications "as Bio-Lab's specifications".
	• Justification for the acceptance limit between 9.0 – 12.0, for the pH test shall be submitted.	• Firm has submitted revised finished product specifications wherein limit for test of pH has been changed to "Between 3.0 & 4.0"

888.	Name and address of Manufacturer / Applicant	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore **Contract manufacturing by:** M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Remdesivir IV Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12578; 04-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per PRC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Bio-lab: Last inspection dated 18 & 23-04-2019 concluded acceptable level of GMP compliance

Remarks of Evaluator:

Observations	Firm's response
• Form-5 has been submitted by the applicant, while Form 5D shall be submitted from the applicant	• The applicant has submitted Form 5D.
• Submit manufacturing outline specific to the applied product.	• Firm has submitted outline of method of manufacturing including steps of mixing, solution preparation, filtration, vial filling & Lyophilization.
• The submitted raw material testing method of Remdesivir declares the description as "white to off-white to yellow lyophilized powder". Clarification shall be submitted for use of lyophilized API, while the finished product is itself to be manufactured by way of Lyophilization.	Firm has submitted revised raw material specifications for Remdesivir wherein description has been changed to "off-white to yellow colored powder".
• Test for reconstitution has not been included in the finished product specifications.	• Firm has submitted revised finished product specifications, wherein tests for reconstitution and water content have been included.
• Test for water content has not been included in finished product specifications.	• Note: *Acceptance criteria for reconstitution time has not been declared in the finished product specifications.*
• Reference for finished product specifications shall be submitted.	• While firm has referred to their specifications "as Bio-Lab's specifications".
• Justification for the acceptance limit between 9.0 – 12.0, for the pH test shall be submitted.	• Firm has submitted revised finished product specifications wherein limit for test of pH has been changed to "Between 3.0 & 4.0"

889.	Name and address of Manufacturer / Applicant	M/s MTI Medical Pvt. Ltd. 586-587 Sundar Industrial Estate, Lahore, Pakistan
	Brand Name+DosageForm+Strength	Remdevir Lyophilized Injection 100mg/Vial
	Composition	EachVial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12804; 05-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	MTI Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	--

Remarks of Evaluator:

Observations	Firm's response
• You have submitted proposed storage condition for the diluted Remdesivir solution instead of the applied finished product of Dry powder injection.	• Firm has proposed revised storage condition as "Store below 25^{o}C protect from heat, light & moisture"
• Submitted master formulation is qualitatively different from the reference product of M/s Gilead pharma, since it does not contain any solubilizing agent for Remdesivir.	• Firm has submitted revised master formulation which is qualitatively similar to innovator but the quantity of SBECD is not as per innovator.
• Submitted manufacturing method involves initial mixing of Remdesivir with NaOH only, which is not in line with the manufacturing outline of the reference product of M/s Gilead pharma, as revealed by the literature from US FDA & EMA.	• Firm has submitted revised manufacturing outline wherein step of Lyophilization is missing.
• Submitted raw material specifications declare the solubility of Remdesivir in water as "Freely soluble in water". Scientific justification shall be submitted in this regard since available literature from US FDA & EMA suggest that Remdesivir is practically insoluble in water.	• Solubility in water now mentioned as insoluble, while no revised document is submitted for this regard.
• Submitted Raw material testing method describes the standard and sample solution preparation for "Remifentanil HCl" instead of "Remdesivir". Clarification shall be submitted in this regard.	• Remifentanil HCL is typographic error.We Submitted Remdesivir testing method instead of Remifentanil HCl • No revised document is submitted for this regard
• Submitted finished product specifications declare the "filling weight range" as 100mg $\pm$ 10%. The said fill weight does not suggest incorporation of any ingredient other than the API, which is not in line with the reference product of M/s Gilead pharma, as revealed by the literature from US FDA & EMA.	• Filling weight Range: 110 mg 2% • This is still not rationale considering the innovator's formulation.
• The pH range of 9 -12, specified in the finished product specifications shall be justified.	• Finish product (PH range: 3….4)
• Test for reconstitution & water content has not been included in the submitted finished product specifications.	• Water content limit : Not more than :2% • Test for reconstitution still not mentioned.
• Reference for proposed finished product specifications shall be submitted.	• It's as per innovators specification
• Submitted finished product testing method	• Remifentanil HCL is typographic error.

	describe the standard solution preparation for "Remifentanil HCl" instead of "Remdesivir". Clarification shall be submitted in this regard.	We Submitted Remdesivir testing method instead of Remifentanil HCL

890.	Name and address of Manufacturer / Applicant	M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Remdes Lyophilized Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy. No.12903; 08-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	N/A
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	GMP certificate issued dated: 14-06-2018
	Remarks of Evaluator:	

Observations	**Firm's response**
• Form 5D mentions dosage form as "Suspension."	It was typographic error. Corrected form 5D submitted
• The submitted finished product specification does not include tests for water content.	Revised specifications with desired test have been submitted.
• Reference for proposed specifications shall be submitted.	Firm has referred to EMA summary for compassionate use document.

891.	Name and address of Manufacturer / Applicant	M/s Hilton Pharmaceuticals, Plot No.13, Sector 15, Korangi, Karachi **contract manufacturing by** M/s Nabiqasim Industries Ltd, 17/24, Korangi Industrial Area, Korangi Highway, korangi, Karachi
	Brand Name+DosageForm+Strength	Hildesvir Injection 100mg
	Composition	Each Vial contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13034; 08-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Nabiqasim: Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
	Remarks of Evaluator:	
892.	Name and address of Manufacturer / Applicant	M/s Pharm Evo Pvt Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi. **contract manufacturing by** M/s Nabiqasim Industries Ltd, 17/24, Korangi Industrial Area, Korangi Highway, korangi, Karachi
	Brand Name+DosageForm+Strength	Redvir Injection 100mg
	Composition	Each Vial contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13035; 08-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Nabiqasim: Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
	Remarks of Evaluator:	

893.

Name and address of Manufacturer / Applicant	M/s The Searle Company Limited. F-319 S.I.T.E. Karachi, Pakistan.
Brand Name+DosageForm+Strength	Bemsivir IV Injection 100mg
Composition	Each Vial Contains: Remdesivir…100mg
Diary No. Date of R&I & fee	Dy. No.12378; 03-06-2020 ; Rs.100,000
Country of origin	Bangladesh
Market authorization holder	M/s Beximco Pharmaceuticals Ltd., Tongi, Gazipur, Dhaka
Manufacturer	M/s Beximco Pharmaceuticals ltd, 126, Kathaldia, Auchpara, tongi-1711, Ghazipiur, Bangladesh
Pharmacological Group	Anti-Viral
Type of Form	Form 5A
Finished Product Specification	Manufacturer specification
Pack Size & Demanded Price	As Per SRO
Approval status of product in Reference Regulatory Authorities	
Me-too status	
DSL	Valid copy of DSL submitted.

Remarks of Evaluator:

Observations	Firm's response
• The document issued by Director General DGDA of Bangladesh with title of "Formulation for manufacture of Remdesivir Lyophilized powder for IV injection by M/s Beximco Pharmaceuticals Ltd., Tongi, Gazipur" declares the quantity of Sulfobutyl ether-beta-cyclodextrin as 10.0gm per vial, whereas the Batch formula submitted by manufacturer declares the quantity of Sulfobutyl ether-beta-cyclodextrin 3.3 gm per vial. Clarification shall be submitted for this variation.	Previous quantity of this excipient is 10g/vial but the manufacturer has revised the Formulation to use the optimum quantity. Actual quantity of this excipients is 3.3gm per vial which is mentioned in Batch formula (Submitted with the dossier).
• Submitted batch formula declares 2% overage of Remdesivir. Justification shall be submitted for incorporating overage.	• 2% overage has been added in the formulation to compensate manufacturing loss.
• Submitted raw material specifications declares the storage condition as 2 – 8°C. Justification shall be submitted in this regard since the literature of reference product of Gilead Pharma, available from EMA declares the performance of drug substance stability at 30°C/75%RH & 40°C/75%RH.	The API used for manufacturing Beximco's Remdesivir Injection has storage condition of 2-8°C. This is also mentioned in the COA of the API supplier. Firm submitted during personal representation that the API is stable even at 30°C, but the API manufacturer had set precautionary storage condition of 2 – 8°C

	• Test for degradation products & Uniformity of dosage units have not been included n finished product specifications.	Test of Related Substances is a part of routine testing of API. However, test of related substance and uniformity of Dosage unit will be included in revised Finished product specification.
	• Submitted stability protocol does not include test for degradation products. Justification shall be submitted in this regard.	Degradation product test will be included in the stability protocol once the method is developed.
	• Justification shall be submitted for proposed shelf life of two years.	• Since innovator is also claiming one-year shelf life therefore please grant us shelf life as per innovator product.
	• Reference for proposed finished product specifications shall be submitted.	The reference for Finished Product is In-house since the molecule and product is not included any Pharmacopoeia yet.
	• Original legalized COPP / Free Sale Certificate shall be submitted.	Legalization is in process. Will submit to your good office once received.
	• Original legalized GMP certificate shall be submitted.	Legalization is in process. Will submit to your good office once received.
	• Original notarized Letter of authorization shall be submitted.	Legalization is in process.
	• The submitted GMP certificates for the manufacturer issued by various reference agencies does not endorse the GMP status of the required manufacturing facility i.e., "Lyophilized Vial Injectable", hence justification shall be submitted for consideration of your request to waive off the facility inspection in light of "Policy for inspections of Manufacturer abroad".	Various products / sections of Beximco Pharmaceuticals Limited (126 Kathaldia, Auchpara, Tongi 1711 Gazipur, Dhaka, Bangladesh) are already approved (See Annexure – 5) by Stringent Regulatory Authorities: • Germany • TGA Australia • WHO • GCC • Malta • FDA • Health Canada On the basis of above inspection report/GMP Certificates, we would request you to waive off facility inspection in current pandemic situation as per rule 29 (8) of Drug Act, 1976.

894.	Name and address of Manufacturer / Applicant	M/s OBS Healthcare Pvt Limited. Plot No. 10 & 25, Sector 20, Korangi Indsutrial Area, Karachi,-74900
	Brand Name+DosageForm+Strength	Ninavir IV Infusion 100mg
	Composition	EachVial Contains: Remdesivir…100mg
	Country of origin	Bangladesh
	Market authorization holder	M/s Incepta Pharmaceuticals Limited., 40, Shahid Tajuddin Ahmed Sarani, Tejgaon I/A, Dhaka 208, Bangladesh
	Manufacturer	M/s Incepta Pharmaceuticals Limited. Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341, Bangladesh
	Drug Sale License	Valid copy of DSL submitted
	Diary No. Date of R&I & fee	Dy No.12807; 05-06-2020 ; Rs.100,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5A
	Finished Product Specification	N/A
	Pack Size & Demanded Price	MRP: Rs.25,000/01 Vial Per Pack
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	--

Remarks of Evaluator:

Observations	Firm's response
• Original Form 5A shall be submitted, since photocopy ha sbeen submitted.	• Submitted.
• Submitted raw material specifications declares the solubility of Remdesivir as "Sparingly soluble in water" whereas the literature from US FDA and EMA for the reference product of Gilead pharma, declares the solubility of Remdesivir as "Practically insoluble ion water". Justification shall be submitted in this regard.	• The revised specification of Raw material is submitted declaring it soluble in methanol and insoluble in water • The clarification from manufacturer is also submitted declaring it typographical error.
• Test for degradation products & Uniformity of dosage units have not been included in finished product specifications.	• The degradation products (Related substances) testing and uniformity of dosage units have been included in finished product specifications. • The revised Finished product specification is enclosed.
• Submitted stability protocol does not include test for degradation products. Justification shall be submitted in this regard.	• Revised stability protocol is enclosed after the addition of degradation product (Related substances) testing.
• Justification shall be submitted for proposed shelf life of two years.	The shelf life in Bangladesh is one year. One year shelf life will be claimed in Pakistan also. The revised original Form 5A is enclosed with clarification of manufacturer.
• Reference for proposed finished product specifications shall be submitted.	• The product has "in-house finished product specifications" as the product is not included in any pharmacopeia.
• Original legalized COPP / Free Sale Certificate shall be submitted.	• The COPP is under issuance process. The undertaking from the manufacturer and OBS healthcare is enclosed.
• Original legalized GMP certificate shall be submitted.	• The legalization of GMP is under process. The undertaking from the manufacturer and OBS healthcare is enclosed.
Original notarized Letter of authorization shall be submitted.	• The undertakings are enclosed in this regard.

895.

Name and address of Manufacturer / Applicant	M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st floor, Shafi court, Civil lines Karachi
Brand Name+DosageForm+Strength	Cipremi 100mg Injection
Composition	Each lyophilized Vial contains : Remdesivir ….. 100mg
Country of Origin	India
Manufacturer	M/s Cipla Ltd. Plot No. m-61, M-62 & M-63, Verna Industrial Estate, Verna-Goa, India
DSL	--
Diary No. Date of R&I & fee	Dy. No.12996; 08-06-2020 ; Rs.50,000
Pharmacological Group	Anti-Viral
Type of Form	Form 5A
Finished Product Specification	Innovator's Specs
Pack Size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	
Me-too status	

Remarks of Evaluator:

Observations	Firm's response
Submitted master formula declares Quantity of Remdesivir = 105 mg	Remdesvir for Injection 100 mg/ vial contains about 5% Overfill to accommodate displacement

		per vial, whereas submitted label claim is "Each vial contains Remdesivir=100 mg".	volume of powder when reconstituted with 19 mL Water for Injection. The 5% is overfill is necessary to obtain the labelled 5 mg/mL Remdesivir concentration in the reconstituted solution when reconstituted with 19 mL of sterile water for injection. The proposed overfill and reconstitution instructions are is same as Gilead product.
		Test for reconstitution time and Uniformity of dosage units have not been included in finished product specifications	Firm has submitted revised finished product specifications with desired test.
		Justification shall be submitted for proposed shelf life of 24 months since no product development and stability data has been submitted in the dossier	We would like to inform Agency that, Cipla has undertaken a significant initiative through collaboration and licensed Remdesivir for manufacturing and marketing in 127 countries including India from Gilead Sciences Inc. (Address: 333 Lakeside Drive, Foster city, California 9440, USA) for making this drug accessible to needy patients fighting this Covid-19 pandemic. As part of the licensing arrangement Gilead has shared the Tech Pack of Remdesivir development and manufacturing processes with Cipla for both API and formulation. The proposed shelf life for the Cipla's product is based on the stability of product assessed by Gilead. The stability program has been designed to establish the stability profile of Remdesivir for injection,100mg, in support of an appropriate storage condition and shelf-life. The stability assessment of Remdesivir for injection was conducted at the long-term storage condition of 30°C/75% RH and at the accelerated condition of 40 °C/75% RH. Stability data for all batches of Remdesivir for injection, tested under formal stability studies following the principles outlined in the ICH Q1A Stability Testing of New Drug Substances and Products, met the acceptance criteria for all attributes tested following long-term storage at 30 °C/75% RH for up to 36 months, and accelerated storage at 40 °C/75% RH for up to 6 months.
		Reference for proposed finished product specifications shall be submitted	Cipla's Remdesvir for Injection 100 mg/ vial is set similar to the Innovator Gilead's drug product specification.
		Valid copy of DSL of the applicant shall be submitted	Valid copy of DSL submitted.
		Original legalized COPP/Free Sale Certificate from relevant regulatory authority of country of origin shall be submitted	Commitment letter for submission of legalized COPP
		Original legalized GMP Certificate of the manufacturer shall be submitted	WHO GMP of FP mfg. site (Cipla Goa unit IX) is enclosed as along with Commitment letter for submission of legalized GMP
		Original notarized Letter of authorization shall be submitted	We have supply and distribution agreement in place between Cipla Ltd. India and AJM Pharma Pvt. Ltd. Pakistan.

II. Applications for "Dry Powder Injection" (applied by way of using ready to fill dry powder for injection)

896.	Name and address of Manufacturer / Applicant	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Brand Name+DosageForm+Strength	Remvir for Injection 100mg
	Composition	Each vial contains: Remdesivir Lyophilized Sterile powder ……100mg
	Diary No. Date of R&I & fee	Dy. No.9971; 05-05-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Emergency use authorization granted by USFDA
	Me-too status	--
	GMP status	The firm was inspected on 25.06.2018 with the following conclusion: Keeping in view the above facts, detailed visit of establishment and supporting documents provided by the management and verification of rectification of plan/action with reference to previous shortcomings identified and company has shown good response and rectified the problems

Remarks of Evaluator:

Observations	Firm's response
• The composition table declares the content of applied product as "Remdesivir Lyophilized Sterile powder = 3100mg/vial", while the section 4 of Form 5D mentions following against the strength: "Each vial contains: Remdesivir lyophilized sterile powder ….. 100mg". Clarification shall be submitted in this regard.	• M/S Horizon Pharma use Remdesivir Lyophilized Sterile powder as ready to fill powder in which Remdesivir active drug substance is 3-4% remaining contents weight contains SBECD which is 96-97%. • In form 5D section 4 shows label claim that is: Each vial contain Remdesivir Lyophilized Powder eq. to Remdesivir……100mg
• Submitted specifications for the Remdesivir drug substance declares the limit for Assay test as 90.0% - 110%. Justification shall be submitted for this wide range for Assay test.	• M/S Horizon use Remdesivir lyophilized ready to fill powder the given assay limit is according to supplier assay limit .Typographic mistake is corrected "Remdesivir" drug substance with "Remdesivir Lyohpilized powder"and assay limit is provided for Remdesivir Lyophilized Powder. COA of material provided by supplier is attached herewith as evidence. • The submitted COA of "Remdesivir Lyophilized powder" from API manufacturer declares the Assay limits as NLT 2.9& NMT 3.5 of labelled amount of T611
• Submitted specifications declare the solubility for Remdesivir as "Practically soluble in water", whereas the literature from US FDA and EMA for the reference product of Gilead pharma, declares the solubility of Remdesivir as "Practically insoluble ion water". Justification shall be submitted in this regard.	M/S Horizon use Remdesivir lyophilized ready to fill powder that is soluble in water. Typographic mistake is corrected after replacing "Remdesivir" drug substance with "Remdesivir Lyohpilized powder". Specifications for the material are attached as evidence.
• The lit rature from US FDA and	• M/S Horizon use Remdesivir lyophilized ready to fill

	EMA for the reference product of Gilead pharma, declares content of Sulfobutylether-β-cyclodextrin sodium (SBECD) as s lubilizing agent, but you have not provided any such detail for SBECD in the dossier.	powder. Manufacturer COA are attached here as evidence that SBECD is used as solubilizing agent. • The submitted COA of "Remdesivir Lyophilized powder" from API manufacturer does not declare the content of SBECD
	• Test for reconstitution and pH of reconstituted solution have not been included in the finished product specifications.	• Test for reconstitution and PH of reconstituted solution have been included in the finished product specifications. • Acceptable limit for reconstitution time has not been mentioned.
	• Reference for proposed finished product specifications shall be submitted.	• M/S Horizon use Remdesivir lyophilized ready to fill powder. Finished product specifications are same as supplier specifications.

897.	Name and address of Manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Viso-Rem for Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12409; 03-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Vision's Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	GMP certificate issued on basis of inspection conducted on 26-1-2018.

Remarks of Evaluator:

Observations	**Firm's response**
• The submitted master formulation mentions Remdesivir = 100mg only. Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.	• The API will be used as ready to fill lyophilized powder. Updated details are described below i. Lyophilized powder containing 3.23%w/w of Remdesivir (Lyophilized powder will also contain Sulfobutylether-β-cyclodextrin sodium salt (SBECD) USP-NF as solubilizing agent and HCl or NaoH for pH adjustment) ii. Pr posed Qty. er Vial = 3.095gm Eq. to 100mg Remedesivir
• The literature from US FDA and EMA for the reference product of Gilead pharma, declares content of Sulfobutylether-β-cyclodextrin sodium (SBECD) as solubilizing agent, but you have not provided any such details or SBECD in the dossier.	• Firm has submitted updated master formulation wherein details of SBECD have described as below: "Lyophilized powder containing 3.23%w/w of Remdesivir" (Lyophilized powder will also contain Sulfobutylether-β-cyclodextrin sodium salt (SBECD) USP-NF as solubilizing agent and HCl or NaoH for pH adjustment)
• Submitted fi ished product specifications declare the acceptance limit for assay test of Remdesivir as 99-110%. Clarification shall be submitted in this regard.	• Firm has submitted revised raw material specifications: "Lyophilized powder containing 3.23%w/w of Remdesivir"

	• Test for appearance, identification, reconstitution, pH of reconstituted solution, uniformity of dosage units, sterility, bacterial endotoxins and particulate matter. Finished product testing method has not been submitted.	• Firm has submitted revised finished product specifications wherein test for reconstitution time has still not been included. • Finished product testing method has been submitted, wherein mobile has been used as diluent for sample & standard solution preparation while the chromatographic conditions mention the gradient of two different solutions over 60 minutes as mobile phase.
	• In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials (as evident from available literature by US FDA & EMA), you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	• In Viso-Rem 100mg for injection, similar composition formulation has been followed for the lyophilized powder as used by the Innovator. • The manufacturing of lyophilized powder is being carried out under aseptic condition that subsequently filled into the vials also under aspectic condition and in amount which corresponds to the labeled quantity. Therefore, we can say that our product is pharmaceutically equivalent to that of Gilead Pharma

898.	Name and address of Manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name+DosageForm+Strength	Remdi-Wrd Injection 5mg/ml
	Composition	Each Vial Contains: Remdesivir …… 100mg
	Diary No. Date of R&I & fee	Dy. No.12474; 03-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	**Conclusion:** During the inspection, dated 12-11-2018 M/ s Welwrd are considered to be operating at satisfactory level of GMP.

Remarks of Evaluator:

Observations	**Firm's response**
• Firm has submitted application on Form 5 instead of Form 5D.	• Firm has submitted revised Form 5D. • The dosage form of applied product has now been declared in Form-5D, as "Dry powder injection"
• Submitted Form 5 has not been signed by any authorized person.	
• The dosage form of applied product shall be clearly declared in Form-5D, whether it is "Dry powder for injection" or "Liquid injectable solution."	
• Undertaking of Form 5 has not been signed by any authorized person.	
• The literature from US FDA and EMA for the reference product of Gilead pharma, d clares content o	• Firm has submitted updated composition wherein details of SBECD have described as below: "Remdesivir lyophilized ready to fill powder*"

	Sulfobutylether-β-cyclodext in sodium (SBECD) as solubilizing agent, but ou have not provided ny such details for SBECD in the dossier.	*Lyophilized ready to powder containing 100mg Remdesivir, 3300 mg Betadex Sulfobut l ether odium as solubilizing agent.
	• Test for reconstitution, pH of reconstituted solution, water content, uniformity of dosage units & bacterial endotoxins have not been included in the finished product specifications.	• Firm has submitted revised finished product specifications wherein, pH of reconstituted solution, water content & bacterial endotoxins have been included • While test for reconstitution & uniformity of dosage units have still not been included in the finished product specifications.
	• Reference for proposed finished product specification shall be submitted.	• Firm has mentioned in revised finished product specifications that "Product complies with Innovator's specifications."
	• The Assay test in the submitted finished product testing method describes the use of water as diluent for standard preparation, whereas as per available literature from US FDA & EMA, Remdesivir is insoluble in water. Justification shall be submitted in this regard.	• Firm has submitted revised finished product testing method which now describes the use of Mobile phase (0.1% TFA in water) as diluent for standard & sample solution preparation.
	• In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	--
	• The submitted master formulation mentions Remdesivir = 100mg only. Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.	• Firm has submitted updated composition wherein details of API have been described as below: "Remdesivir lyophilized ready to fill powder*" • *Lyophilized ready to powder containing 100mg Remdesivir, 3300 mg Betadex Sulfobutyl ether sodium as solubilizing agent. • Quantity per vial = 3400mg

899.	Name and address of Manufacturer / Applicant	M/s OBS Pakistan Private Limited. C-14, S.I.T.E, Karachi, Pakistan **contract manufacturing by** M/s Radiant Pharma Pvt Ltd, 43-E Sunder Industrial Estate, Lahore
	Brand Name+DosageForm+Strength	Remvid Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12580; 04-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer's specifications
	Pack Size & Demanded Price	As Per DPC
	Approval status of product in Reference Regulatory Authorities	

	Me-too status	
	GMP status	**Conclusion:** Last inspection dated 09-03-2018 grant of dry powder injection sections to M/s Radiant Pharma Lahore

Remarks of Evaluator:

Observations	Firm's reply
• Firm has submitted application on Form 5 instead of Form 5D.	• Form 5D Submitted
• Submitted master formulation declares the quantity of Remdesivir per vial as 105mg, whereas applied label claim is "Each vial contains Remdesivir = 100 mg". Clarification shall be submitted for this variation.	• In submitted master formulation actual quantity of REMDESIVIR is100mg per vial, 105mg is typing mistake.
• The submitted master formulation mentions Remdesivir = 105mg per vial only. Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.	As mention in point 2 actual quantity of REMDESIVIR IS 100mg per vial. It is in premixed form Lyophilized powder for injection. i.e. REMDESIVIR is equivalent to 100mg per vial (100% assay adjustment) without solubilizing agent, after water contents and assay adjustment etc.
• The literature from US FDA and EMA for the reference product of Gilead pharma, declares content of Sulfobutylether-β-cyclodextrin sodium (SBECD) as s lubilizing agent, but you have not provided any such details for BECD in the do sier.	•
• Test for reconst tution, pH of reconstituted solution, water con ent have not been included in the finished product specifications.	•
• Reference for proposed finished roduct s ecifications shall be submitted.	•
• Justification shall be submitted for applying g UV spectrophotometric method instead of HPLC method for the Assay test of finished product.	•
• In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	•
• The submitted master formulation mentions Remdesivir = 100mg per vial only. Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.	•

900.	Name and address of Manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name+DosageForm+Strength	Remdisol Injection 100mg
	Composition	Each Vial Contains: Remdesivir Lyophillized Powder for Infusion…100mg
	Diary No. Date of R&I & fee	Dy No.12585; 04-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral

Type of Form	Form 5D
Finished Product Specification	Pharmasol's Specs
Pack Size & Demanded Price	As Per SRO
Approval status of product in Reference Regulatory Authorities	
Me-too status	
GMP status	Last inspection dated 08-07-2019 & 25-07-2019 concluded that M/s Pharmasol, Lahore was operating at satisfactory level of GMP compliance.

Remarks of Evaluator:

Observations	**Firm's response**
• Justification shall be submitted for proposed storage condition of "Store below 25°C".	• Remdisol 100mg injection containing Remdesivir Lyophilized Powder for injection 100 mg, to be stored below 30°C (below 86°F) until required for use.
• Submit master formulation for per unit dosage form.	• Following master formulation is submitted: Each Vial Contains Remdesivir lyophilized powder (3.24% w/w) = 3.1 gram [Remdesivir = 100mg + Sulfobutylether-ß-cyclodextrin sodium salt (SBECD)= 3.0g].
• Submitted raw material specifications declare the assay limit as 99.0 to 102.0%. Clarification shall be submitted whether the API intended to be used in formulation will be in pure form or as a pre-mix.	• API will be premix and revised specifications have been submitted.
• The Assay test in the submitted raw material testing method describes the use of water as diluent for standard preparation, whereas as per available literature from US FDA & EMA, Remdesivir is insoluble in water. Justification shall be submitted in this regard.	• Acetonitrile will be used as a Diluent
• Tests for sterility and bacterial endotoxins have not been included in raw material specifications.	• Sterility Test & Bacterial Endotoxins are incorporated. Revised Raw material specification
• Tests for reconstitution, pH of reconstituted solution, water content & bacterial endotoxin have not been included in the finished product specifications.	• Finished product specifications have been revised for desired tests. Limit for reconstitution time has not been identified.
• Reference for proposed finished product specifications shall be submitted.	• Manufacturer's Specifications
• Submitted finished product specifications declare the Average weight of contents of 20 vials equal to 100 mg. Justification shall be submitted in this regard.	• Average weight of contents of 20 Vials = 3.1g ± 2% (3038mg – 3162mg)
• The Assay test in the submitted finished product testing method describes the use of water as diluent for standard solution preparation, whereas as per available literature from US FDA & EMA, Remdesivir is insoluble in water. Justification shall be submitted in this regard.	• Acetonitrile will be used as a Diluent
• In contrary to the reference product of M/s Gilead pharma which is produced by way of	• As per definition of Pharmaceutical Equivalent,

	Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	It is identical to reference product in term of dosage forms, route(s) of administration, amount of the active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety. • Raw Material Composition [Remdesivir (as API) + Sulfobutylether-ß-cyclodextrin sodium salt (As excipient to enhance drug solubility)] is similar to that of the Reference Product. • Further as far as the manufacturing method (using Ready to fill lyophilized powder) is concerned, it can be referred to other Products (ready to fill lyophilized powders) e.g. Acyclovir, Vancomycin HCl, Omeprazole sodium, Pantoprazole Sodium, Esomeprazole Sodium etc.
	• The literature from US FDA and EMA for the reference product of Gilead pharma, de lares content of Sulfobutylet er-β-cyclo extrin sodium (SBECD) as solubilizing agent, but you have not provided any such details fo SBECD in the dossier.	• Remdesivir lyophilized powder 3.24% w/w will be used that contains. Remdesivir (as API) = 100mg Sulfobutylether-ß-cyclodextrin sodium salt (As excipient to enhance drug solubility)= 3.0g Further drug solubility aspect will be ensured by finish product testing (Test for Completeness & clarity of reconstituted Solution).

901.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Brand Name+DosageForm+Strength	Remz IV Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg Lyophillized Powder
	Diary No. Date of R&I & fee	Dy No.12656; 04-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Tabros Specs
	Pack Size & Demanded Price	As Per DPC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	**Conclusion:** "On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection." 07/02/18

Remarks of Evaluator:

Observations	Firm's response
• Original Form 5 D shall be submitted, whereas firm has submitted photocopy.	• Original Form 5D submitted. (not received in R&I till 5th of june 2020)
• You have submitted storage conditions for reconstituted solution, while storage condition for applied finished pharmaceutical product shall be submitted.	• Firm has proposed following storage condition now: "Store Remdesivir for injection, 100mg vials below 30°C until required for use.
• Proposed shelf life of 2 years shall be justified since the document available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8°C, while any reference for shelf life is not available form US FDA.	• Firm has referred to "Summary for compassionate use" wherein shelf life of 51 months have been assigned at the storage condition "Store below 30°C", based upon the available stability data.
• Submitted master formulation declares the content of Remdesivir Lyophilized powder per vial = 100mg. Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.	• Firm has submitted revised master formula, wherein target for quantity of Remdesivir lyophilized per vial has been declared as 3.077gm base upon the potency of API in the lyophilized powder.
• Tests for reconstitution, water content & bacterial endotoxin have not been included in the finished product specifications.	• Firm has submitted revised finished product specifications wherein tests for reconstitution, water content & bacterial endotoxin have been included. • Note: Acceptance criteria for reconstitution time has not been declared in the finished product specifications.
• Reference for proposed finished product specifications shall be submitted.	• Firm has submitted that EMA assessment report (Summary for compassionate use) is used for the preparation of finished product specifications
• Submitted finished product testing method recommends use of UHPLC-MS/MS for the performance of Assay test whereas submitted List of equipment of QC does not include UHPLC-MS/MS.	• The product will be tested from outsource. In the meanwhile we will try to develop and validate the method on HPLC.
• In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	• We do not have lyophilization facility therefore we use ready to fill lyophilized powder for the production of Remdesivir injection, which is manufactured as per innovator.
• The literature from US FDA and EMA for the reference product of Gilead pharma, declares content of Sulfobutylether-β-cyclodextrin sodium (SBECD) as solubilizing agent, but you have not provided any such details for SBECD in the submitted dossier.	• Our API manufacturer is producing Remdesivir using Sulfobutyl-β-cyclodextrin sod um (SBECD) as per Gilead Pharma (as mentioned in USFDA & EMA literature)

902.	Name and address of Manufacturer / Applicant	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name+DosageForm+Strength	Codesvir Infusion 100mg

Composition	Each 20ml Contains: Remdesivir…100mg
Diary No. Date of R&I & fee	Dy No.12663; 04-06-2020 ; Rs.20,000
Pharmacological Group	Anti-Viral
Type of Form	Form 5
Finished Product Specification	Innovator's Specs
Pack Size & Demanded Price	As Per SRO
Approval status of product in Reference Regulatory Authorities	
Me-too status	
GMP status	Certificate of GMP Issued on 16-01-2018.

Remarks of Evaluator:

Observations

- Form-5D shall be submitted for applied formulation along with differential fee of Rs. 30,000/-
- Form 5 declares the Dosage form of applied product as "Infusion", whereas submitted composition and manufacturing method describe the applied formulation as "Dry powder for injection". Clarification shall be submitted in this regard.
- You have submitted storage conditions for diluted Remdesivir solution for infusion, while storage condition for applied finished pharmaceutical product shall be submitted.
- Proposed shelf life of 2 years shall be justified since the document available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8^{o}C, while any reference for shelf life is not available form US FDA.
- The Type of packaging in Form 5 has been declared as under:
  "Each 20ml of lyophilized powder for solution for infusion contains 100 mg of Remdesivir in clear glass vial"

  Clarification shall be submitted for the term "Each 20ml of lyophilized powder" against the applied dosage form.

- Submitted master formulation declares the content of Remdesivir Sterile (Lyophilized powder) per vial = 100mg. Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.
- Submitted master formulation declares 5% overage of Remdesivir. Scientific justification shall be submitted for incorporation of 5% overage.
- The literature from US FDA and EMA for the reference product of Gilead pharma, declares content of Sulfobutylether-β-cyclodextrin sodium (SBECD) as solubilizing agent, but you have not provided any such details for SBECD in the submitted dossier.
- Test for reconstitution has not been included in finished product specifications.
- Test of "Loss on Drying" has been included instead of test of "Water content" in finished product specifications.
- Submitted Finished product analytical procedure mentions the test of Dissolution with following statement:
  "Comply with the requirements for monographs of British Pharmacopoeia in the dissolution test for infusion, Appendix XII B1". Finally it states to "Calculate the total content of Metformin hydrochloride in the medium."

Justification shall be submitted for above cited content of finished product testing method

- Submitted finished product specifications declare the Average filled weight equal to 100 mg, while the submitted Raw material specification for Remdesivir declare the Assay limits as "NLT 3 & NMT 3.5 % w/w". Justification shall be submitted for the Average filled weight equal to 100 mg for finished drug product when Assay limits for the API are between 3 – 3.5% w/w.
- In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.
- Firm has submitted Stability study report for the applied product i.e., Codesvir Infusion, wherein

results for 24 months long term stability studies and 06 months accelerated stability studies for three batches have also been reported, while the manufacturing date for three batches has been mentioned as under:
TRI-001: 04-2017
TRI-002: 06-2017
TRI-003: 08-2017

- Justify the above cited stability study report along with relevant analytical & performance record for the said stability studies.

903.

Name and address of Manufacturer / Applicant	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
Brand Name+DosageForm+Strength	Wemeda Injection 5mg/ml
Composition	Each Vial Contains: Remdesivir…100mg
Diary No. Date of R&I & fee	Dy No.12478; 03-06-2020 ; Rs.50,000
Pharmacological Group	Anti-Viral
Type of Form	Form 5D
Finished Product Specification	Innovator's Specs
Pack Size & Demanded Price	As Per SRO
Approval status of product in Reference Regulatory Authorities	
Me-too status	
GMP status	**Recommendations:** Last panel inspection dated 30-9-2018 & 29-10-2018 recommends grant of GMP certificate

Remarks of Evaluator:

Observations	**Firm's response**
• Firm has submitted application on Form 5 instead of Form 5D.	• Firm has submitted Form 5D. • Dosage form of applied product in revised Form-5D, has been declared as "Dry powder injection"
• The dosage form of applied product shall be clearly declared in Form-5D, whether it is "Dry powder for injection" or "Liquid injectable solution."	
• Undertaking of Form 5 has not been signed by any authorized person.	
• The literature from US FDA and EMA for the reference product of Gilead pharma, declares content of Sulfobutylether-β-cyclodextrin sodium (SBECD) as solubilizing agent, but you have not provided any such details for SBECD in the dossier.	• Firm has submitted updated composition wherein details of SBECD have described as below: "Remdesivir lyophilized ready to fill powder*" *Lyophilized ready to powder containing 100mg Remdesivir, 3300 mg Betadex Sulfobutyl ether sodium as solubilizing agent.
• Test for reconstitution, pH of reconstituted solution, water content, uniformity of dosage units & bacterial endotoxins have not been included in the finished product specifications.	• Firm has submitted revised finished product specifications wherein, pH of reconstituted solution, water content & bacterial endotoxins have been included • While test for reconstitution time & uniformity of dosage units have still not been included in the finished product specifications.
• Reference for proposed finished product specification shall be submitted.	• Firm has mentioned in revised finished product specifications that "Product complies with Innovator's specifications."
• The Assay test in the submitted finished product testing method describes the use of water as diluent for standard preparation, whereas as per available literature from US FDA & EMA, Remdesivir is insoluble in	• Firm has submitted revised finished product testing method which now describes the use of Mobile phase (0.1% TFA in water) as diluent for standard & sample solution preparation.

	water. Justification shall be submitted in this regard.	
	• In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	--
	• The submitted master formulation mentions Remdesivir = 100mg per vial only. Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.	• Firm has submitted updated composition wherein details of API have been described as below: "Remdesivir lyophilized ready to fill powder*" • *Lyophilized ready to powder containing 100mg Remdesivir, 3300mg Betadex Sulfobutyl ether sodium as solubilizing agent. • Quantity per vial = 3400mg

904.	Name and address of Manufacturer / Applicant	M/s Wnsfield Pharmaceuticals.Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Brand Name+DosageForm+Strength	Ramyr Dry Powder Injection 100mg
	Composition	Each Vial (20ml) Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12660; 04-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	**Conclusion:** "As per observations made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall CGMP compliance status of the firm, the panel unanimously recommend the renewal of DML no. 000610 by way of formulation granted to M/s Wnsfield Pharma Hattar." 18-01-2018.

Remarks of Evaluator:

Observations	**Firm's response**
• Test for reconstitution, water content, uniformity of dosage units & bacterial endotoxins have not been included in the finished product specifications.	• Firm has submitted revised finished product specifications wherein, pH of reconstituted solution, water content & bacterial endotoxins have been included • While test for reconstitution time & uniformity of dosage units have still not been included in the finished product specifications.
• Reference for proposed finished product specification shall be submitted.	• Firm has mentioned in revised finished product specifications that "Product complies with Innovator's specifications."
• The Assay test in the submitted	• Firm has submitted revised finished product testing

	finished product testing method describes the use of water as diluent for standard preparation, whereas as per available literature from US FDA & EMA, Remdesivir is insoluble in water. Justification shall be submitted in this regard.	method which now describes the use of Mobile phase (0.1% TFA in water) as diluent for standard & sample solution preparation.
	• In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	--

905.	Name and address of Manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name+DosageForm+Strength	Remvir for Injection 100mg
	Composition	Each Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12413; 03-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Last inspection dated 10-04-2019 concluded acceptable level of GMP compliance

Remarks of Evaluator:

Observations	**Firm's response**
• The submitted covering letter mentions subject as "Application for registration of a drug containing (Teicoplanin) on Form 5D for local manufacture. Clarification shall be submitted in this regard.	Due to typographical error, correction is attached.
• You have mentioned Pharmacological group for applied drug as "Antibiotic" in Form 5. Justification shall be submitted in this regard.	Due to typographical error, correction is attached as Antiviral
• Evidence of approval of required manufacturing facility from Licensing Division shall be submitted.	• Firm has submitted copy of section approval letter issued by Secretary CLB for "Dry Powder Injectable (General)".
• The submitted master formulation mentions Remdesivir = 100mg only.	• API used as premix equivalent to 100 mg of Remdesivir. Master formula attached wherein

	Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.	Quantity of Remdesivir lyophilized powder per vial is mentioned equal to 3.077gm with a note that fill weight may vary according to potency of API. • According to the literature of reference product minimum fill weight shall be 3100mg (100mg Remdesivcir+3000mg SBECD)
	• Submitted finished product specifications declare acceptance limit for Assay as "Not less than 3 and Not more than 3.5". Clarification shall be submitted in this regard.	• Revised finished product specifications have been submitted wherein Assay limit has been declared as "90%-110%" of labeled amount
	• Test for reconstitution, pH of reconstituted solution, water content, uniformity of dosage have not been included in the finished product specifications.	• Firm has submitted revised finished product testing method wherein test for water content and reconstitution time are still not included.
	• Reference for proposed finished product specifications shall be submitted.	• As per US or EMA guidelines
	• The literature from USFDA and EMA for the reference product of Gilead pharma, declares content of Sulfobutyl ether-ß-cyclodextrin sodium (SBECD) as solubilizing agent, but you have not provided any such details for SBECD in the dossier.	• COA of Remdesivir Lyophilized power ready to fill for injection is attached.
	• In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	• COA of Remdesivir Lyophilized power ready to fill for injection is attached and filling process under goes through aseptic filling

906.	Name and address of Manufacturer / Applicant	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name+DosageForm+Strength	Remida Injection 5mg/ml
	Composition	Each ml Contains: Remdesivir…5mg
	Diary No. Date of R&I & fee	Dy No.11859; 28-05-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Emergency use authorization granted by USFDA
	Me-too status	--
	GMP status	Last inspection report of M/s Weather folds dated 20/02/2019, recommends the grant of GMP certificate.

Remarks of Evaluator:

Observations	**Firm's response**
• The submitted fee challan specifies application for	• Firm has submitted revised Form 5D, but it

	export purpose, while the submitted application is for local use. Clarification is required in this regard. • Specify the exact dosage form, whether liquid injection of lyophilized powder for injection. • Evidence of approval of requisite manufacturing facility / section from Licensing Division DRAP, since the applied label claim is "each vial contains" while the evidence of liquid (vial) section is not provided. • Justify the application on Form 5, since the product is not yet registered in Pakistan. • Justify the applied formulation in ampoule, since Emergency Use Authorization by USFDA, EMA and MHRA is only granted for vials. • Justify the use of lyophilized powder for manufacturing of liquid injection. • Remdesivir is practically water insoluble drug, justify how the solubility of API is ensured in the formulation. • Provide exact fill volume of the finished drug. • Method of manufacturing needs to be provided in line with the submitted master formulation. The method of manufacturing specifies dry powder filling, while the master formulation is of liquid injection. • Finished product specification are for "powder for injection" while the applied product in the master formulation is liquid injection. • Justify how the standard solution of Remdesivir API (a practically water insoluble drug) will be prepared using DI water. • Provide details of container closure system. • Reference for proposed finished product specifications needs to be submitted.	is not signed by the authorised person. • Firm has declared the applied dosage form as "Dry Powder Injection' in the revised form. • Firm has submitted copy of section approval letter for "Dry Powder Injection" section. • Firm has revised the container closure to vial in revised Form. • Firm has submitted revised master formulation declaring the incorporation of "Remdesivir lyophilised ready to fill powder along with along with content of SBECD. • Manufacturing outline for dry powder filling has been submitted.

907.	Name and address of Manufacturer / Applicant	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi **Contract manufacturing by:** M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name+DosageForm+Strength	Resvir Injection 100mg
	Composition	Each Vial Contains: Remdesivir Powder Concentrate for Injection/Infusion……100mg
	Diary No. Date of R&I & fee	Dy No.12767; 05-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	N/A
	Pack Size & Demanded Price	As Per PRC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Genix:Last inspection dated 10-04-2019 concluded acceptable level of GMP compliance
	Remarks of Evaluator:	

Observations
• Original Form 5 D shall be submitted, whereas firm has submitted photocopy.

- Finished product specifications have been submitted from M/s Genix Pharma from the product Remvir Injection, while the applied product is Resvir Injection 100 mg. Clarification shall be submitted in this regard.
- Submitted finished product specifications declare the storage condition of finished product as "Store at 25°C". Justification shall be submit din this regard.
- Evidence of approval of required manufacturing facility from Licensing Division shall be submitted.
- The submitted master formulation mentions Remdesivir = 100mg only. Clarification shall be submitted whether the API will be used in pure form or as a pre-mix.
- Submitted finished product specifications declare acceptance limit for Assay as "Not less than 3 and Not more than 3.5". Clarification shall be submitted in this regard.
- Test for reconstitution, pH of reconstituted solution, water content, uniformity of dosage have not been included in the finished product specifications.
- Reference for proposed finished product specifications shall be submitted.
- The literature from US FDA and EMA for the reference product of Gilead pharma, declares content of Sulfobutylether-β-cyclodextrin sodium (SBECD) as solubilizing agent, but you have not provided any such details for SBECD in the dossier.
- In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials, you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.

908.		
	Name and address of Manufacturer / Applicant	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Brand Name+DosageForm+Strength	Remdiza Injection 100mg
	Composition	EachVial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12807; 05-06-2020 ; Rs.100,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	--

Remarks of Evaluator:

Observations

- Form 5D has not been signed by any authorized person.
- Reference for proposed finished product specifications shall be submitted.
- Test for reconstitution, water content, uniformity of dosage units & bacterial endotoxin test has not been included in the submitted finished product specifications.
- The Assay test in the submitted finished product testing method describes the use of water as diluent for the preparation of standard solution, whereas literature available from US FDA & EMA declare Remdesivir as practically insoluble in water. Justification shall be submitted in this regard.
- In contrary to the reference product of M/s Gilead Pharma which is produced by way of Lyophilization in the glass vials, you have used ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product, how applied could be considered as "Pharmaceutical equivalent" to the reference product.

909.		
	Name and address of Manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore **Contract manufacturing By:** M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Remi Lyophilized Powder for Injection 100mg

	Composition	EachVial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12915; 08-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Vision's Specs
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Vision Pharma: GMP Certificate issued on 08.05.2018.

Remarks of Evaluator:

Observations	**Firm's response**
• Form 5D has not been signed by any authorized person.	Submitted
• Proposed master formulation mentions use of USP type-II glass vials whereas reference product has used USP Type I glass vial. Justification shall be submitted in this regard.	Mistakenly, the Vial type of REMDESIVIR is mentioned as USP Type II in the master formulation however the correct one is USP Type I. We undertake that we will use Clear glass vial of USP Type I, according to reference product.
• Submitted finished product specifications declare the acceptance limit for assay test of Remdesivir as 99-110%. Clarification shall be submitted in this regard.	Refer to your finding regarding finished product specification, where previously acceptance limit was declared as 99-110% , we undertake that the Assay Content limit for Remdesivir in finished product will be 90-110% of labeled claim i.e., 90mg-110mg/20ml vial.
• Reference for proposed finished product specifications shall be submitted.	
• Finished product testing method shall be submitted.	Submitted
• In contrary to the reference product of M/s Gilead pharma which is produced by way of Lyophilization in the glass vials (as evident from available literature by US FDA & EMA), you have used the ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product how applied product could be considered as "Pharmaceutical equivalent" to the reference product.	Reference to your observation regarding equivalent study of Remi 100mg lyophilized powder for, We will perform the comparative study of "Remi 100mg Lyophilized powder for Injection" against the reference product of M/S. Gilead Pharma, and submit the report to justify that both products are Pharmaceutically Equivalent.

910.	Name and address of Manufacturer / Applicant	M/s Neutro Pharma Pvt Ltd, 9.5-Km, Sheikhupura Road, Lahore.
	Brand Name+DosageForm+Strength	Medvir-19 100mg Injection
	Composition	Each Vial contains : Remdesivir ….. 100mg
	Diary No. Date of R&I & fee	Dy. No.13037; 08-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	

	GMP status	GMP certificate issued dated: 11-07-2019. GMP certificate does not include the required section.

Remarks of Evaluator:

Observations	Firm's response
• You have submitted proposed storage condition as "Store at 20°C - 25°C, Justification shall be submitted in this regard since the literature available from US FDA & EMA for the reference product of M/s Gilead Pharma, recommends storage condition as "Store below 30˚C."	We had submitted storage condition at "20 – 25 °C for Medvir-19 injection 100 mg. As per reference product literature storage conditions are below 30°C. Although 20 – 25 °C is also below 30 °C but we shell change it according to reference product literature i.e. below 30 °C
• Submitted finished product specifications declare the "Average weight/ glass vial" as 105mg/vial. The said weight does not suggest incorporation of any ingredient other than the API, which is not in line with the reference product of M/s Gilead pharma, as revealed by the literature from US FDA & EMA.	Average weight 105 mg/vial is a typographic mistake. As according to COA of API the theoretical weight/ vial should be 3.125 gm. As the assay of API is 3.24% w/w (ODS) by HPLC (Assay Limit 3.0 - 3.5% w/w)
• You have submitted section approval letter for "General Lyophilization Section", whereas your applied formulation is for "Dry powder Injection by way of filling ready to fill powder." Evidence of approval of required facility of "Dry powder filling" in "General Lyophilization Section" shall be submitted.	Feeling jubilant by informing you that in our approved general lypholization area we have both facilities. 1- Pre lypholized powder filling 2- Liquid filling by way of lypholization. Along this we already have taken approval of products for both type of manufacturing methods.
• The submitted finished product specification does not include tests for reconstitution time.	According to the literature of reference product of M/s Gilead Pharma, • Immediately shake the vial for 30 seconds. • Allow the contents of the vial to settle for 2 to 3 minutes. A clear solution should result. • If the contents of the vial are not completely dissolved, shake the vial again for 30 seconds and allow the contents to settle for 2 to 3 minutes. Repeat this procedure as necessary until the contents of the vial are completely dissolved. • Following reconstitution, each vial contains 100 mg/20mL (5mg/mL) of Remdesivir solution.
• Finished product analytical procedure describes preparation of sample solution by using "25 mg of test sample", instead of the reconstituted solution. Clarification shall be submitted in this regard.	This is typographic mistake; According to finished product analytical procedure preparation of sample solution we have taken reconstituted sample eq. to 25 mg of Remdesvir according to testing method sent us by LEE Pharma. (Testing Method is attached as reference)
• Submitted COA from API manufacturer i.e., M.s Lee Pharma, India for "Remdesivir Lyophilized Powder" does not make any declaration about the contents of Sulfobutylether-β-cyclodextrin sodium salt (SBECD).	Declaration letter of M/s Lee Pharma regarding SBECD is Attached
• Submitted COA from API manufacturer i.e., M.s Lee Pharma, India is for "Remdesivir Lyophilized Powder", while the submitted raw material analytical procedure & Stability data is for Remdesivir pure API. Clarification shall be submitted in this regard.	**Note:** REMDESIVIR lyophilized powder for injection is ready to fill ,no change in formulation stability study of raw material is similar to that of finished product .so vendor stability data for REMDESIVIR lyophilized powder for injection is justifiable to that of finished product Medvir-19 powder for Injection

		Stability further more we shell ask the manufacturer to provide us stability data of Lyophilized powder of Remdesvir if any. We are also undertaking to submit the stability data of our initial commercial batches at accelerated and real time studies.
	• The literature from US FDA and EMA for the reference product of Gilead pharma, declares content of Sulfobutylether- -cyclodextrin sodium (SBECD) as solubilizing agent, but you have not provided any such details for SBECD in the dossier.	The attached declaration letter of Lee Pharma India declared that they manufactured Remdesvir Lyophilized powder by using the Sulfobutlye ether- Beta cyclodextrin sodium salt as inactive in there process. (Letter Attached)
	• In contrary to the reference product of M/s Gilead Pharma which is produced by way of Lyophilization in the glass vials, you have used ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product, how applied could be considered as "Pharmaceutical equivalent" to the reference product.	Lee Pharma Claimed Lyophilized powder for Injection is similar to that of reference product of M/s Gilead Pharma As the API and solubilizing ingredient SBECD is the same for Both Pharma. The only difference is that Gilead Pharm is manufacturing it in small glass vial while Lee Pharma is manufacturing it in Bulk as the final product of both Pharma are similar having same pharmacological effects and they are therapeutically equivalent, on the basis of these grounds these are also consider as Pharmaceutical equivalents.

911.

Name and address of Manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E Sunder Industrial Estate, Lahore.
Brand Name+DosageForm+Strength	Medvir-19 100mg Injection
Composition	Each Vial contains : Remdesivir ….. 100mg
Diary No. Date of R&I & fee	Dy. No.13037; 08-06-2020 ; Rs.50,000
Pharmacological Group	Anti-Viral
Type of Form	Form 5D
Finished Product Specification	Innovator's Specs
Pack Size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	
Me-too status	
GMP status	GMP certificate issued dated: 11-07-2019. GMP certificate does not include the required section.

Remarks of Evaluator:

Observations	**Firm's response**
• You have submitted proposed storage condition as "Store at 20°C - 25°C, Justification shall be submitted in this regard since the literature available from US FDA & EMA for the reference product of M/s Gilead Pharma, recommends storage condition as "Store below 30˚C."	We have corrected storage conditions below 30C
• The submitted composition and master formula annexure declares the label claim as under: "Each vial contains: Remdesivir (Lyophilized water for injection) = 100mg". Clarification shall be submitted in this regard.	We have corrected composition as Each Vial Contains: Remdesivir (Lyophilized powder for injection) 100mg
• Submitted finished product specifications declare the "Average weight/ glass vial" as 100mg/vial. The said weight does not suggest incorporation	We have corrected average weight/ glass vial as 3.086 g, in which 100mg is Remdesivir and remaining 2.986 g is SBECD

		of any ingredient other than the API, which is not in line with the reference product of M/s Gilead pharma, as revealed by the literature from US FDA & EMA.	
		• Finished product analytical procedure describes preparation of sample solution by using "25 mg of test sample", instead of the reconstituted solution. Clarification shall be submitted in this regard.	We have made correction in finished product analytical procedure take 25 mg from reconstituted vial
		• Submitted COA from API manufacturer i.e., M.s Lee Pharma, India for "Remdesivir Lyophilized Powder" does not make any declaration about the contents of Sulfobutylether-β-cyclodextrin sodium salt (SBECD).	Declaration letter is submitted, indicating SBECD.
		• Submitted COA from API manufacturer i.e., M.s Lee Pharma, India is for "Remdesivir Lyophilized Powder", while the submitted raw material analytical procedure & Stability data is for Remdesivir pure API. Clarification shall be submitted in this regard.	In submitted raw material COA from Lee Pharma Remdesivir is 3.24%, Declaration letter show other is SBECD Same case in stability is covered.
		• The literature from US FDA and EMA for the reference product of Gilead phar a, declares content f Sulfobutylether-β-cyclodextrin sodium (SBECD) as solubi iz ng agent, but you have not provided any such details for BECD in the dossier.	• Lee Pharma will provide Lyophilized powder for injection similar to that of reference product of Gilead Pharma. SBECD will be same as in Gilead Pharma , mention in Declaration letter. • Radiant Pharma now have add SBECD in the composition of dossier.
		• In contrary to the reference product of M/s Gilead Pharma which is produced by way of Lyophilization in the glass vials, you have used ready to fill powder of Remdesivir for the production of Remdesivir injection. Scientific justification shall be submitted that with aforementioned variation in method of manufacturing from the reference product, how applied could be considered as "Pharmaceutical equivalent" to the reference product.	We will perform Comparative Study our product comparative to INNOVATOR PRODUCT.

III. Applications for "Liquid Injection"

912.

Name and address of Manufacturer / Applicant	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan
Brand Name+Dosage Form+Strength	Remvir concentrated solution for Infusion 100mg
Composition	Each vial contains: Remdesivir…100mg
Diary No. Date of R&I & fee	Dy. No.9970; 05-05-2020 ; Rs.50,000
Pharmacological Group	Anti-Viral
Type of Form	Form 5D
Finished Product Specification	Manufacturer's specifications
Pack Size & Demanded Price	As Per SRO
Approval status of product in Reference Regulatory Authorities	Emergency use authorization granted by USFDA
Me-too status	--
GMP status	Last inspection dated 01-01-2020 concluded GMP compliant status.

Remarks of Evaluator:

Observations	Firm's response
• Evidence of approval of required manufacturing facility of "Liquid Injectable Vial (general) small volume parenteral section" shall be submitted.	• Firm has submitted copy of section approval letter for "Injection Ampoule (general) & Injection vial (general antibiotic) in the name of M/s Evergreen Pharmaceuticals, Lahore dated 27-01-2010 issued by Secretary CLB. • A copy of letter dated 26-03-2011 issued by Deputy Drug Controller (L&A) for the change of company name from "M/s Evergreen Pharmaceuticals Pvt. Ltd" to "M/s Allmed (Pvt.) Ltd." • Copy of letter for "Approval of revised lay out plan" dated 06th February, 2020 issued by Assistant Director (Lic) has been submitted including "Injectable (Vial) (SVP/LVP) (general) section (Revised).
• Proposed shelf life of 2 years shall be justified with storage condition of (-25 to -10°C).	Storage conditions have been revised to 2-8°C as per innovator product.
• Submitted raw material specifications of Remdesivir declare the solubility for Remdesivir as "slightly soluble in water", whereas the literature from US FDA and EMA for the reference product of Gilead pharma, declares the solubility of Remdesivir as "Practically insoluble in water". Justification shall be submitted in this regard.	• Firm has submitted revised raw material specifications of Remdesivir declare the solubility for Remdesivir as "practically insoluble in water"
• Submitted raw material specifications of Remdesivir declare the storage condition as "Store at -20°C temperature". Justification shall be submitted in this regard.	• Firm has submitted revised raw material specifications wherein storage condition has been changed to "Store at room temperature"
• Evidence of availability of cold room facility with temperature range of (-25 to -10°C) at raw material store, in-process quarantine and finished goods store, must be submitted.	• Storage conditions for finished product has been revised to 2-8°C. • Moreover firm has referred to following observation from the GMP inspection report dated 12-11-2018 under the section of "**Raw Material Store**": "It had a refrigerator for storage of products at

		2-8°C
	• Reference for proposed finished product specifications shall be submitted.	• Firm has referred to USP general chapters <1>,<1151> & ICH Q6A guidelines as well as innovator's specification.

913.	Name and address of Manufacturer / Applicant	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Brand Name+DosageForm+Strength	Remvir Injection 5mg/ml
	Composition	Each 20ml Vial Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.11267; 18-05-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Manufacturer's Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Emergency use authorization granted by USFDA
	Me-too status	--
	GMP status	The firm (M/s walt danzey) was inspected on 25.06.2018 with the following conclusion Keeping in view the above facts, detailed visit of establishment and supporting documents provided by the management and verification of rectification of plan/action with reference to previous shortcomings identified and company has shown good response and rectified the problems

Remarks of Evaluator:

Observation
• Evidence of approval of required manufacturing facility of "Liquid Injectable Vial (general) section" shall be submitted. • Proposed shelf life of 2 years shall be justified since the document available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8°C, while any reference for shelf life is not available for m US FDA • Submitted manufacturing outline mentions the step of terminal sterilization while the available literature from EMA for the reference product of Gilead Pharma states that the finished product, when exposed to a typical autoclaving cycle of 121 °C for 30 minutes, results in significant degradation of Remdesivir. Justification shall be submitted in this regard. • Submitted manufacturing outlines describe the "Ampoule filling" step, whereas applied dosage form is liquid injectable vial. Clarification shall be submitted in this regard. • Evidence of availability of cold room facility at both in-process quarantine and finished goods store, must be submitted. • Details must be submitted for proposed storage condition of API. • Reference for proposed finished product specifications shall be submitted.

Decision:

914.	Name and address of Manufacturer / Applicant	M/s BF Biosciences Ltd. 5-Km,Sundar Raiwind Road, Lahore
	Brand Name+DosageForm+Strength	Remidia Liquid Solution for Infusion 20ml
	Composition	Each Vial Contains: Remdesivir…….100mg
	Diary No. Date of R&I & fee	Dy. No.762 (Dir. PE & R); 28-05-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	MRP Rs. 14,600 TP Rs. 12410 ($ 76.98) per Vial
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	

	GMP status	Last GMP inspection report conducted on 22-08-2019 recommended renewal of DML.

Remarks of Evaluator:

Observations	Firm's response
• Submit evidence of approval of required manufacturing facility for Liquid Injectable Vial from CLB. • Submit master formulation for per unit dosage form. • Proposed shelf life of 18 months shall be justified since the document available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8°C, while any reference for shelf life is not available for m US FDA • Test for pH of solution has not been included in finished product specifications. • Submitted finished product testing method recommends use of UPLC (Ultra Performance Liquid Chromatograph) equipped with Photodiode Array Detector, for the performance of Assay test whereas submitted List of equipment of QC does not include UPLC. • Submitted finished product specification does not include test of identification. • Evidence of availability of cold room facility at both in-process quarantine and finished goods store, must be submitted. • Details must be submitted for proposed storage condition of API. • Reference for proposed finished product specifications shall be submitted.	• The facility is licensed to manufacture liquid and Lyophilized Vials manufacturing. • Master formulation for per unit dosage form has been submitted. • Firm has submitted that "Based on the linear regression analysis of the long-term stability data at 5 °C, a shelf-life of 18 months at the recommended long-term storage condition of "Store at 2–8 °C" is justified" • Revised finished product specification with inclusion of test for pH has been submitted. • UHPLC is not in list of existing equipment as UHPLC is on order (copy of LC attached). Ordered equipment is with PDA (Photo Diode array) detector. • Revised finished product specification with Identification through Chromatographic retention Time has been submitted. • Firm has submitted copy of inspection report conducted on 24-06-2019 by Area FID Lahore, for confirmation of storage & cold storage facility, wherein the said facility has been "recommended" with following remarks: "The company has cold chain system in place from import of raw & finished products ensuring the finished product remains within the temperature range till it reaches the patient." • Firm has referred to following statement: "The stability data support a retest period of 48 months at the recommended long-term storage condition of "Store below 30 °C" and in the recommended packaging configuration." • Firm has referred to "Innovator's specifications.

Keeping in view the current outbreak of Covid-19, the Drug Regulatory Authority of Pakistan in its 84th meeting held on 01st June, 2020 decided as:

- Recommended to the Registration Board under Section 7(c) of DRAP Act, 2012 for permitting M/s BF Biosciences, Lahore for manufacturing of Remdesivir in already approved section for biological drugs on campaign manufacturing basis in light of decision of Appellate Board taken in its 151st sitting held on 16th January, 2019.
- Manufacturing of Remdesivir on campaign basis will also be applicable to other applicants on the same analogy.

915.	Name and address of Manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+DosageForm+Strength	Remedy Solution for Injection 100mg/20ml
	Composition	Each Vial (20ml) Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12410; 03-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral

	Type of Form	Form 5D
	Finished Product Specification	Vision's Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	GMP certificate issued on the basis of inspection conducted on 26-01-2018.

Remarks of Evaluator:

Observations	**Firm's response**
• Proposed shelf life of 2 years shall be justified since the document available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8°C, while any reference for shelf life is not available form US FDA.	• After reviewing the referred Data of Remdesivir, it has been concluded that the shelf life of the solution is 12 months with storage condition of 2-8°C.
• Submitted master formulation declares the content of Remdesivir per vial = 5mg. Clarification shall be submitted in this regard.	Mistakenly, the content of REMDESIVIR is mentioned as 5mg per vial in the master formulation however the correct content per vial is 100mg. Revised master formulation has been submitted.
• Test for appearance, identification, sterility, bacterial endotoxins, particulate matter and volume in container have not been included in finished product specifications.	• Revised finished product specifications have been submitted wherein Test for appearance, identification, sterility, bacterial endotoxins, particulate matter and volume in container have been included
• Finished product testing method has not been submitted.	• Firm has submitted revised finished product testing method for Assay test.
• Evidence of availability of cold room facility at both in-process quarantine and finished goods store, must be submitted.	• At present, a cold storage facility is available for storage of the materials/products at 2-8°C. Moreover, we have already initiated the process of procuring of referred container of suitable size. • This container will be employed for storing of Bulk intermediate, in process/semi-finished and finished products at 2-8°C.
• Details must be submitted for proposed storage condition of API	The storage conditions for API of Remedisivir are: • Should Be Kept at Temperature should below 25°C±2%. • Should be stored in light protected Container • It has also been verified from Active Product Stability Data of LEE Pharmaceuticals

916.	Name and address of Manufacturer / Applicant	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Rememac Injection 5mg/ml
	Composition	Each ml Contains: Remdesivir …… 5mg
	Diary No. Date of R&I & fee	Dy No.12633; 04-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per PRC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	**Conclusion:** Last inspection dated 23-05-02018 concluded good level of GMP compliance at the time of inspection.

Remarks of Evaluator:

Observations	Firm's response
• Evidence of approval of required manufacturing facility of "Liquid Injectable Vial (general) small volume parenteral section" shall be submitted.	• Firm has submitted letter for regularization of layout plan dated 10-12-2019 issued by Secretary CLB, for various sections including "Liquid parenteral (SVP)"
• Proposed shelf life of 2 years shall be justified since the document available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8°C, while any reference for shelf life is not available form US FDA.	As per EMA accelerated stability for 12 month is available at 5°C, on behalf of stability data we proposed shelf life of two years. But we agree for the shelf life as per EMA reference i.e., one year.
• Submitted master formulation mentions only two ingredients i.e., Remdesivir & Water for injection, hence it differs qualitatively from the composition of the reference product of Gilead pharma, as available in the literature from US FDA & EMA.	• Firm has submitted revised composition including other ingredients as per innovator.
• Justification shall be submitted for applied master formulation since available literature from US FDA and EMA for the reference product of Gilead pharma, declares the solubility of Remdesivir as "Practically insoluble in water, while the submitted master formulation does not include only Remdesivir & Water for injection only.	• Firm has submitted revised composition including SBECD as solubilizer.
• Complete manufacturing outline shall be submitted for the applied product.	• Firm has submitted manufacturing procedure.
• Submitted raw material specifications for Remdesivir declare its solubility as "Solubility in water, whereas the available literature from US FDA and EMA for the reference product of Gilead pharma, declares the solubility of Remdesivir as "Practically insoluble in water". Justification shall be submitted in this regard.	• Firm has submitted revised raw material specifications declaring solubility as "Insoluble in water" for Remdesivir.
• Reference for proposed finished product specifications shall be submitted.	Innovator's specifications (as per EMA)
• The Assay test in the submitted finished product testing method describes the use of water as diluent for standard solution preparation, whereas as per available literature from US FDA & EMA, Remdesivir is insoluble in water. Justification shall be submitted in this regard.	Firm has submitted revised finished product testing method with revision of diluent to Acetonitrile: Water (30:70)

917.	Name and address of Manufacturer / Applicant	M/s Wnsfield Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar

Brand Name+DosageForm+Strength	Ramyr Liquid Injection 5mg/ml
Composition	Each Vial (2oml) Contains: Remdesivir…100mg
Diary No. Date of R&I & fee	Dy No.12661; 04-06-2020 ; Rs.50,000
Pharmacological Group	Anti-Viral
Type of Form	Form 5D
Finished Product Specification	Innovator's Specs
Pack Size & Demanded Price	As Per SRO
Approval status of product in Reference Regulatory Authorities	
Me-too status	
GMP status	**Conclusion:** "As per observations made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall CGMP compliance status of the firm, the panel unanimously recommend the renewal of DML no. 000610 by way of formulation granted to M/s Wnsfield Pharma Hattar." 18-01-2018.

Remarks of Evaluator:

Observations	**Firm's response**
• Evidence of approval from CLB, of required manufacturing facility i.e., "Liquid Injectable Vial (General) section shall be submitted.	• We Have General Liquid Injection Section having both facilities Ampoule and Vial Filling. • Section approval letter has not been submitted.
• Justify the proposed storage conditions of "Store at cool and dry place below 30°C", since the available literature from US FDA, EMA & MHRA of UK for the reference product of Gilead Pharma, declares the storage condition of 2–8°C.	Proposed storage condition revised to 2 – 8 °C. Proposed Shelf life revised to 1 year.
• Justify the proposed shelf life of two years with storage condition of "Store at cool and dry place below 30°C" since literature available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8°C.	
• The submitted finished product specification does not includes tests for bacterial endotoxins.	• Revised finished product specifications have been submitted including test of bacterial endotoxin.
• Reference for proposed finished product specification shall be submitted.	Firm has mentioned in finished product specifications as "Product complies innovator's specifications"
• The Assay test in the submitted finished product testing method describes the use of water as diluent for standard solution preparation, whereas as per available literature from US FDA & EMA, Remdesivir is insoluble in water. Justification shall be submitted in this regard.	• Firm has submitted revised finished product testing method which now describes the use of Mobile phase (0.1% TFA in water) as diluent for standard & sample solution preparation.
• Evidence of availability of cold room facility at both in-process quarantine and finished goods store,	• We have Cold room for In Process Quarantine and Freezer for Finished Drug Store.

	must be submitted.	• No report has been submitted in this regard.
	• Details must be submitted for proposed storage condition of API.	--

918.	Name and address of Manufacturer / Applicant	M/s Weather Folds Pharaceuticals, Plot No.62/2, Phase-II Industrial Estate Hattar.
	Brand Name+DosageForm+Strength	Remida Liquid Injection 5mg/ml
	Composition	Each Vial (20ml) Contains: Remdesivir…100mg
	Diary No. Date of R&I & fee	Dy No.12658; 04-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Emergency use authorization granted by USFDA
	Me-too status	--
	GMP status	Last inspection report of M/s Weather folds dated 20/02/2019, recommends the grant of GMP certificate.

Remarks of Evaluator:

Observations	**Firm's response**
• Evidence of approval from CLB, of required manufacturing facility i.e., "Liquid Injectable Vial (General) section shall be submitted.	• We have manufacturing facility for vial & ampoule section together. • Section approval letter has not been submitted.
• Justify the proposed storage conditions of "Store at cool and dry place below 30°C", since the available literature from US FDA, EMA & MHRA of UK for the reference product of Gilead Pharma, declares the storage condition of 2 – 8°C.	Proposed storage condition revised to 2 – 8 °C.
• Justify the proposed shelf life of two years with storage condition of "Store at cool and dry place below 30°C" since literature available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8°C.	
• The submitted finished product specification does not includes tests for bacterial endotoxins.	• Revised finished product specifications have been submitted including test of bacterial endotoxin.
• Reference for proposed finished product specification shall be submitted.	Firm has mentioned in finished product specifications as "Product complies innovator's specifications"
• The Assay test in the submitted finished product testing method describes the use of water as diluent for standard solution preparation, whereas as per available literature from US FDA & EMA, Remdesivir is insoluble in water. Justification shall be submitted in this regard.	• Firm has submitted revised finished product testing method which now describes the use of Mobile phase (0.1% TFA in water) as diluent for standard & sample solution preparation.
• Evidence of availability of cold room facility at both in-process quarantine and finished goods store,	• We have facility of Cold room and to maintain the temperature of 2 – 8°C we have freezer for finished good storage for In Process Quarantine and Freezer

	must be submitted.	for Finished Drug Store. • No report has been submitted in this regard.
	• Details must be submitted for proposed storage condition of API.	--

919.	Name and address of Manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+DosageForm+Strength	Hildesvir Injection 5mg/ml
	Composition	Each Single Dose Vial Contains: Remdesivir…5mg/ml (100mg/20ml Vial)
	Diary No. Date of R&I & fee	Dy No.12781; 05-06-2020 ; Rs.50,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5D
	Finished Product Specification	Hilton Specs
	Pack Size & Demanded Price	As Per DPC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	**Conclusion:** Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Hilton Pharma, it was concluded that M/s Hilton Pharma is operating at a good level of Cgmp compliance on the day of inspection as per Drugs Act, 1976 and rules framed there under. 10-07-2019
	Remarks of Evaluator:	

Observations	**Firm's response**
• Original Form 5 D shall be submitted, whereas firm has submitted photocopy.	• Submitted
• Justify the proposed storage conditions of "Store at cool and dry place below 30°C", since the available literature from US FDA, EMA & MHRA of UK for the reference product of Gilead Pharma, declares the storage condition of 2 – 8°C.	Proposed storage condition revised to 2 – 8 °C.
• Quantity of SBECD per vial mentioned in the master formulation is not as recommended by the reference product of M/s Gilead Pharma, in the literature available from US FDA & EMA	• Firm has submitted revised proposed master formulation wherein quantity of SBECD has been revised as per innovator.
• The submitted finished product specification does not includes tests for pH and volume in container.	• Revised finished product specifications have been submitted including tests for pH and volume in container.
• Reference for proposed finished product specification shall be submitted.	Firm has referred to various general chapters of USP and ICH Q6A guidelines, while test of appearance & pH has been developed in-house.
• Evidence of approval from CLB, of required manufacturing facility i.e., "Liquid Injectable Vial (General) section shall be submitted.	• Firm has submitted copy of letter dated issued by Secretary CLB dated 04-12-2014, for "Regularization/Authentication of Master Layout plan of Sections of existing facility" including "Injectable vial & Ampoule (General).
• Evidence of availability of cold room facility at both in-process quarantine and finished goods store, must be submitted.	• Copy of inspection report for "Verification of storage facility" dated 110-02-2017 has been submitted.

• Details must be submitted for proposed storage condition of API.	• Firm has referred to the extract of EMA "Summary for compassionate use" for the storage condition of API.	

920.	Name and address of Manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name+DosageForm+Strength	Ramvir Infusion 5mg/ml
	Composition	Each ml Contains: Remdesivir…5mg
	Diary No. Date of R&I & fee	Dy No.12800; 05-06-2020 ; Rs.20,000
	Pharmacological Group	Anti-Viral
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per PRC
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP."

Remarks of Evaluator:

Observations	**Firm's response**
• Form 5D shall be submitted instead of Form 5 along with differential fee of Rs. 30,000/- since applied product is not yet registered in Pakistan.	• Frm has submitted Form5D with differential fee of Rs. 30,000/- vide deposit slip# 2003895 dated 08-06-2020.
• You have submitted proposed storage condition as "Store at 20°C to 25°C, excursions permitted between 15°C and 30°C. Store below 30°C". Justification shall be submitted in this regard since the literature available from US FDA & EMA for the reference product of M/s Gilead Pharma, recommends storage condition as 2 – 8°C.	• We have revised the storage conditions of product according to US FDA & EMA, now recommended storage form is 2-8 ^{0}C.
• You have applied for "liquid ampoule" whereas reference product of M/s Gilead Pharma, is available in "glass vial", as evident from the literature available by US FDA & EMA. Clarification shall be submitted in this regard.	We had applied for 20mL glass vial, by mistake ampoules was mentioned. We have corrected. Remdesivir concentrate for solution for infusion,100mg(5mg/mL), is a sterile , preservative-free, clear, colorless to slightly yellow, aqueous based concentrated solution for dilution into intravenous fluids, available in 20ml vials Firm has also submitted section approval letter dated 11-02-2014 issued by Secretary CLB, for the "Liquid Injectable general SVPs (a (Ampoule) (b) (Vial/infusion))
• Reference for proposed finished product specifications shall be submitted.	• Finished products specifications are according to ICH Q6A, USP general Chapter for parenteral product specifications and rest of data from EMA remdesivir dossier. List of analytical test (FPP) and specifications has been attached.
• Evidence of availability of cold room facility at both in-process quarantine and finished goods store must be submitted.	We have cold room in raw material section with approved layout and we have also maximum capacity fridge (Pharmaceutical Grade) in in-process quarantine and for

		finished goods store we will purchased undertaken has attached.
	• You have submitted Analytical method validation data, justify this data along with relevant analytical & performance record for Analytical method validation studies.	• We had submitted Attentative, purposed or predicted SOP for method validation; Here we forgot to mention this SOP is not actual, just supposed. We have corrected the statement. Rest of actual data we will provide after real method validation and undertaken has attached.
	Submitted COA of Remdesivir from "M/s Bright Gene Bio-Medical Technology Co., Ltd, China", declares the storage condition for API as 2 – 8°C. Justification shall be submitted in this regard since the literature of reference product of Gilead Pharma, available from EMA declares the performance of drug substance stability at 30°C/75%RH & 40°C/75%RH.	• Storage condition proposed by supplier is 2- 8° C.

921.

Name and address of Manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore **Contract manufacturing By:** M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
Brand Name+DosageForm+Strength	Remi Solution For Injection100mg/20ml
Composition	Each Vial (20ml) Contains: Remdesivir…100mg
Diary No. Date of R&I & fee	Dy No.12916; 08-06-2020 ; Rs.50,000
Pharmacological Group	Anti-Viral
Type of Form	Form 5D
Finished Product Specification	Vision's Specs
Pack Size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	
Me-too status	
GMP status	Vision Pharma: GMP Certificate issued on 08.05.2018.

Remarks of Evaluator:

Observations	**Firm's response**
• Proposed shelf life of 2 years shall be justified since the document available from MHRA of UK has declared shelf life as 12 months with storage condition of 2 – 8°C, while any reference for shelf life is not available form US FDA.	Refer to your finding regarding Shelf Life of Remi 100mg/20 ml solution for injection ,we have review the referred data and conclude that the shelf life of the solution with storage condition of 2-8ºC may be as per innovator
• Finished product analytical procedure describes preparation of sample solution by using Sample powder eq. to about 25 mg of Remdesivir", instead of the reconstituted solution. Clarification shall be submitted in this regard.	We have reviewed the analytical testing method and found that it is correctly mentioned that to take 5ml of sample solution equivalent to about 25.0 mg of Remdesivir. However, we are submitting the testing method of both Finished products of Remi 100mg Lyophilized powder for injection and Remi Injection 100mg/20ml solution for injection
• Evidence of availability of cold room facility at both in-process quarantine and finished goods store, must be submitted.	At present, a cold storage facility is available for storage of the materials/products at 2-8C. Moreover, we have already initiated the process of procuring of referred container of suitable size. This container will be employed for storing of Bulk intermediate and in process/semi-finished

			at 2-8ºC.
		• Details must be submitted for proposed storage condition of API	As we have reviewed data, the storage conditions for API of Remedisivir are: □ Should be stored in light protected Container □ Temperature should be kept below 25ºC±2%. It has also been verified from Active Product Stability Data of LEE Pharmaceuticals

Proceedings:

The Board was apprised about the decision of DRAP's Authority circulated vide letter No. F.76-DRAP/2020 (PE&R) dated 4th June, 2020 regarding Priority Registration of Remdesivir containing drug products. Various firms submitted Remdesivir applications before & after circulation of above letter.

1. Regulatory status of Remdesivir in various reference regulatory authorities is as follows:

   i. United States Food and Drug Administration (USFDA):

   U.S. Food and Drug Administration on 1st May 2020, issued an "Emergency Use Authorization for Remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease.

   ii. European Medicine Agency:

   During an extraordinary virtual meeting held on 2nd April 2020, EMA's human medicines committee (CHMP) gave recommendations on how the investigational antiviral medicine Remdesivir should be used for treating coronavirus disease (COVID-19) in compassionate use programmes in the European Union.

   iii. Medicines & Healthcare Products Regulatory Agency of UK

   MHRA on 26th May, 2020 gave the first positive scientific opinion under the Early Access to Medicines Scheme (EAMS) for use of Gilead's Remdesivir.

   iv. Pharmaceuticals and Medical Devices Agency (PMDA) of Japan

   Under article 14-3 of the Pharmaceuticals and Medical Devices Act, on 7th May, 2020, PMDA Japan granted "Special Approval for Emergency to Remdesivir" for Covid-19 with the brand name of "Velkury for Intravenous Infusion".

2. Registration Board was apprised that innovator of Remdesivir (M/s Gilead Sciences Inc) has developed the product in following 2 different dosage forms and same has been approved by reference regulatory authorities.
   a. Remdesivir Lyophilized Powder for Injection 100mg (manufactured by way of lyophilization)
   b. Remdesivir Injectable solution (5mg/ml) in 20 ml vial.
3. Registration Board advised PE&R Division to present registration applications of Remdesivir submitted till 8th June 2020 for its consideration. Screening of the received applications revealed that the applications can be divided in following three groups.

Sr. No	Type of formulation	No. of received applications			
		Local self-manufacture	Local contract manufacture	Imported finished product	Total
i.	Remdesivir Lyophilized Powder for Injection 100mg (manufactured by way of lyophilization)	7	5	3	15
ii.	Remdesivir Injectable Solution 5mg/ml	9	1	0	10
iii.	Remdesivir bulk lyophilized powder (ready to fill in vials)	13	3	0	16

4. All applications were evaluated and shortcomings were communicated to the applicant firms on priority via email etc. The representatives of applicant firms were also advised to attend the meeting along with technical / pharmaceutical data and supporting documents for consideration of Registration Board.

5. During discussion with representatives of the firms, matters regarding regulatory approval status of the Active Pharmaceutical Ingredient (API) manufacturer, control of specifications and testing method of API, accelerated and real-time stability study data of API, manufacturing and testing method of the finished product manufacturer and manufacturing, testing and storage facility including cold chain storage facility in quarantine, finished goods store and distribution channel for applications of remdesivir Injectable solution 5mg/ml were discussed in detail. The matter regarding capacity and expertise of manufacturing and testing of Remdesivir by manufacturer(s) for applications of contract manufacturing was also discussed.

6. The Board was apprised regarding three applications for import of Remdesivir from Bangladesh and India as detailed under:

Applications from Bangladesh:

a) M/s Searle Pharmaceuticals Karachi imported from M/s Beximco Pharmaceuticals ltd, 126, Kathaldia, Auchpara, tongi-1711, Ghazipiur, Bangladesh.
b) M/s OBS Healthcare Pvt. Limited Karachi,-74900 imported from M/s Incepta Pharmaceuticals Limited. Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341, Bangladesh

Scrutiny of these applications revealed the following facts:
Both applicants submitted notarized copy of letter of emergency use authorization of Remdesivir in the name of their principal manufacturer issued by Directorate General of Drug Administration, Government of People's Republic of Bangladesh in place of CoPP/FSC. However this letter is for emergency use authorization for use only in Government hospitals or Government designated private hospitals dealing with COVID-19 Patients and is silent about approval status for export. However both firms submitted following explanations.

- M/s Beximco Pharmaceuticals Limited, the principal manufacturer in the application of M/s M/s Searle Pharmaceuticals Karachi has provided an explanation letter dated 9th June 2020 stating as under:
  "We, Beximco pharmaceuticals Limited would like to inform you that our Drug Regulatory Authority (DGDA) have confirmed us the Certificate of Pharmaceutical product is applicable for registered products only. However, we have been granted Emergency use Authorization to Remdesivir Injection. Therefore COPP, is not applicable in this case.
  Further, we have also enclosed Purchase order from a reputed hospitals as a proof of availability of medicine in country.
  However there is no restriction on export of this medicine in current pandemic situation."

- M/s Incepta Pharmaceuticals, the principal manufacturer in the application of M/s OBS Healthcare Pvt. Limited Karachi has submitted a clarification dated 09-06-2020 stating as under:
  "We, Incepta Pharmaceuticals Ltd., would like to declare that, we have applied for the certificate of Pharmaceutical product (COPP) of Ninavir 1200 IV infusion to Bangladesh National Drug Regulatory authority, Directorate General of Drug Administration on 03-06-2020 for exporting purpose in pakistan. The received copy of application is attached with this declaration letter (The application is in Bengali which is DGDA format).
  The approved and legalized (from Pakistan Embassy, Bangladesh) COPP will be provided as soon as available."

In both cases, the manufacturer abroad has developed the product as "Lyophilized Powder for IV Injection" and are in process of concurrent stability studies of their developed products.

Application from India:

a. M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st floor, Shafi court, Civil lines Karachi imported from M/s Cipla Ltd. Plot No. m-61, M-62 & M-63, Verna Industrial Estate, Verna-Goa.

Scrutiny of this application revealed the following facts:

- Certificate of Pharmaceutical Product (CoPP) or Free Sale Certificate is not available in the application, while only GMP certificate is provided.
- As per firm's representative, manufacturer of this product in India i.e. M/s Cipla has not been granted approval to manufacture Remdesivir by Indian Regulatory Authority / Government rather firm has provided a copy of letter for permission to manufacture "Remdesivir for Injection 100mg/vial" for export purpose only. However, they have not yet manufactured this product as it is under production expected to be marketed in last week June/1st week of July.

Decision:

Keeping in view the above status in reference regulatory authorities of remdesivir and Authority's directions for priority consideration for such applications; the Registration Board considered and made following decisions under Rule 29(6)(8) of Drugs (LR&A) Rules, 1976:

I. Applications for Local Manufacturing:

a) Approved registration of following products of Remdesivir Lyophilized Powder for Injection 100mg (Emergency use authorization) for applicants having facility of Lyophilization.

Sr. No	Name of applicant / manufacturer	Brand Name Applied Formulation / composition Finished Product specification	Pack Size Demanded Price	Shelf life & recommended storage conditions
1.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Coriv Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per PRC	24 months/Store below 30°C
2.	M/s BF Biosciences Ltd. 5-Km,Sundar Raiwind Road, Lahore	Remidia Lyophilized Powder for Infusion 100mg/Vial Each Lyophilized vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	MRP Rs. 14,600 TP Rs.12410 ($ 76.98) per Vial	24 months/Store below 30°C
	• Campaign manufacturing of Remdesivir in already approved section for biological drugs of M/s BF Biosciences is allowed as per decision of Authority taken in its 84th meeting held on 01st June, 2020 and Appellate Board taken in its 151st sitting held on 16th January, 2019 with same terms & conditions as decided by the Appellate Board in its aforementioned sitting. • Registration Board further directed to communicate above decision to secretary Appellate Board for appraisal of the Board.			
3.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot No. 209, Sector 23, Korangi Indsutrial Area, Karachi, Pakistan	Remivir Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per PRC	24 months/Store below 30°C
4.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221-223, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Besivir Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per PRC	24 months/Store below 30°C
5.	M/s Bio Labs Pvt. Ltd. Plot # 145, Industrial Triangle,	Biovir IV Injection 100mg Each Lyophilized vial contains:	As Per DRAP's	24 months/Store below 30°C

	Kahuta Road, Islamabad	Remdesivir …… 100mg (As per Innovator's specifications)	Pricing Policy	
6.	M/s MTI Medical Pvt Ltd. 586-587 Sundar Industrial Estate, Lahore, Pakistan	Remdevir Lyophilized Injection 100mg/Vial Each Lyophilized vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per SRO	24 months/Store below 30°C
7.	M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan	Remdes Lyophilized Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	--	24 months/Store below 30°C

b) Approved registration of following products of Remdesivir Injectable solution 5mg/ml (Emergency use authorization) for applicants having manufacturing facility of liquid injectable Vial (General) section with cold chain storage facility in quarantine, finished goods store and distribution channel to ensure storage of drug product between 2 – 8°C. The process for verification of cold chain storage facility shall be initiated immediately after approval of minutes and registration letters shall be issued after verification.

Sr. No	Name of applicant / manufacturer	Brand Name Applied Formulation / composition Finished Product specification	Pack Size Demanded Price	Shelf life & recommended storage conditions
1.	M/s Allmed Pvt. Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Remvir concentrated solution for Infusion 100mg Each vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per SRO	12 months/ 2 – 8°C.
2.	M/s BF Biosciences Ltd. 5-Km,Sundar Raiwind Road, Lahore	Remidia Liquid Solution for Infusion 20ml Each vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	MRP Rs. 14,600 TP Rs. 12410 ($ 76.98) per Vial	12 months/ 2 – 8°C.
	• Campaign manufacturing of Remdesivir in already approved section for biological drugs of M/s BF Biosciences is allowed as per decision of Authority taken in its 84th meeting held on 01st June, 2020 and Appellate Board taken in its 151st sitting held on 16th January, 2019 with same terms & conditions as decided by the Appellate Board in its aforementioned sitting. • Registration Board further directed to communicate above decision to secretary Appellate Board for appraisal of the Board.			
3.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Remedy Solution for Injection 100mg/20ml Each vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per SRO	12 months/ 2 – 8°C.
4.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan	Rememac Injection 5mg/ml Each vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per PRC	12 months/ 2 – 8°C.
5.	M/s Wnsfield Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Ramyr Liquid Injection 5mg/ml Each vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per SRO	12 months/ 2 – 8°C.
6.	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan	Hildesvir Injection 5mg/ml Each vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per DPC	12 months/ 2 – 8°C.

7.	M/s Ameer & Adnan Pharmaceutical Pvt. Ltd. Plot No.47, Sundar Industrial Estate, Lahore	Ramvir Infusion 5mg/ml Each vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As per PRC	12 months/ 2 – 8°C.

c) Rejected following registration applications of Remdesivir bulk lyophilized powder (ready to fill in vials) 100mg as applied way of manufacturing method is not approved by any reference regulatory authority and since the exemption of Form 5F & out of queue consideration granted by the Authority is applicable to only those dosage forms as authorized by the reference regulatory authorities hence its safety, efficacy and quality is not fully determined.

Sr. No	Name of applicant / manufacturer	Brand Name, Applied Formulation / composition Finished Product specification
1.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Remvir for Injection 100mg Each vial contains: Remdesivir Lyophilized Sterile powder ……100mg
2.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Viso-Rem for Injection 100mg Each Vial Contains: Remdesivir…100mg
3.	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK	Remdi-Wrd Injection 5mg/ml Each Vial Contains: Remdesivir…100mg
4.	M/s OBS Pakistan Private Limited. C-14, S.I.T.E, Karachi, Pakistan **contract manufacturing** by M/s Radiant Pharma Pvt Ltd, 43-E Sunder Industrial Estate, Lahore	Remvid Injection 100mg Each Vial Contains: Remdesivir…100mg
5.	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore	Remdisol Injection 100mg Each Vial Contains: Remdesivir Lyophilized Powder for Infusion…100mg
6.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Remz IV Injection 100mg Each Vial Contains: Remdesivir…100mg
7.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore	Codesvir Infusion 100mg Each 20ml Contains: Remdesivir…100mg
8.	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Wemeda Injection 5mg/ml Each Vial Contains: Remdesivir…100mg
9.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Ramyr Dry Powder Injection 100mg Each Vial (20ml) Contains: Remdesivir…100mg
10.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Remvir for Injection 100mg Each Vial Contains: Remdesivir…100mg
11.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	Remida Injection 5mg/ml Each ml Contains: Remdesivir…5mg
12.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi **Contract manufacturing by** M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Resvir Injection 100mg Each Vial Contains: Remdesivir Powder Concentrate for Injection/Infusion ……. 100mg
13.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II,	Remdiza Injection 100mg EachVial Contains:

	Industrial Estate, Hattar, Pakistan	Remdesivir ……. 100mg
14.	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore **Contract manufacturing** By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Remi Lyophilized Powder for Injection 100mg EachVial Contains: Remdesivir…..100mg
15.	M/s Neutro Pharma Pvt Ltd, 9.5-Km, Sheikhupura Road, Lahore.	Medvir-19 100mg Injection Each Vial contains : Remdesivir ….. 100mg
16.	M/s Radiant Pharma Pvt Ltd, 43-E Sunder Industrial Estate, Lahore.	Medvir-19 100mg Injection Each Vial contains : Remdesivir ….. 100mg

d) Deferred following registration applications of Remdesivir till contract manufacturer develop the product and initiate stability studies and present at least 3 months stability data for initial consideration of their cases of contract manufacturing by Registration Board.

Sr. No	Name of applicant / manufacturer	Brand Name Applied Formulation / composition Finished Product specification	Pack Size Demanded Price
a. Lyophilized Powder for Injection 100mg (manufactured by way of lyophilization)			
1.	M/s The Nextar Pharma Private Limited. Plot No. E-58, North Western Industrial Zone, Port Qasim, Pakistan **Contract manufacturing by** M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Hildesvir Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg	As per DPC
2.	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad **Contract manufacturing by** M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Desivir Injection 100mg IV Each Lyophilized vial contains: Remdesivir …… 100mg	As per PRC
3.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore contract manufacturing by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	Remdesivir IV Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg	As Per PRC
4.	M/s Hilton Pharmaceuticals, Plot No.13, Sector 15, Korangi, Karachi **contract manufacturing by** M/s Nabiqasim Industries Ltd, 17/24, Korangi Industrial Area, Korangi Highway, korangi, Karachi	Hildesvir Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg	As per SRO
5.	M/s Pharm Evo Pvt Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi. **contract manufacturing by** M/s Nabiqasim Industries Ltd, 17/24, Korangi Industrial Area, Korangi Highway, korangi, Karachi	Redvir Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg	As per SRO
Applications for "Liquid Injection"			

6.	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore Contract manufacturing By M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad	Remi Solution For Injection100mg/20ml Each Lyophilized vial contains: Remdesivir …… 100mg	As per SRO

e) Rejected following registration application of Remdesivir Injectable solution 5mg/ml (Emergency use authorization) for applicant not having manufacturing facility of liquid vial injectable

Sr. No	Name of applicant / manufacturer	Brand Name Applied Formulation / composition Finished Product specification
1.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Remvir Injection 5mg/ml Each 20ml Vial Contains: Remdesivir …… 100mg

f) Deferred following product of Remdesivir Injectable solution 5mg/ml (Emergency use authorization) for confirmation of evidence of approval of required manufacturing facility i.e., "Liquid injectable Vial (General) section" from Licensing Division.

Sr. No	Name of applicant / manufacturer	Brand Name Applied Formulation / composition Finished Product specification
1.	M/s Weather Folds Pharaceuticals, Plot No.62/2, Phase-II Industrial Estate Hattar.	Remida Liquid Injection 5mg/ml Each Vial (20ml) Contains: Remdesivir ……. 100mg

II. Finished Import:

a. Approved following registration applications of Remdesivir Lyophilized Powder for Injection 100mg (Emergency use authorization) for following cases. As manufacturing sites of imported finished products are inspected for GMP purpose. As during current pandemic situation, inspection abroad is not possible thus Registration Board recommended case for exemption of inspection may be referred to DRAP's Authority for its consideration. If approved by DRAP's Authority then every imported lot of Remdesivir will be subjected to quality tests performed by CDL Karachi on priority basis.

Sr. No	Name of applicant / manufacturer	Brand Name Applied Formulation / composition Finished Product specification	Pack Size Demanded Price	Shelf life & recommended storage conditions
1.	M/s The Searle Company Limited. F-319 S.I.T.E. Karachi, Pakistan **Import from** M/s Beximco Pharmaceuticals ltd, 126, Kathaldia, Auchpara, tongi-1711, Ghazipiur, Bangladesh	Bemsivir IV Injection 100mg Each Lyophilized vial contains: Remdesivir …… 100mg (As per Innovator's specifications)	As Per SRO	Shelf life 24 months / Store below 30°C
2.	M/s OBS Healthcare Pvt Limited. Plot No. 10 & 25, Sector 20, Korangi Indsutrial Area, Karachi,-74900 **Import from** M/s Incepta Pharmaceuticals Limited. Dewan Idris Road, Bara Rangamatia, Zirabo, Ashulia, Savar, Dhaka-1341, Bangladesh	Ninavir IV Infusion 100mg Each Lyophilized vial contains: Remdesivir …… 100mg	MRP: Rs.25,000/01 Vial Per Pack	Shelf life 24 months /Store below 30°C

- Rejected registration application of Cipremi 100mg Injection (Remdesivir Lyophilized Powder for Injection 100mg) applied by M/s A.J. Mirza Pharma (Pvt.) Ltd. 1st floor,

Shafi court, Civil lines Karachi **manufactured by** M/s Cipla Ltd. Plot No. m-61, M-62 & M-63, Verna Industrial Estate, Verna-Goa, India, as firm failed to submit any document confirming approval / authorization status of Remdesivir by Indian regulatory authority / Government even for Indian market rather firm has provided a copy of letter for permission to manufacture "Remdesivir for Injection 100mg/vial" for export purpose only. However, they have not yet manufactured this product as it is under production expected to be marketed in last week June/1st week of July.

Moreover applicant could not share any data regarding development of any batch for their domestic market.

All approved registrations are subject to following conditions:

i. Remdesivir API / drug substance shall only be procured from sources/manufacturers having valid API manufacturing license / GMP certificates by respective drug regulatory authority and concurrent accelerated and real time stability study data of API as per the conditions of zone IV-A.
ii. Registration of Remdesivir is subject to performance of product development, process validation and concurrent real time and accelerated stability study of drug product for the first three commercial batches as per zone IVA climatic conditions.
iii. This medicine will only be supplied to healthcare facilities dealing with COVID-19 Patients under strict supervision of a qualified specialist physician.
iv. Registration of Remdesivir (Emergency Use Authorization) shall remain valid upto current COVID-I9 pandemic situation and shall be reviewed regularly in line with its regulatory status by reference regulatory authorities.
v. The firm shall conduct stability studies at monthly interval during the initial six months and submit the data to P.E&R Division DRAP on quarterly basis.
vi. The firm shall immediately inform respective FID for taking sample of 1st three commercial batches for its testing to be performed by CDL on priority basis.
vii. Firm shall ensure that the Remdesivir drug product shall be accompanied with the authorized labeling is distributed to hospitals and healthcare facilities as directed by Registration Board, consistent with the terms of this letter.
viii. Firm shall ensure the appropriate storage and cold chain facility during manufacturing and distribution cycle.
ix. Firm shall ensure that terms & conditions of this registration are made available to all relevant stakeholders (Government Agencies, Authorized distributors, Healthcare facilities, Healthcare providers).
x. Firm will report monthly to National Pharmacovigilance Centre, Pharmacy Services Division DRAP, serious adverse events and all medication errors associated with the use of the authorized Remdesivir that are reported to the firm during the pandemic.
xi. The firm shall maintain complete records of distribution of Remdesivir (i.e. lot numbers, Quantity, Receiving site, receipt date) and will be provided to any government organization (if required).
xii. Product will be recalled in case of any quality issues or any adverse decision by the reference regulatory authorities regarding safety/efficacy of Remdesivir injection or as decided by Registration Board.

Following applications has been received on Form-5/Form 5-D instead of Form 5-F as per details mentioned against each.

S. No.	Name of applicant	Brand Name	composition	Diary no. Date /Fee & Date/ form
922.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Evomec Tablet 12mg	Each Tablet Contains: Ivermectin…12mg	Dy.No. 5586 dated 06/04/2020Rs. 20,000/- dated 06-04-2020 Form 5

923.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Evomec Tablet 6mg	Each Tablet Contains: Ivermectin…6mg	Dy.No. 5585 dated 06/04/2020Rs. 20,000/- dated 06-04-2020 Form 5
924.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Evomec Tablet 3mg	Each Tablet Contains: Ivermectin…3mg	Dy.No. 5584 dated 06/04/2020Rs. 20,000/- dated 06-04-2020 Form 5
925.	M/s Don Valley Pharmaceuticals Pvt. Ltd. 31-km, Main Ferozpur Road, Lahore	Pravostat Tablet 40mg	Each Film Coated Tablet Contains: Pravastatin Sodium…40mg	Dy.No. 5546 dated 06/04/2020Rs. 20,000/- dated 02-04-2020 Form 5
926.	M/s Global Pharmaceuticals Pvt Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad	Norm Tablet 6mg	Each Tablet Contains: Ivermectin…6mg	Dy.No. 6246 dated 08/04/2020Rs. 20,000/- dated 08-04-2020 Form 5
927.	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore	Mecvir Tablet 6mg	Each Tablet Contains: Ivermectin…6mg	Dy.No. 5936 dated 07/04/2020Rs. 20,000/- dated 07-04-2020 Form 5
928.	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore	Mecvir Tablet 3mg	Each Tablet Contains: Ivermectin…3mg	Dy.No. 5937 dated 07/04/2020Rs. 20,000/- dated 07-04-2020 Form 5
929.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Helpy Oral Suspension 120mg/5ml	Each 5ml Contains: Paracetamol…120mg	Dy.No. 7613 dated 15/04/2020Rs. 20,000/- dated 15-04-2020 Form 5
930.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Helpy Oral Suspension 250mg/5ml	Each 5ml Contains: Paracetamol…250mg	Dy.No. 7614 dated 15/04/2020Rs. 20,000/- dated 15-04-2020 Form 5
931.	M/s Linear Pharma Plot # 18, Street # S-4, National Industrial Zone, RCCI Rawat, Islamabad	Iver Tablets 3mg	Each Tablet Contains: Ivermectin…3mg	Dy.No. 6562 dated 09/04/2020Rs. 20,000/- dated 09-04-2020 Form 5
932.	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore	Nextvet Tablet 3mg	Each Tablet Contains: Ivermectin…3mg	Dy.No. 6153 dated 08/04/2020Rs. 20,000/- dated 08-04-2020 Form 5
933.	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Glitquon Suspension 750mg/5ml	Each 5ml Contains: Atovaquone…750mg	Dy.No. 6757 dated 10/04/2020Rs. 20,000/- dated 09-04-2020 Form 5
934.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	Iverso Tablets 3mg	Each Tablet Contains: Ivermectin…3mg	Dy.No. 6200 dated 07/04/2020Rs. 20,000/- dated 08-04-2020 Form 5
935.	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Glitquon Tablet	Each Film Coated Tablet Contains: Atovaquone…250mg Proguanil…100mg	Dy.No. 6756 dated 10/04/2020Rs. 20,000/- dated 09-04-2020 Form 5

936.	M/s Wilson's Parmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Fen-Plus 801mg Tablet	Each Film Coated Tablet Contains: Pirfenidone…801mg	Dy.No. 9977 dated 05/05/2020Rs. 20,000/- dated 05-05-2020 Form 5
937.	M/s Wilson's Parmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Fen 267mg Tablet	Each Film Coated Tablet Contains: Pirfenidone…267mg	Dy.No. 9976 dated 05/05/2020Rs. 20,000/- dated 05-05-2020 Form 5
938.	M/s Wilson's Parmaceuticals. 387-388,I-9/3, Industrial Area, Islamabad	Fen 267mg Capsule	Each Capsule Contains: Pirfenidone…267mg	Dy.No. 9975 dated 05/05/2020Rs. 20,000/- dated 05-05-2020 Form 5
939.	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Pulm Capsules 267mg	Each capsule contains: Pirfenidone….267mg	Dy.No. 9979 dated 05/05/2020Rs. 20,000/- dated 05-05-2020 Form 5
940.	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Pulm Tablets 801mg	Each tablet contains: Pirfenidone….801mg	Dy.No. 9980 dated 05/05/2020Rs. 20,000/- dated 05-05-2020 Form 5
941.	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Ezitab Tablets 20mg	Each tablet contains: Telmisartan….20mg	Dy.No. 8131 dated 20/04/2020Rs. 20,000/- dated 20-04-2020 Form 5
942.	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Pulm Tablets 267mg	Each tablet contains: Pirfenidone….267mg	Dy.No. 9976 dated 05/05/2020Rs. 20,000/- dated 05-05-2020 Form 5
943.	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Worth Capsules 20mg	Each capsule contains: Duloxetine as Hcl enteric coated pellets…20mg	Dy.No. 8130 dated 20/04/2020Rs. 20,000/- dated 20-04-2020 Form 5
944.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Revina Tablet 3mg	Each tablet contains: Ivermectin…300mg	Dy.No. 8764 dated 23/04/2020Rs. 20,000/- dated 22-04-2020 Form 5
945.	M/s Zanctok Pharmaceuticals Laboratories Pvt Ltd. F/5 Site Hyderabad, Pakistan	Ze-Lol Liquid	Each ml Contains: Choloroxylenol…4.8%	Dy.No. 11924 dated 29/05/2020Rs. 20,000/- dated 29-05-2020 Form 5
Decision: Registration Board deferred above cases and directed the firms to apply on Form-5F.				

B. Division of Biological Evalautaion & Research (B. E & R)

1. Permission of exemption from the Drugs Labelling & Packaging Rules, 1986 for Actemra 80mg (Reg. No. 083134) & Actemra 400mg (Reg. No. 083136) at the time of import applied by M/s Roche Pakistan Limited, Karachi granted by circulation of agenda to members of Registration Board.

M/s Roche Pakistan Limited, Karachi applied for the exemption from the Drugs Labelling & Packaging Rules, 1986 at the time of import for their already registered products Actemra 80mg (Reg. No. 083134) & Actemra 400mg (Reg. No. 083136). The firm submitted that we all are informed that there is no targeted drug for COVID-19 and it is only being treated symptomatically and supportively. The "Clinical Management Guidelines for Covid-19 Infections" (issued by NHSRC, Govt. of Pakistan) has mentioned one of their registered products, Actemra (tocilizumab), as an important drugs for COVID-19 management, which has exponentially increased its demand and they have been receiving the requests for the said drug from miscellaneous medical institutions and hospitals (of which some notable are SIUT, AKUH and DOW) for the urgent supply of it.

Since, the said product is imported from their principal F. Hoffmann-La Roche Ltd., Basel, Switzerland and due to high demand of this product from all over the world, it will take them at least six months to import the shipment on local (Pakistan make-up) label, which includes Urdu text, local MRP and local registration number. The shipment will be received in parts.

The firm has submitted the following documents:

a. Fee challan of Rs. 10000/-
b. Copies of purchase orders & e-mails for supply of Actemra.

Moreover, the online available news show that Roche has announced that the US Food and Drug Administration (FDA) has formally approved its phase 3 trial of Actemra in severely ill COVID-19 patients, who have been hospitalized with pneumonia. The trial – named COVACTA – will recruit around 330 patients around the world, with an expected start date sometime in early April. The primary and secondary endpoints will include assessing clinical status, mortality, mechanical ventilation and intensive care unit variables in the patient population. Despite a number of clinical trials evaluating Actemra already ongoing across the world, Genentech has maintained that the COVACTA study is pivotal because there are still no well-controlled studies and limited published evidence on the safety or efficacy of the drug in COVID-19. (https://www.pmlive.com/pharma_news/fda_approves_roches_actemra_covid-19_trial_1329887)

The firm has requested to grant them exemption from the Drugs Labelling & Packaging Rules, 1986 for Actemra 80mg (Reg. No. 083134) & Actemra 400mg (Reg. No. 083136) at the time of import.

In this context, it is submitted that the above products have already been registered as per following details:

Reg. No.	Name of Manufacturer	Brand Name & Composition	Pack Size
083134	M/s Utsunomiya Plant of Chugai Pharma Manufacturing Co., Ltd., 16-3, Kiyohara Kogyodanchi, Utsunomiya-city, Tochigi, Japan	Actemra 80mg (Concentrate for Solution for Infusion) Each vial(4ml) contains: Tocilizumab (Genetical Recombination)…….80 mg	1's Vial
083136	M/s Utsunomiya Plant of Chugai Pharma Manufacturing Co., Ltd., 16-3, Kiyohara Kogyodanchi, Utsunomiya-city, Tochigi, Japan	Actemra 400mg (Concentrate for Solution for Infusion) Each vial(20ml) contains: Tocilizumab (Genetical Recombination)…….400 mg	1's Vial

It is submitted that initially the firm applied for permission for Actemra 200mg (Reg. No. 083135). Accordingly, the case was considered in 294th meeting of Registration Board wherein the Board decided as follows:

"Registration Board deliberated the case in light of prevailing COVID-19 emergency situation and considered Clinical Management Guidelines for COVID-19 Infections issued by M/o NHSR&C, requirements of Actemra 200mg by leading medical institutions of the country (AKUH, SIUT, Indus, HMC, DOW etc) for management of their COVID-19 patients and Rule 3 of Drugs (Labeling & Packing) Rules, 1986 and decided as under:

a. Acceded to request of the firm for import of registered Actemra 200mg, Reg. No. 083135 in Standard Export Packs.

b. The firm shall make necessary arrangement for local printing of MRP and Registration Number at least on secondary packing before sale of drug, at any licensed premises having. Firm shall be responsible for providing requisite cold chain facility during local printing process under supervision of relevant experts of manufacturing and Quality Assurance. Complete batch processing record shall be maintained for aforementioned process.

c. Actemra 200mg, Reg. No. 083135 shall be supplied only to medical institutions for use under strict medical supervision of relevant experts / Registered Medical Practitioner and shall not be sold either to retail pharmacies or whole sale market.

d. Complete import, sale / supply and printing record shall be maintained and will be provided if required by DRAP.

e. This permission shall be valid for three (03) months only. During this period, M/s Roche shall make efforts for future import of finished product as per requirements of Drugs (Labeling & Packing) Rules, 1986."

The firm then submitted that due to high demand of Actemra 20mg, it is not available for supply and requested to extend the above permission for 2000 packs each of Actemra 80mg (Reg. No. 083134) & Actemra 400mg (Reg. No. 083136).

It was evident from the above that the said products are included in the "Clinical Management Guidelines for Covid-19 Infections" (issued by NHSRC, Govt. of Pakistan) and approval has already been granted for one strength of Actemra i.e 200mg in 294th meeting of Registration Board and **then the firm had requested for extension of the permission for Actemra 80mg (Reg. No. 083134) & Actemra 400mg (Reg. No. 083136)**. Due to current situation of COVID 19, the meeting of registration Board was not held, therefore, being the matter of public interest the agenda was being circulated for the approval from members of Registration Board so that permission may be granted to the firm at the earliest. The following comments were received on whatsapp from members of Registration Board:

Name of Member	Comments
Dr. RafeeqAlam	Agreed
Dr Noor us Saba	Agreed
Dr. HafsaKaramElahi	Agreed
Abdullah	Agreed
Maj. Gen. Tahir Mukhtar	Agreed Please
DrQurban	Agreed as proposed, please.
Iftikhar ch	Agreed in the public interest but now according to the decision of supreme court Lock down is over so regular meeting of the registration board is the need of the hour and we must hold meetings. **Email** Respected Abdullah sahib Asslamoallikum I have given my consent to you through WhatsApp as you desired.i agree in the public interest in prevailing covid 19 situation but now after the decision of supreme court and ease of Lock down we have to hold regular meeting of board for discussion and decisions. I hope you will note and consider my request.

Dr. Amanullah	Assalam-u-Alaikum to all my fellow members , Submitted my points of concern 1) Is the product in question is safe . 2) Is the product has completed its all required trial phases and declared safe for human use . 3) At the time of approval in 294 registration board meeting I can't remember that product is discussed about its trial phase(s) and in the past I remember that Board has never approved any product which has not completed it's all trial phases and if I'm not wrong in case of Dengue we have not approved the product due to incomplete studies and in Philippine the same Dengue product was banned due to deaths noted so is the case here if studies are incomplete we may not allow and even registration of the product approved in 294 -M may be suspended till the time the study is completed. 3) I have already shown my serious concerned about 294 registration board meeting which was on line rather it was Off-line meeting because we were not able to participate due to poor communication system from DRAP and every thing was in hurry . 4) Approval through E-mail and Whattsapp is not appropriate because it's a matter of human lives so the DRAP may not compromise for holding such meetings and taking approval on email / Whattsapp and on line . If my points are addressed and the product is safe for human consumption then it's ok otherwise it is not approved from my side.
M. Aslam	Dear Abdullah can we approved any item on whatsapp or proceed the registration Board meeting on WhatsApp? If yes then I have no objection. Kindly share relevant section of DRAP Act for the purpose of taking approval of any medicine or consent of members on any drug via email. Otherwise all process will be unlawful. Things must be done in proper manner SMCr.
Dr. Obaid	Dear Members as matter is of high public health importance due to potential use of instant medicine in COVID-19 management & no other alternate is registered as well, thus opinion of members is hereby solicited. Date of Registration Board meeting will be shared immediately after Eid holidays.
Mujtaba IPO	DR sb The matter is critical and may kindly be discussed in next meeting for approval which is appropriate forum. Regards
Adnan Rizvi	FDA approved phase 3 clinical trial not management of Covid19. It is blockbuster drug of Roach is an immunosuppressive agent, exclusively use in Arthritis. It has many side effects one of the most common is upper respiratory tract infection (10%) and common Cold. It's much expensive drug. FDA approved for trial not treatment/management of Covid19. Not agreed For any further approval please call proper meeting of Registration Board as flight operation is also started. We had given exemption in one strength it is enough we should wait the next meeting of Registration Board or until the FDA approve for the treatment of Covid19 rather clinical trial. Dear sir firstly FDA approve the Acterna in the treatment of Covid19 now it is on phase 3 clinical trial then put this matter in upcoming meeting. Otherwise not, our peoples are not guniea pigs Strongly agreed with the concern of DrAmanullah It was online rather it was Off-line.
Khalid Javed KPK	If rules allow approval in such a manner then I agree with the proposal.
Muzzammil DTL Punjab	Strongly agreed with drammansb

After above comments, the Director PE&R/Chairman Reg. Board explained the case keeping in view the Covid-19 public health urgency situation. Later on, all members agreed the approval of case through Whatsapp group as tabulated under:

	Dr. Obaidullah	Reference queries in previous messages, I want to clarify that Actemra 80mg and 400mg are both registered drugs vide No. 083134 and 084136. Product is approved by almost all reference regulatory authorities including USFDA and EMA for various indications. After emergence of COVID-19, national clinical management guidelines for COVID-19 infections has been issued where it is categorically mentioned as treatment option (see page 6). Same treatment option has been adopted by various reference countries including USA, Spain, Italy, Ireland and various non-reference countries aswell. As per information provided by M/s Roche, presently Actemra orders are pending from SKMCH&RC, DOW, PIMS, LGH, DG Health KPK & Baluchistan, CMH Quetta, Farooq Hospital Lhr, Hameed Lateef Lhr, QIH Islamabad, BehriaLhr, AKUH, SIUT and Indus karachi being used for COVID-19 management exclusively to treat extensive and bilateral lung disease or severely ill patients with elevated IL-6 levels. In 294th meeting, it was decided to exempt Urdu version only with certain conditions for already registered drugs. DRAP proposal is to follow same pathway for Actemra 80mg and 200mg with same conditions. Firm informed that 8 packs of Actemra 200mg and 10 packs of 80mg are available in stocks throughout country. As per information provided by M/s Roche and non-approval at this stage, DRAP's apprehend that product Actemra will not be available for use in management of COVID-19 infection in above hospitals and can have devastating and life threatening effects as well. As far as query regarding approval through WhatsApp/ email is concerned, definitely it has never been practiced in past as Pakistan And health related organisations as well has never faced such Public health emergency situation. If members consented for granting approval as per details in agenda then we will issue Urdu exemption letter All proceedings are only done to save COVID patients in such extraordinary public health urgency situation Across the globe including Pakistan.
	Dr. Qurban	Clarification is much appreciated; Agreed.
	Gh. Mujtaba	Yes clarification is appropriated and Agreed with Dr. Obaid sb proposal.
	DrRafiqAlam	I endorsed the justification given by Dr. Obaid
	Maj. Gen. Tahir	I strongly endorse the clarification and Recomend Approval
	Dr Noor us Saba	In novel pandemic situations priority is to save lives with all possible methods. Therefore with this timely decision DRAP will project itself as a responsible organisation. All members are requested to grant the approval.
	DrRafiqAlam	Agreed Exemption from Urdu printing should be granted for three months in present scenario of urgency
	Khalid Javed KPK	I totally agree with DrOdaid clarification. keeping in view present scenerio I strongly recommend for its approval.
	M Aslam Law	Dear Obaid sb when a thing is to be done in a particular manner, it must be done in that way and not authorize any deviation there from will render the action as illegal and unlawful. Reliance is placed a judgement of the Supreme Court in case Tehsil Nazim TMA, Okara versus Abbas Ali and others reported as 2010 SCMR p 1437. Solution in this situation is that Board may take the measures but in the next meeting take retrospective approval of the said medicine
	DrHafsa	Agreed
	Muzzamil	I endorse

	DrAkram	Keeping in view the established indication of drug i.e adult arthritis and side efects as mentuoned by Mradnan and dramanullah relaxation of rules in hurry may not not advisable. Better deliberate thoroughly. It is not the only drug which is IL-6 inhibitor alternate available. I suggest call a meeting in person following SOPs.

Accordingly, the approval was granted and letter was issued on 21-05-2020. Chairman Registration Board further advised to include the case in forth coming Registration Board for concurrence.

Decision: Registration Board acknowledged the above approval. Registration Board further extended the already granted permissions regarding import of standard export packs and local printing of MRP and registration number on at least secondary packaging for Actemra 80mg, 200mg and 400mg for nine (09) months from the date of permissions.

2. Application for permission of import of Actemra 400mg/20ml from M/s Genetech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA applied by M/s Roche Pakistan Limited, Karachi.

M/s Roche Pakistan Limited, Karachi applied for the permission to import Actemra 400mg/2ml from M/s Genetech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA. The firm submitted that considering the unfortunate pandemic situation of COVID-19 and the fact that Actemra is in extremely high-demand throughout the world, their global supply chain is unable to fulfil the demands of many international markets from the existing manufacturing facility (Chugai Pharma Manufacturing Co Ltd, 16-3 Kiyohara-Kogyodanchi, Utsunomiya, Japan). Therefore, Roche has initiated the production of additional batches of Actemra 400mgvial in their Genentech's Hillsboro (HTO) site, located at 4625 NE Brookwood Parkway, Hillsboro, OR97124, United States. This operation is being carried out on an interim basis only in order to mitigate the potential Actemra supply disruptions due to the exponentially increasing demand.

The firm further submitted that it is worthy to mention here that Actemra is already the part of COVID-19 management as per the following local guidelines:

- Clinical Management Guidelines for COVID-19 Infections, issued by the Federal Govt.
- Clinical Management Guidelines for COVID-19 Infections, issued by the Punjab Govt.

Moreover, it is also the part of clinical management guidelines in the following notable countries/hospitals:

- China (Wuhan guidelines)
- US (NIH)
- Italy
- Spain
- Ireland
- Russia
- Poland
- Saudi Arabia
- Qatar
- Lebanon
- Egypt
- Israel
- International Pulmonologist's Consensus Group on COVID-19
- US Hospitals – University of Michigan/Yale Medical Center/Swedish Hospital
- US Organization Guidance – ASHP, Compendia

While Roche Pakistan Limited has been able to meet most of the immediate demand through a variety of measures, looking ahead to the mid-to-long term, demand is expected to increase further. So far, we have the pending supply orders from following hospitals:

Karachi

- Tabba Heart Institute
- SIUT
- Ziauddin Hospital

Lahore

- Al-Shafi Hospital
- Baharia Hospital
- National Hospital
- PKLI
- Mayo Hospital
- Lahore General Hospital
- Hameed Latif

- University of Lahore Teaching Hospital
- KEMU
- Govt. Kot Khawaja Saeed Teaching Hospital
- Jinnah Hospital Lahore
- Surgimed Hospital
  Doctors Hospital & Medical Centre
- Fatima Memorial Hospital
- Imran Adrees Hospital

Faisalabad

- General Hospital
- Family Care Hospital

Islamabad/Rawalpindi

- Shifa International
- PIMS

Considering the above-mentioned facts and status, we request your special approval to avail the opportunity of importing Actemra 400mg vial from Hillsboro manufacturing site in the United States. Currently there are only 95 packs available in stock for Actemra 80mg vial, which will be consumed by today, Monday 1st June, and the next expected shipment contains a very limited number of packs as compared to the market demand.

For this purpose, we are submitting a set of available administrative and technical documents (as mentioned in the attached checklist), the same against which the US FDA has allowed the manufacturing and release of Actemra 400mg vial from Hillsboro site. We have tried our level best to provide the maximum documents which would establish the credibility and validity of the site. It is worthy to note that the said site is already the existing approved site for our product Herceptin (trastuzumab) 440mg vial, hence, the credibility and authenticity of the new site is already established and accepted by the DRAP.

Moreover, M/s Roche Pakistan Limited, Karachi has submitted the following commitments:

- To ensure that the quality of the finished product will not be compromised. The finished product will be manufactured at Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, United States, which operates in accordance with FDA GMP guidelines and have been inspected by US and Japanese health authorities.
- A minimum of 3 consecutive batches of drug product (ca. 40,000 vials per batch) will be released in accordance with an ongoing process verification protocol.
- The first 3 batches will be placed in long term (2-8°C) and accelerated stability (25°C), according to the stability protocol. *The shelf life initially claimed is 6 months at 2-8°C.* The shelf life will be extended in accordance to the stability protocol. Each extension will not be more than twice the time points available, for a maximum 12 months.
- The vials are shorter and wider compared to the commercial material and the vial cap is *dark blue (instead of red).*
- *The batches imported from the Hillsboro site shall only be used for the treatment of COVID-19 patients, and not in any other indication of the product.*

The firm has submitted the following documents:

a. Fee Challan of Rs. 50000/-
b. Copies of orders from different institutes/ hospitals.
c. Copy of email from Mr. Robert G. Kosko, Jr., Pharm D, MPH, Commander USPHS Senior Programme Management Officer, FDA/CDER/Drug Shortage Staff regarding no objection to Roche/ Genetech's distribution within the U.S. of following:
   Actemra (Tocilizumab) mg/ml lot number 3378172
   The email further states that this discretion is contingent on the following points:
   i. It does not extend beyond the product and lot number specified above.
   ii. Roche/ Genetech will distribute a Dear Healthcare provider letter to alert prectitioners to the differences between the two configurations of Actemra 400mg/20ml which will be on the market at the same time.

In this context, it is submitted that the aforementioned product was initially registered as per following details:

Reg. No.	Name of Manufacturer	Brand Name & Composition	Pack Size
083136	M/s Utsunomiya Plant of	Actemra 400mg	1's Vial

	Chugai Pharma Manufacturing Co., Ltd., 16-3, Kiyohara Kogyodanchi, Utsunomiya-city, Tochigi, Japan	(Concentrate for Solution for Infusion) Each vial(20ml) contains: Tocilizumab (Genetical Recombination)…….400 mg	

Now, the firm submitted that Actemra is in extremely high-demand throughout the world, their global supply chain is unable to fulfil the demands of many international markets from the existing manufacturing facility (Chugai Pharma Manufacturing Co Ltd, 16-3 Kiyohara-Kogyodanchi, Utsunomiya, Japan). Therefore, Roche has initiated the production of additional batches of Actemra 400mg vial in their Genentech's Hillsboro (HTO) site, located at 4625 NE Brookwood Parkway, Hillsboro, OR97124, United States. The firm has requested to grant the permission to import Actemra 400mg/20ml from M/s Genetech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA. Moreover, the new site has already been approved for another product Herceptin 440mg (Reg. No. 032130) in 276th meeting of Registration Board.

Decision: **Registration Board deliberated the case in the light of prevailing COVID-19 emergency situation, shortage of availability of Actemra from already approved manufacturing site and approvals of EMA & USFDA for additional site & new container closure system and decided as under:**

a. **Approved the addition of M/s Genetech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA as manufacturing Site for Actemra 400mg/20ml (Reg. No. 083136)**
b. **Approved the addition of new container closure system wherein the vials will be shorter and wider compared to the commercial material and the vial cap is dark blue instead of red.**
c. **Complete import, sale and supply record shall be maintained and will be provided if required by DRAP.**
d. **The shelf life of the product manufactured at Hillsboro site shall be 06 months.**

This permission shall be valid for nine (09) months from the date of issuance of approval letter.

Item No. III Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Evaluator PEC-I (Mr. Farooq Aslam)

Evaluator PEC-II (Mr. Ammar Ashraf Awan)

Evaluator PEC-III (Mr. Muhammad Haseeb Tariq)

Evaluator PEC-IV (Ms. Farzana Raja)

Evaluator PEC-V (Ms. Iqra Aftab)

Evaluator PEC-VI (Mr. Umar Latif)

Evaluator PEC-VII (Ms Sidra Khalid)

Evaluator PEC-VIII (Ms. Haleema Sharif)

Evaluator PEC-IX (Mr. Hanifullah)

Evaluator PEC-XI (Mr. Farhadullah)

Evaluator PEC-XII (Ms Saima Hussain)

Evaluator PEC-XIII (Ms Mehwish Javed)

Evaluator PEC-XIV (Mr. Muhammad Ahsan Hafiz)

Evaluator PEC-XII

Case No. 1: Registration of Vitamin-Mineral Formulations

Registration of vitamin-mineral formulations are pending for deliberations and decision regarding consideration as Drug or otherwise. Registration of formulations containing Vitamin-mineral was discussed in 291st meeting of Registration Board and following decision has been taken:

291st Meeting of Registration Board:

Vitamin Policy was placed in 291st meeting of Registration Board and following decision has been taken:

Decision: Registration Board deliberated the decision of the Policy Board and the Authority for Vitamin Policy and decided that:-

i. Those vitamins and minerals above RDA as defined in the Vitamin Policy (18th meeting of Policy Board) will be considered as drug. If any one of the ingredient of multiple ingredient dosage form falls above RDA, it will be considered as a drugs.

ii. Those combinations already having registration in Pakistan and marketing proof of availability of 5-7 years in market with no reported adverse reactions, shall be considered as reference for safety and efficacy of these combinations.

iii. For new combinations, availability in already defined reference regulatory authorities will be considered as a reference.

iv. For already submitted dossier, applicant will be given 3 months time for amendment / correction in their applied formulations in light of above recorded decision and submission of differential fee and registration application.

v. Registration dossiers will be considered on FIFO basis from date of completion of dossiers including all codal formalities.

- In this regard, following is submitted for the consideration of Registration board:
  1. Those Vitamins and minerals above Recommended Daily Allowance (RDA) up to Tolerable upper intake level (UL) may be considered as drug.
  2. If any ingredient in the vitamin and mineral formulation is above UL, then it may allow only, if it is available in already defined Reference Regulatory Agencies, *for intended therapeutic purpose,* otherwise the Firm has to revise its formulation. Furthermore single ingredient vitamins for certain disease conditions may be registered with therapeutic claim as per approved Reference Regulatory Agencies.
  3. Point (ii) of decision of Registration Board needs further deliberation regarding the documents required for consideration as reference.
  4. As per direction given in point (iv) of above mentioned decision of Registration Board, circular has been issued vide letter no. F.291-DRB/2019(PE&R) dated 14th January,2020 for the information/compliance of all Pharmaceutical Manufacturer/Importer of Pakistan.However as per record no such amendment/correction has recived in the given timeline.
  5. Applicant firm shall give reference of conversion of units (e.g. IU to mcg/mg or vice versa) and equivalency in elemental form as required in RDA or UL table.
  6. The pharmaceutical companies shall ensure the availability of requisite manufacturing & testing facilities including atomic absorption spectrophotometer.
  7. Renewal application of already registered drug will be considered in the light of above given submission.

Decision: Registration Board deliberated in detail on the above points and decided to approve following futher points in addition to aforesaid decision of Regisatration Board in its 291st meeting.

1. **Those Vitamins and minerals above Recommended Daily Allowance (RDA) up to Tolerable upper intake level (UL) shall be considered as drug for registration purpose.**

2. **If any ingredient in the vitamin and mineral formulation is above UL, then it shall be allowed only, if it is available in already defined Reference Regulatory Agencies, *for intended therapeutic purpose,* otherwise the applicant firm shall have to revise its formulation in line with RRA.**
3. **Single ingredient vitamin for certain disease conditions shall be registered with therapeutic claim in line with Reference Regulatory Agencies.**
4. **New formulations shall be considered if approved by Reference Regulatory Authorities.**
5. **Multivitamin/minerals injectable shall be registered, if they are approved by Reference Regulatory Authorities.**
6. **Applicant firm shall give reference of conversion of units (e.g. IU to mcg/mg or vice versa) and equivalency in elemental form as required in RDA or UL table.**
7. **The applicant firm shall ensure the availability of requisite manufacturing & testing facilities like atomic absorption spectrophotometer for test purposes.**
8. **For Point (ii) of decision of Registration Board in 291st meeting, following documents will be required for consideration.**
    i. **Name of product, Registration No and composition for confirmation of generic status alongwith unit carton of available formulation..**
    ii. **For Adverse Drug Reaction, Pharmacy Services Division will be approached to provide the data.**
9. **Registration Board noted the information that circular has been issued vide letter no. F.291-DRB/2019(PE&R) dated 14th January,2020 for the information/compliance of all Pharmaceutical Manufacturer/Importer of Pakistan. However as per record, no such amendment/correction has been received in the given timeline. Registration Board extended the timeline for further six month for amendment / correction in the applied formulations from date of issuance of new circular in light of above recorded decision and submission of differential fee and registration application.**
10. **For consideration of renewal application of already registered vitamin-mineral formulations following will be the criteria:**
    i. **All those formulations which are in line with above guidelines will be granted the renewal as per delegation already approved by Registration Board.**
    ii. **In those formulations which donot fulfill the above criteria, cases will be placed before Registration Board for consideration.**

In the light of above, following registration applications of vitamin and mineral formulation have been considered by Regisration Board and decided accordingly as mentioned against each:

1.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals,I-10/3,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Tablets (Effervescent Tablet) Orange Flavor
	Diary No. Date of R& I & fee	(Duplicate Dossier)Dy. No.148 dated 18/03/2009 Rs.8,000/- Differential fee (Photocopy) of Rs.12,000/- submitted on 26/10/2017
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3 …..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O

	Approval Status of Product in Reference Regulatory Authorities	Quantity of vitamin and mineral in the applied formulation is between RDA and UL according to the decision of Registration Board in its 291st meeting.
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too.
	Decision: Deferred as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL). Furthermore Registration Board directed M/s. GSK OTC for justification of existing formulation of CaC-1000 Plus Effervescent Tablet for quantity of Vitamin D3 as it is upper tolerable intake level (UL).	
2.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals,I-10/3,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Sachet (Orange Flavor)
	Diary No. Date of R& I & fee	(Duplicate Dossier)Dy.188 No.dated 19/12/2008 Differential fee (Photocopy) of Rs.12,000/- submitted on 26/10/2017
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Quantity of vitamin and mineral in the applied formulation is between RDA and UL according to the decision of Registration Board in its 291st meeting.
	Me-too Status	CaC-1000 sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
3.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals,I-10/3,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Tablets (Mango Flavor) (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3 …..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations

	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL). Furthermore Registration Board directed M/s. GSK OTC for justification of existing formulation of CaC-1000 Plus Effervescent Tablet for quantity of Vitamin D3 as it is upper tolerable intake level (UL). Application is required to be submitted on Form5F and will be considered on its turn.	
4.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals,I-10/3,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Tablets (Lemon Flavor) (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3 …..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too.
	Decision: Deferred as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL). Furthermore Registration Board directed M/s. GSK OTC for justification of existing formulation of CaC-1000 Plus Effervescent Tablet for quantity of Vitamin D3 as it is upper tolerable intake level (UL). Application is required to be submitted on Form5F and will be considered on its turn.	
5.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals,I-10/3,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Tablets (Cola Flavor**)** (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg

		Vitamin D3 …..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Effervescent Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too.
	Decision: Deferred as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL). Furthermore Registration Board directed M/s. GSK OTC for justification of existing formulation of CaC-1000 Plus Effervescent Tablet for quantity of Vitamin D3 as it is upper tolerable intake level (UL). Application is required to be submitted on Form5F and will be considered on its turn.	
6.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals ,I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Sachet (Lemon Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs.20,000/-
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3 …..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and then submission on requiste form and will be considered on turn.	
7.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals ,I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Sachet (Mango Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs.20,000/-
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg

		Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3 …..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GlaxoSmithKline OTC (Pvt.) Ltd., Petaro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 2. Application is received on Form-5 instead of Form 5-F. 3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and then submission on requiste form and will be considered on turn.	
8.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals,I-10/3,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Sachet (Cola Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6423 dated 08/04/2020 Rs.20,000/-
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and then submission on requiste form and will be considered on turn.	
9.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals,I-10/3,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH-C 1000 Sugar Free Sachet
	Diary No. Date of R& I & fee	(Duplicate Dossier)Dy. No.1606 dated 18/01/2011

		Differential Fee (Photocopy) of Rs.12,000/- submitted by the firm dated 08/04/2020
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	Calvin-C 500 Sachets by M/s. Bloom Pharmaceuticals
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of Evaluator.AD(PEC-XII)	
	Decision: Approved with innovator's specificatins. Fee shall be verified as per procedure adopted in 285th meeting.	
10.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals,I-10/3,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	CALTAB-D TABLET (CHEWABLE TABLET SUGAR FREE) (Mix Fruit Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6420 Dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Carbonate….1250mg Vitamin D3…..125IU
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's, 20's & 30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	Qalsan D Chewable Tablet by M/s. GSK OTC (Pvt.) Ltd., Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Firm applied with manufacturer specifications while the me-too product has given the Registration with USP Specifications. However the product is non-Pharmacopeial.
	Decision: Deferred for submission of application on Form 5-F and consideration on turn.	
11.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	CALTAB-D TABLET (CHEWABLE TABLET SUGAR FREE) (Mango Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6421 Dated 08/04/2020 Rs 20,000/-
	Composition	Each tablet contains: Calcium Carbonate….1250mg Vitamin D3…..125IU
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's, 20's & 30's
	Approval Status of Product in Reference Regulatory Authorities	…..

	Me-too Status	Qalsan D Chewable Tablet by M/s. GSK OTC (Pvt.) Ltd., Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5F. 2. Firm applied with manufacturer specifications while the me-too product has given the Registration with USP Specifications. However the product is non-Pharmacopeial.
	Decision: Deferred for submission of application on Form 5-F and consideration on turn.	
12.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Nutrition-Z Tablet
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No.398 Dated 01/11/2011 Rs.8,000/- Differential fee (Photocopy) of Rs.12,000/- has been submitted on 08/04/2020
	Composition	Each tablet contain: Zinc (As Zinc Sulphate)…22.5mg Tocopherol (Vitamin E)…..30IU Ascorbic Acid (Vitamin C)….500mg Folic Acid…..150mcg Thiamine HCl (Vitamin B1)….15mg Riboflavin (Vitamin B2)…..15mg Nicotinamide…..100mg Pyridoxine HCl (Vitamin B6)…..20mg Cyanocobalamin(Vitamin B12)….12mcg Pantothenic Acid (as Calcium Pantothenate)….20mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10’s, 20’s & 30’s
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	Surbex-Z Tablet by M/s. Abbott Laboratories
	GMP Status	Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.
	Remarks of Evaluator. AD(PEC-XII)	
	Decision: Approved with innovator’s specificatins. Fee shall be verified as per procedure adopted in 285th meeting.	
13.	Name and address of manufacturer / Applicant	M/s. Wilson’s Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Tablet (Effervescent Tablet) (orange Flavor)
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No.157 Dated 18/03/2009 Rs.8,000/- Differential fee (photocopy) of Rs.12,000/- has been submitted on 26/10/2017
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3 …..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10’s
	Approval Status of Product in Reference Regulatory Authorities	…..

	Me-too Status	CaC-1000 Plus Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator. AD(PEC-XII)	Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL). Furthermore Registration Board directed M/s. GSK OTC for justification of existing formulation of CaC-1000 Plus Effervescent Tablet for quantity of Vitamin D3 as it is upper tolerable intake level (UL). Application is required to be submitted on Form5F and will be considered on its turn.	
14.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical,I-9,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Sachet (Orange Flavor)
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No…..dated 19/12/2008 Rs.8,000/- Differential fee (Photocopy) of Rs.12,000/- submitted on 26/20/2017
	Composition	Each Sachet contains: Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator. AD(PEC-XII)	1. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. **2.** Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and then submission on requiste form and will be considered on turn.	
15.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical,I-9,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Tablet (Mango Flavor) (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6415 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification

	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL). Furthermore Registration Board directed M/s. GSK OTC for justification of existing formulation of CaC-1000 Plus Effervescent Tablet for quantity of Vitamin D3 as it is upper tolerable intake level (UL). Application is required to be submitted on Form5F and will be considered on its turn.	
16.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical,I-9,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Tablet (Lemon Flavor) (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6413 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too.
	Decision: Deferred as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL). Furthermore Registration Board directed M/s. GSK OTC for justification of existing formulation of CaC-1000 Plus Effervescent Tablet for quantity of Vitamin D3 as it is upper tolerable intake level (UL). Application is required to be submitted on Form5F and will be considered on its turn.	
17.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical,I-9,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Tablet (Cola Flavor) (Effervescent Tablet)
	Diary No. Date of R& I & fee	Dy. No. 6414 dated 08/04/2020 Rs.20,000/-
	Composition	Each tablet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg

	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's,20's &30's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Plus Tablet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred as the quantity of Vitamin D3 used in the composition is above upper tolerable intake level (UL). Furthermore Registration Board directed M/s. GSK OTC for justification of existing formulation of CaC-1000 Plus Effervescent Tablet for quantity of Vitamin D3 as it is upper tolerable intake level (UL). Application is required to be submitted on Form5F and will be considered on its turn.	
18.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical,I-9,Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Sachet (Lemon Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6417 dated 08/04/2020 Rs.20,000/-
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Form 5-F. 2. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and then submission on requiste form and will be considered on turn.	
19.	Name and address of manufacturer / Applicant	M/s. Wilson's Pharmaceutical, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Calcee-D Sachet (Cola Flavor)
	Diary No. Date of R& I & fee	Dy. No. 6416 dated 08/04/2020 Rs.20,000/-
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg

		Vitamin C (Ascorbic Acid)…..500mg Vitamin D3…..4mg Vitamin B6…..10mg
	Pharmacological Group	Vitamin and mineral formulations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O & Pack: 10's
	Approval Status of Product in Reference Regulatory Authorities	…..
	Me-too Status	CaC-1000 Sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road,Jamshoro
	GMP Status	Last inspection report dated 24/01/2018, by Area FID rated the firm operating at a very good level of GMP compliance.
	Remarks of the Evaluator. AD(PEC-XII)	1. Application is received on Form-5 instead of Forssm 5F. 2. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition. 3. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and then submission on requiste form and will be considered on turn.	
20.	Name and address of manufacturer / Applicant	M/s.Genix Pharma (Private) Limited 44,45-B,Korangi Creek Road, Karachi
	Brand Name +Dosage Form + Strength	Viltplex Tablet
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.No.393 dated 30/4/2011 Rs.8,000/- Differential fee (Photocopy) of Rs.42,000/-submitted on 02/09/2015
	Composition	Each tablet contains: Vitamin A (29% as Beta Carotene)…..3500IU Vitamin C (as Ascorbic Acid)….60mg Vitamin D (as Cholecalciferol)…..1000IU Vitamin E (as D-Alpha Tocophenyl Acetate)….30IU Vitamin K (as Phytonadione)….25mg Thiamin (as Thiamine Mononitrate)….1.5mg Riboflavin….1.7mg Niacin (as Niacinamide)…..20mg Vitamin B6 (as Pyridoxine HCl)….2mg Folic Acid….400mcg Vitamin B12 (as Cyanocobalmine)….6mcg Biotin……30mcg Pantothenic acid (as Calcium Pantothenate)…10mg Calcium (as Calcium Carbonate)…200mg Iron (as Ferrous Fumarate)….18mg Phosphorus (as Di Basic Calcium Phosphate)…20mg Iodine (as Potassium Iodide)….150mcg Magnesium (as Magnesium Oxide)….50mg Zinc (as Zinc Oxide)….11mg Selenium (as Sodium Selenate)…..55mcg Copper (as cupric Sulphate)….0.5mg Manganese (as Manganeese Sulphate)….2.3mg Chromium (as Chromium Picolinate)….35mcg Molybdenum (as Sodium Molybdate)…..45mcg Chloride (as Potassium Chloride)….72mg Potassium (as Potassium Chloride)….80mg Nickel (as Nickelous Sulphate)……5mcg

		Silicon (as Silicon Dioxide)…2mg Vanadium (as Sodium Metavanadate)…..10mcg Tin (as Stannous Chloride)…..10mcg
	Pharmacological Group	Vitamin and mineral Supplements
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Firm provide the evidence of Centrum Tablet Wyeth Pharma, USA which could not be verified.
	Me-too Status	Firm did not provide the evidence of me too product
	GMP Status	Last inspection report dated 10/04/2019, by Area FID rated the firm operating at an acceptable level of compliance with cGMP guidelines.
	Remarks of the Evaluator and Response of the Firm AD(PEC-XII)	• Evidence of Me Too product which are already registered in Pakistan is required to be submitted by the firm or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required. • Firm in their reply stated that Centrum is a brand of multivitamins produced by Pfizer (formerly Wyeth).Centrum is worldwide available product, further internationally vitamins are not treated as drug it comes under food supplements. Firm also submitted the reference of TGA Australia. • Reference of TGA Australia, as provided by the firm has different composition.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-277) in case of new combination OR Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
21.	Name and address of manufacturer / Applicant	M/s.Genix Pharma (Private) Limited 44,45-B,Korangi Creek Road, Karachi
	Brand Name +Dosage Form + Strength	Viltplex Ultra Men's Tablet
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.No.390 dated 30/4/2011 Rs.8,000/- Differential fee(photocopy) of Rs.42,000/-submitted on 02/09/2015
	Composition	Each tablet contains: Vitamin A (29% as Beta Carotene)…..3500IU Vitamin C (as Ascorbic Acid)….90mg Vitamin D (as Cholecalciferol)…..1000IU Vitamin E (as D-Alpha Tocophenyl Acetate)….451IU Vitamin K (as Phytonadione)….60mcg Thiamin (as Thiamine Mononitrate)….1.2mg Riboflavin….1.3mg Niacin (as Niacinamide)…..16mg Vitamin B6 (as Pyridoxine HCl)…..2mg Folic Acid….200mcg Vitamin B12 (as Cyanocobalmine)….6mcg Biotin……40mcg Pantothenic acid (as Calcium Pantothenate)…15mg Calcium (as Calcium Carbonate)…210mg Iron (as Ferrous Fumarate)….8mg Phosphorus (as Di Basic Calcium Phosphate)…20mg Iodine (as Potassium Iodide)….150mcg Magnesium (as Magnesium Oxide)….100mg Zinc (as Zinc Oxide)….11mg Selenium (as Sodium Selenate)…..100mcg

		Copper (as cupric Sulphate)….0.9mg Manganese (as Manganeese Sulphate)….2.3mg Chromium (as Chromium Picolinate)….35mcg Molybdenum (as Sodium Molybdate)…..50mcg Chloride (as Potassium Chloride)….72mg Potassium (as Potassium Chloride)….80mg Nickel (as Nickelous Sulphate)……5mcg Silicon (as Silicon Dioxide)…2mg Vanadium (as Sodium Metavanadate)…..10mcg Tin (as Stannous Chloride)…..10mcg Lycopene…..600mcg
	Pharmacological Group	Vitamin and mineral Supplements
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Centrum Ultra Men's Tablet by Wyeth Pharma USA, which could not be verified.
	Me-too Status	Firm did not provide the evidence of Me-Too product.
	GMP Status	Last inspection report dated 10/04/2019, by Area FID rated the firm operating at an acceptable level of compliance with cGMP guidelines.
	Remarks of the Evaluator. AD(PEC-XII)	• Evidence of Me Too product which are already registered in Pakistan is required to be submitted by the firm or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required. • Firm in their reply stated that Centrum is a brand of multivitamins produced by Pfizer (formerly Wyeth).Centrum is worldwide available product, further internationally vitamins are not treated as drug it comes under food supplements. Firm also submitted the reference of TGA Australia. • Reference of TGA Australia, as provided by the firm has different composition.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-277) in case of new combination OR Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
22.	Name and address of manufacturer / Applicant	M/s.Genix Pharma (Private) Limited 44,45-B,Korangi Creek Road, Karachi
	Brand Name +Dosage Form + Strength	Viltplex Performance Tablet
	Diary No. Date of R& I & fee	(Duplicate Dossier)Dy.No.394 dated 30/04/2011 Rs.8,000/- Differential fee (Photocopy) of Rs.42,000/-submitted on 02/09/2015
	Composition	Each tablet contains: Vitamin A (29% as Beta Carotene)…..800mcg Vitamin C (as Ascorbic Acid)….120mg Vitamin D (as Cholecalciferol)….5mcg Vitamin E (as D-Alpha Tocophenyl Acetate)….26.8mg Vitamin K (as Phytonadione)….25mcg Thiamin (as Thiamine Mononitrate)….4.2mg Riboflavin…..4.8mg Niacin (as Niacinamide)……36mg Vitamin B6 (as Pyridoxine HCl)…..6mg Folic Acid….400mcg Vitamin B12 (as Cyanocobalmine)….18mcg Biotin……40mcg

		Pantothenic acid (as Calcium Pantothenate)…10mg Iron (as Ferrous Fumarate)….14mg Iodine (as Potassium Iodide)….150mcg Zinc (as Zinc Oxide)….7.5mg Selenium (as Sodium Selenate)…..70mcg Copper (as cupric Sulphate)….700mcg Manganese (as Manganeese Sulphate)…..4mg Chromium (as Chromium Picolinate)….120mcg Molybdenum (as Sodium Molybdate)…..75mcg Ginkgo Biloba…..60mcg Ginseng Extract…..50mg
	Pharmacological Group	Vitamin and mineral Supplements
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Centrum Performance Tablet by Wyeth Pharma USA, which could not be verified.
	Me-too Status	Firm did not provide evidence of Me-Too product.
	GMP Status	Last inspection report dated 10/04/2019, by Area FID rated the firm operating at an acceptable level of compliance with cGMP guidelines.
	Remarks of the Evaluator. AD(PEC-XII)	• Evidence of Me Too product which are already registered in Pakistan is required to be submitted by the firm, or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required. • Firm in their reply stated that Centrum is a brand of multivitamins produced by Pfizer (formerly Wyeth).Centrum is worldwide available product, further internationally vitamins are not treated as drug it comes under food supplements. Firm also submitted the reference of TGA Australia. • Reference of TGA Australia, as provided by the firm has different composition.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-277) in case of new combination OR Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
23.	Name and address of manufacturer / Applicant	M/s. Genix Pharma (Private) Limited 44,45-B,Korangi Creek Road, Karachi
	Brand Name +Dosage Form + Strength	Viltplex Silver Ultra Women Tablets
	Diary No. Date of R& I & fee	(Duplicate Dossier)Dy.No.391 dated 30/4/2011 Rs.8,000/- Differential fee (Photocopy) of Rs.42,000/-submitted on 02/09/2015
	Composition	Each tablet contains: Vitamin A (43% as Beta Carotene)…..3500IU Vitamin C (as Ascorbic Acid)….100mg Vitamin D (as Cholecalciferol)….1000IU Vitamin E (as D-Alpha Tocophenyl Acetate)….35IU Vitamin K (as Phytonadione)…..50mcg Thiamin (as Thiamine Mononitrate)…..1.1mg Riboflavin……1.1mg Niacin (as Niacin amide)……14mg Vitamin B6 (as Pyridoxine HCl)…..5mg Folic Acid….400mcg Vitamin B12 (as Cyanocobalamin)….50mcg Biotin……30mcg

		Pantothenic acid (as Calcium Pentothenate)…5mg Calcium (as Calcium Carbonate)……300mg Iron (as Ferrous Fumarate)…..8mg Phosphorus(as Di Basic Calcium Phosphate)…20mg Iodine (as Potassium Iodide)….150mcg Magnesium (as Magnesium Oxide)…..100mg Zinc (as Zinc Oxide)…..15mg Selenium (as Sodium Selenite)…..22mcg Copper (as cupric Sulphate)….0.5mcg Manganese (as Manganese Sulphate)…..2.3mg Chromium (as Chromium Picolinate)…..52mcg Molybdenum (as Sodium Molybdate)…..50mcg Chloride (as Potassium Chloride)….72mg Potassium (as Potassium Chloride)….80mg Nickel (as Nickelous Sulphate)……5mcg Silicon (as Silicon Dioxide)…2mg Vanadium (as Sodium Metavanadate)…..10mcg Lutein….300mcg
	Pharmacological Group	Vitamin and mineral Supplements
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Centrum Silver Ultra Women's Tablet by Wyeth Pharma USA, which could not be verified.
	Me-too Status	Firm did not provide evidence of Me-Too product.
	GMP Status	Last inspection report dated 10/04/2019, by Area FID rated the firm operating at an acceptable level of compliance with cGMP guidelines.
	Remarks of the Evaluator. AD(PEC-XII)	• Evidence of Me Too product which are already registered in Pakistan is required to be submitted by the firm, or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required. • Firm in their reply stated that Centrum is a brand of multivitamins produced by Pfizer (formerly Wyeth).Centrum is worldwide available product, further internationally vitamins are not treated as drug it comes under food supplements. Firm also submitted the reference of TGA Australia. • Reference of TGA Australia, as provided by the firm has different composition.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-277) in case of new combination OR Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
24.	Name and address of manufacturer / Applicant	M/s. Genix Pharma (Private) Limited 44,45-B,Korangi Creek Road, Karachi
	Brand Name +Dosage Form + Strength	Viltplex Silver Ultra Men Tablets
	Diary No. Date of R& I & fee	(Duplicate Dossier)Dy.No. 392 dated 30/4/2011 Rs.8,000/- Differential fee(photocopy)of Rs.42,000/-submitted on 02/09/2015
	Composition	Each tablet contains: Vitamin A (29% as Beta Carotene)…..3500IU Vitamin C (as Ascorbic Acid)….120mg Vitamin D (as Cholecalciferol)….1000IU Vitamin E (as D-Alpha Tocophenyl Acetate)….60IU Vitamin K (as Phytonadione)…..60mcg

		Thiamin (as Thiamine Mononitrate)…..1.5mg Riboflavin……1.7mg Niacin (as Niacin amide)……20mg Vitamin B6 (as Pyridoxine HCl)…..6mg Folic Acid….300mcg Vitamin B12 (as Cyanocobalamin)….100mcg Biotin……30mcg Pantothenic acid (as Calcium Pentothenate)…10mg Calcium (as Calcium Carbonate)……210mg Phosphorus(as Di Basic Calcium Phosphate)…20mg Iodine (as Potassium Iodide)….150mcg Magnesium (as Magnesium Oxide)…..75mg Zinc (as Zinc Oxide)…..15mg Selenium (as Sodium Selenite)…..21mcg Copper (as cupric Sulphate)….0.5mcg Manganese (as Manganese Sulphate)…..4mg Chromium (as Chromium Picolinate)…..60mcg Molybdenum (as Sodium Molybdate)…..50mcg Chloride (as Potassium Chloride)….72mg Potassium (as Potassium Chloride)….80mg Nickel (as Nickelous Sulphate)……5mcg Silicon (as Silicon Dioxide)…2mg Vanadium (as Sodium Metavanadate)…..10mcg Lutein….300mcg Lycopene……600mcg
	Pharmacological Group	Vitamin and mineral Supplements
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Centrum Silver Ultra Men's Tablet by Wyeth Pharma USA, which could not be verified.
	Me-too Status	Firm did not provide evidence of Me-Too product
	GMP Status	Last inspection report dated 10/04/2019, by Area FID rated the firm operating at an acceptable level of compliance with cGMP guidelines.
	Remarks of the Evaluator. AD(PEC-XII)	• Evidence of Me Too product which are already registered in Pakistan is required to be submitted by the firm, or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required. • Firm in their reply stated that Centrum is a brand of multivitamins produced by Pfizer (formerly Wyeth).Centrum is worldwide available product, further internationally vitamins are not treated as drug it comes under food supplements. Firm also submitted the reference of TGA Australia. • Reference of TGA Australia, as provided by the firm has different composition.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-277) in case of new combination OR Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
25.	Name and address of manufacturer / Applicant	M/s. Genix Pharma (Private) Limited 44,45-B, Korangi Creek Road, Karachi
	Brand Name +Dosage Form + Strength	Viltplex Kids Complete Tablets
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.No.397dated 30/04/2011 Rs.8,000/- Differential fee (photocopy)of Rs.42,000/-submitted on

		02/09/2015
	Composition	Each tablet contains: Vitamin A (53% as Beta Carotene)…..1500IU Vitamin C (as Ascorbic Acid)….60mg Vitamin D (as Cholecalciferol)….400IU Vitamin E (as D-Alpha Tocophenyl Acetate)….13.5IU Vitamin K (as Phytonadione)…..10mcg Thiamin (as Thiamine Mononitrate)…..1.5mg Riboflavin……1.7mg Niacin (as Niacin amide)……20mg Vitamin B6 (as Pyridoxine HCl)…..2mg Folic Acid….400mcg Vitamin B12 (as Cyanocobalamin)….6mcg Biotin……45mcg Pantothenic acid (as Calcium Pentothenate)…10mg Calcium (as Calcium Carbonate)……108mg Iron (as Ferrous Fumarate)….18mg Phosphorus(as Di Basic Calcium Phosphate)…50mg Iodine (as Potassium Iodide)….150mcg Magnesium (as Magnesium Oxide)…..40mg Zinc (as Zinc Oxide)…..15mg Copper (as cupric Sulphate)….2g Manganese (as Manganese Sulphate)…..1mg Chromium (as Chromium Picolinate)…..20mcg Molybdenum (as Sodium Molybdate)…..20mcg
	Pharmacological Group	Vitamin and mineral Supplements
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Centrum Kids complete Tablet by Wyeth Pharma USA, which could not be verified.
	Me-too Status	Firm did not provide evidence of Me-Too
	GMP Status	Last inspection report dated 10/04/2019, by Area FID rated the firm operating at an acceptable level of compliance with cGMP guidelines.
	Remarks of the Evaluator. AD(PEC-XII)	• Evidence of Me Too product which are already registered in Pakistan is required to be submitted by the firm or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required. • Firm in their reply stated that Centrum is a brand of multivitamins produced by Pfizer (formerly Wyeth).Centrum is worldwide available product, further internationally vitamins are not treated as drug it comes under food supplements. Firm also submitted the reference of TGA Australia. • Reference of TGA Australia, as provided by the firm has different composition.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-277) in case of new combination OR Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
26.	Name and address of manufacturer / Applicant	M/s. Genix Pharma (Private) Limited 44,45-B,Korangi Creek Road, Karachi
	Brand Name +Dosage Form + Strength	Viltplex Silver Tablets
	Diary No. Date of R& I & fee	**(**Duplicate Dossier) Dy.No.398 dated 30/4/2011 Rs.8,000/- submitted

		Differential fee (photocopy)of Rs.42,000/-submitted on 02/09/2015
	Composition	Each tablet contains: Vitamin A (40% as Beta Carotene)…..2500IU Vitamin C (as Ascorbic Acid)….60mg Vitamin D (as Cholecalciferol)….1000IU Vitamin E (as D-Alpha Tocophenyl Acetate)….50IU Vitamin K (as Phytonadione)…..30mcg Thiamin (as Thiamine Mononitrate)…..1.5mg Riboflavin……1.7mg Niacin (as Niacin amide)……20mg Vitamin B6 (as Pyridoxine HCl)…..3mg Folic Acid….400mcg Vitamin B12 (as Cyanocobalamin)….25mcg Biotin……30mcg Pantothenic acid (as Calcium Pentothenate)…10mg Calcium (as Calcium Carbonate)……220mg Phosphorus(as Di Basic Calcium Phosphate)…20mg Iodine (as Potassium Iodide)….150mcg Magnesium (as Magnesium Oxide)…..50mg Zinc (as Zinc Oxide)…..11mg Selenium (as Sodium Selenite)…..19mcg Copper (as cupric Sulphate)….0.5mg Manganese (as Manganese Sulphate)…..2.3mg Chromium (as Chromium Picolinate)…..50mcg Molybdenum (as Sodium Molybdate)…..45mcg Chloride (as Potassium Chloride)….72mg Potassium (as Potassium Chloride)….80mg Nickel (as Nickelous Sulphate)……5mcg Silicon (as Silicon Dioxide)…2mg Vanadium (as Sodium Metavanadate)…..10mcg Lutein….250mcg Lycopene……300mcg
	Pharmacological Group	Vitamin and mineral Supplements
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Centrum Silver Tablet by Wyeth Pharma USA, which could not be verified.
	Me-too Status	Firm did not provide evidence of Me-Too product
	GMP Status	Last inspection report dated 10/04/2019, by Area FID rated the firm operating at an acceptable level of compliance with cGMP guidelines.
	Remarks of the Evaluator. AD(PEC-XII)	• Evidence of Me Too product which are already registered in Pakistan is required to be submitted by the firm, or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required. • Firm in their reply stated that Centrum is a brand of multivitamins produced by Pfizer (formerly Wyeth).Centrum is worldwide available product, further internationally vitamins are not treated as drug it comes under food supplements. Firm also submitted the reference of TGA Australia. • Reference of TGA Australia, as provided by the firm has different composition.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory	

	authorities/agencies which were declared/approved by the Registration Board (M-277) in case of new combination OR Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
27.	Name and address of manufacturer / Applicant	M/s. Genix Pharma (Private) Limited 44,45-B,Korangi Creek Road, Karachi
	Brand Name +Dosage Form + Strength	Viltplex Cardio Tablets
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.No.396 dated 30/04/2011 Rs.8,000/- submitted. Differential fee (photocopy)of Rs.42,000/-submitted on 02/09/2015
	Composition	Each tablet contains: Vitamin A (29% as Beta Carotene)…..1750IU Vitamin C (as Ascorbic Acid)….30mg Vitamin D (as Cholecalciferol)….200IU Vitamin E (as D-Alpha Tocophenyl Acetate)….15IU Vitamin K (as Phytonadione)…..12.5mcg Thiamin (as Thiamine Mononitrate)…..0.75mg Riboflavin……0.85mg Niacin (as Niacin amide)……10mg Vitamin B6 (as Pyridoxine HCl)…..2.5mg Folic Acid….200mcg Vitamin B12 (as Cyanocobalamin)….100mcg Biotin……15mcg Pantothenic acid (as Calcium Pentothenate)….5mg Calcium (as Calcium Carbonate)……54mg Iron (as Ferrous Fumarate)…..3mg Phosphorus(as Di Basic Calcium Phosphate)…40mg Iodine (as Potassium Iodide)….75mcg Magnesium (as Magnesium Oxide)…..20mg Zinc (as Zinc Oxide)…..3.75mg Selenium (as Sodium Selenite)…..10mcg Copper (as cupric Sulphate)….0.35mg Manganese (as Manganese Sulphate)…..1mg Chromium (as Chromium Picolinate)…..60mcg Molybdenum (as Sodium Molybdate)…..37.5mcg Chloride (as Potassium Chloride)….29mg Potassium (as Potassium Chloride)….32mg Boron…….16mcg Nickel (as Nickelous Sulphate)……2.5mcg Tin (as stannous Chloride)….5mcg Vanadium (as Sodium Metavanadate)…..5mcg Phytosterols….400mcg Lycopene……300mcg
	Pharmacological Group	Vitamin and mineral Supplements
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specification
	Pack Size & Demanded Price	As per S.R.O
	Approval Status of Product in Reference Regulatory Authorities	Centrum Cardio Tablet by Wyeth Pharma USA, which could not be verified.
	Me-too Status	Firm did not provide evidence of Me-Too product.
	GMP Status	Last inspection report dated 10/04/2019, by Area FID rated the firm operating at an acceptable level of compliance with cGMP guidelines.
	Remarks of the Evaluator. AD(PEC-XII)	• Evidence of Me Too product which are already registered in Pakistan is required to be submitted by the firm, or in case of new combination evidence of availability of formulation in Reference Regulatory Authorities is required.

		• Firm in their reply stated that Centrum is a brand of multivitamins produced by Pfizer (formerly Wyeth).Centrum is worldwide available product, further internationally vitamins are not treated as drug it comes under food supplements. Firm also submitted the reference of TGA Australia. • Reference of TGA Australia, as provided by the firm has different composition.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-277) in case of new combination OR Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
28.	Name and address of Manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	Multibar Tablet
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.No. 12332 Dated : 06/03/2019 Rs.20,000/-
	Composition	Each film coated tablet contains: Vitamin A ….4000 IU Beta Carotene ….1000 IU Vitamin D …..400 IU Vitamin E ….30 IU Vitamin C ….90mg Vitamin B1….3mg Vitamin B2….3.4mg Vitamin B6…..3mg Vitamin B12….9mcg Pantothenic Acid…..10mg Folic Acid …..0.4mg Biotin….30mcg Niacin…..20mg Iron…….27mg Calcium……40mg Phosphorus…..31mg Iodine……150mcg Magnesium…..100mg Copper…..2mg Zinc…..15mg Manganese…..5mg Selenium…..10mcg Molybdenum……15mcg Chromium…..15mcg Potassium…..7.5mg Chloride…….7.5mg
	Pharmacological Group	Vitamin and Mineral Formulation
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	30's; Rs. 630/- 60's ; Rs. 1260/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Theragran Ultra, GSK
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	• Quantity of iodine used in Me-Too is 150mg while the firm used 150mcg, clarification required from the firm in this regard.

		• In USP Monograph assay of chloride is not included, so justification is required for using USP specs. • Firm submitted the evidence QC Equipment list which is the part of DML renewal inspection report and list includes Atomic Absorption Spectrophotometer duly signed by the concerned DRAP Officer.
	Decision: Deferred for consideration of application on its turn.	
29.	Name and address of Manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	Multiwel Tablet
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy No.12334 (06 /3/2019) Rs. 20,000/-
	Composition	Each tablet contains: Vitamin A….800mcg (2667 IU) Vitamin D….. 5mcg (200 IU) Vitamin E ….10mg Vitamin C…..60mg Thiamin (Vitamin B1)…..1.4mg Riboflavin (Vitamin B2) …..1.6mg Niacin…..18mg Pyridoxine (Vitamin B6)….. 2mg Vitamin B12….1mcg Folacin (Folic acid)…..200mcg Biotin …..0.15mg Pantothenic acid…..6mg Calcium…..80mg Iron…..14mg Magnesium…..50mg Zinc…..7.5mg Iodine …..150mcg Chromium…..25mcg Selenium…..25mcg
	Pharmacological Group	Vitamins and Minerals formulation
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	30's; Rs. 225/- 45's ; Rs. 350/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Revitale, GSK,
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	Firm submitted the evidence QC Equipment list which is the part of DML renewal inspection report and list includes Atomic Absorption Spectrophotometer duly signed by the concerned DRAP Officer.
	Decision: Deferred for consideration of application on its turn.	
30.	Name and address of Manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	Z-Grow Tablet
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.No.13611 (07/03/2019) Rs.20,000/-
	Composition	Each film coated tablet contains: Zinc USP (as zinc Sulphate)….22.5mg Vitamin E….30IU Vitamin C….500mg Folic acid…..150mcg

		Vitamin B1…..15mg Vitamin B2….15mg Nicotinamide….100mg Vitamin B6….20mg Vitamin B12….12mcg Pantothenic acid USP (as calcium Pantothenate)….20mg
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	20's; Rs. 240/- 30's; Rs. 350/- 60's ; Rs. 700/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Surbex-Z, Abbott Laboratories
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	Firm submitted the evidence QC Equipment list which is the part of DML renewal inspection report and list includes Atomic Absorption Spectrophotometer duly signed by the concerned DRAP Officer.
	Decision: Deferred for consideration of application on its turn.	
31.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	Nutrabar Syrup
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy No.7498 (04/07/2017) Rs.20,000/-
	Composition	Each 4ml contains: Thiamine HCl (B1) USP ….2.0mg Riboflavin (B2)…. BP 2.0mg Niacinamide USP …..10.0mg Pyridoxine HCl (B6) USP…. 0.2mg Pantothenic acid (as D-Panthenol USP) ….2.0mg Choline USP ….20.0mg Inositol USP …..10.0mg Vitamin B12 USP …..5.0mcg
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications.
	Pack size & Demanded Price	120 ml; Rs. 80/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	……..
	Me-too status	Lederplex, Wyeth
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	In Me-too choline is used in the form of Choline Dihydrogen citrate, while the COA submitted by the firm mentioned that choline is in the form of L+Choline Bitartrate.
	Decision: Deferred for revision/correction of salt form of choline from L-Choline Bitartrate to Choline Dihydrogen citrate as per generic product along with submission of revised Form 5 and applicable fee.	
32.	Name and address of Manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	Lysobar Syrup
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy No. 3448 (22 /05/2017) Rs.20,000/-
	Composition	Each 5ml contains: Thiamine HCl ….4.16mg

		Riboflavin….1.66mg Pyridoxine HCl …..1mg Niacinamide…..18.0mg D-Panthenol….2.5mg Cyanocobalamine….8.33mcg Ascorbic Acid…..75mg Inositol…..5mg Lysine Monohydrochloride……33.33mg
	Pharmacological Group	Vitamins and Amino Acid Formulation
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications.
	Pack size & Demanded Price	120 ml; Rs. 100/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	…….
	Me-too status	Lysovit Syrup, Pfizer
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	
	Decision: Approved with innovator's specificatins. Fee shall be verified as per decision of 285th Registration Board meeting	
33.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	V-Day Syrup
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.No.13607 (07/3/2019) Rs.20,000/-
	Composition	Each 10ml contains: Amino acids: Glutamic acid…..3mg L-Lysine…..10mg L-Ornithine …..5mg Methionine…..5mg L-Aspartate…..5mg Calcium……15mg Chromium…..5mcg Cobalt…..25mcg Copper…..1mg Iodine…..50mcg Iron…..10mg Manganese…..2mg Magnesium……30mg Molybdenum…..5mcg Potassium……2mg Selenium…..3mcg Zinc……5mg Vitamin A……0.9mg Vitamin B1…..1.5mg Vitamin B2…..1.2mg Vitamin B6……1mg Vitamin B12…..3mcg Vitamin C……50mg Vitamin D…….10mcg Vitamin E…… 3mg Nicotinamide……10mg Panthenol…….5mg Folic acid…..0.1mg Inositol…….5mg Biotin….50mcg Lecithin …….10mg

		Choline…….10mg
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications.
	Pack size & Demanded Price	120 ml; Rs. 225/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Regnum Syrup by M/s. Novamed Pharma (Pvt.) Ltd.
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	Firm submitted the evidence QC Equipment list which is the part of DML renewal inspection report and list includes Atomic Absorption Spectrophotometer duly signed by the concerned DRAP Officer. In Me-Too product quantity of Iodine is 50 mg which is above UL, while in applied formulation 50mcg of iodine is used.
	Decision: Deferred for consideration of application on its turn.	
34.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	(Duplicate Dossier) Visip-M Syrup
	Diary No. Date of R& I & fee	Dy No.12333Dated :06/03/2019 Rs.20,000/-
	Composition	Each 5 ml contains: Vitamin A….0.9mg (3000 IU) Vitamin D …..10mcg (400 IU) Vitamin B1……1.5mg Vitamin B2…..1.2mg Vitamin C……50mg Nicotinamide……10mg Iron(as ferrous gluconate)…….3mg Iodine (as potassium iodide)……75mcg Calcium(as calcium carbonate & calcium lactate)……..40mg Phosphorus…….43mg Vitamin B6……...1mg Vitamin B12……3mcg Magnesium (as magnesium Gluconate)…. 3mg Panthenol……..5mg Manganese (as manganese Gluconate) ….0.5mg Zinc (as zinc glucoheptonate)…….0.5mg Choline……. 5mg Inositol……. 5mg
	Pharmacological Group	Vitamins and Minerals Formulation
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications.
	Pack size & Demanded Price	120 ml; Rs. 170/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Vidalyin – M Syrup, Abbott Laboratories
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	Firm submitted the evidence QC Equipment list which is the part of DML renewal inspection report and list includes Atomic Absorption Spectrophotometer duly signed by the concerned DRAP Officer.
	Decision: Deferred for consideration of application on its turn.	

35.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	Visip-L Syrup
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy No. 3446 (22.05.2017) Rs. 20,000/-
	Composition	Each 5 ml contains: Vitamin A……0.9mg Vitamin D ……...10mcg Vitamin B1….1.5mg Vitamin B2……1.2mg Vitamin B 6…..1.0mg Vitamin B12…..3.0mcg Vitamin C….50mg Nicotinamide….10mg Choline…….5.0mg Inositol……5.0mg Lysine Monohydrochloride……..300.0mg
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications.
	Pack size & Demanded Price	120 ml; Rs. 150/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Vidalyin – L Syrup, Abbott Laboratories
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	Quantity of vitamin A mentioned on Form-5 is 0.9mcg while the quantity mentioned in master formulation is 0.9mg and same quantity is used in Me-Too product. Correction/ amendment of composition on Form-5 is required. Firm submitted the evidence QC Equipment list which is the part of DML renewal inspection report and list includes Atomic Absorption Spectrophotometer duly signed by the concerned DRAP Officer. Firm submitted the fee of Rs.5,000/- dated 11-06-2020 for the correction of quantity of Vitamin A on Form-5.
	Decision: Deferred for submission of remaining fee for correction in composition.	
36.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	Visip Drops
	Composition	Each 0.6 ml contains: Vitamin A…..1.5mg Vitamin D……10mcg Vitamin B1…..1.5mg Vitamin B2……1.2mg Vitamin C……..50mg Nicotinamide……10mg Vitamin B6……0.5mg
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No. 3447 Dated : 22/05/2017 Rs.20,000/-
	Pharmacological Group	Multivitamins Formulation
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications.
	Pack size & Demanded Price	10 ml; Rs. 80/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	……..
	Me-too status	Vidalyin Drops, Abbott Laboratories

	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	
	Decision: Approved. Fee shall be verified as per decision of 285th Registration Board meeting	
37.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form +Strength	Visip Syrup
	Diary No. Date of R& I & fee	**(**Duplicate Dossier**)**Dy.No. 3650 (23.05.2017) Rs.20,000/-
	Composition	Each 5 ml contains: Vitamin A …..0.9mg Vitamin D……10mcg, Vitamin B1……..1.5mg Vitamin B2…….1.2mg Vitamin B6…..1.0mg Vitamin B12 ….3.0mcg Vitamin C…….50mg Nicotinamide……10mg
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications.
	Pack size & Demanded Price	120 ml; Rs. 100/- or as per DRAP's Pricing Policy
	Approval status of product in Reference Regulatory Authorities	….
	Me-too status	Vidalyin Syrup, Abbott Laboratories
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator AD(PEC-XII)	
	Decision: Approved with innovator's specificatins. Fee shall be verified as per decision of 285th Registration Board meeting	
38.	Name and address of manufacturer / Applicant	AJM Pharma, Plot No. 44, sector No. 27 korangi Inustrial Area Karachi
	Brand Name +Dosage Form + Strength	Uspan-D Tablet
	Diary No. Date of R& I & fee	Dy. No. 1289 dated 03/05/2017 Re. 20,000/-
	Composition	Each film coated tablet contains: Vitamin D……..400 IU Ossein mineral complex……830mg corresponding to; Calcium……..177.6mg Phosphorus…….....82.2mg Residual mineral salts……24.9mg Collagen…….224mg Other proteins…….66.4mg Trace elements (F, Mg, Fe, Zn, Cu, Ni) corresponding to 440mg of hydroxyapatite
	Pharmacological Group	Mineral complex/vitamin
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	Rs. 225/- per pack of 3×10's
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Ossopan 800 Tablets by M/s Eli Lilly, Reg. No. 036422
	GMP Status	Same as for the previous case
	Remarks of the Evaluator.	The firm has applied for In-House specifications and the product is not present in available pharmacopoeia (USP, BP,IP, JP). The firm has submitted an undertaking that the atomic absorption spectrophotometer will be purchased before start of manufacturing of the product. Alternate brand names:

		Boni-D Bone Plus
	Previous Decision	Registration Board in its 293rd meeting decided as follows: 1. Evidence of purchase of Atomic Absorption Spectrophotometer. 2. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Remarks of evaluator: AD(PEC-XII)	Firm has provided the evidence of Me-Too product registered in Pakistan from past 5-7 years i.e. Ossopan 800 Tablets by M/s Eli Lilly, Reg. No. 036422
	Decision: Deferred for the evidence of purchase of Atomic Absorption Spectrophotometer.	
39.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals, 13- Km, Lahore.
	Brand Name +Dosage Form + Strength	Dewcal Sachet
	Composition	Each sachet contains: Calcium Lactate Gluconate……1000mg Vitamin C ……....500mg Calcium Carbonate…….……..327mg
	Diary No. Date of R& I & fee	Dy. No. 9046, 28-09-2016;Rs.20,000 (28-09-2016)
	Pharmacological Group	Calcium Supplement with high potency Vitamin C
	Type of Form	Form -5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	----
	Me-too status	ZF-C 1000 Sachet of M/s Zafa, Karachi (Reg. # 070744)
	GMP status	Not provided
	Previous remarks of the Evaluator	• The applied formulation is not available in the reference regulatory authorities as sachet. Instead tablet dosage form is approved in MHRA. • The latest GMP inspection report is not provided by firm. • Letter was issued to the firm on 3rd May, 2018 and reminder has been issued on 10th July, 2018.
	Previous decision	Deferred in 284th DRB meeting for further deliberation.
	Evaluation by PEC	• The applied formulation is non- pharmacopoeial. • Firm has General Sachet section as mentioned in the submitted section approval letter. • Firm has submitted its latest GMP inspection report dated 03-05-2019 and concludes renewal of DML. • The applied formulation is not available in the reference regulatory authorities as sachet. Instead tablet dosage form is approved in MHRA.
	Previous decision	Registration Board in its 291st decided as follows: Deferred as the applied formulation is not available in the reference regulatory authorities as sachet. Instead tablet dosage form is approved in MHRA.
	Evaluation by PEC AD(PEC-XII)	Firm has provided the evidence of Me-Too product ZF-C 1000 Sachet of M/s Zafa, Karachi (Reg. # 070744)
	Decision: Approved with innovator's specificatins.	
40.	Name and address of Manufacturer/ Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Nerin- B Ampoule
	Composition	Each 3 ml ampoule Contains: Thiamine hydrochloride…100mg Pyridoxine hydrochloride… 100mg

		Cyanocobalamin…. 1000mcg
	Diary No. D of R & I & Fee	Dy No. 8933 ; 17-07-17: Rs.20,000
	Pharmacological group	Vitamin Supplement
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specifications
	Pack Size & demanded price	25's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in Germany (as provided by the firm)
	Me-too status	Neurobion of Martin Dow (001486) (pharmaguide)
	GMP Status	GMP Certificate issued on 03-01-2018 with following sections: 1- Tablet section (Non-Antibiotic, Antibiotic & Psychotropic) 2- Capsule Section (Non Antibiotic, Antibiotic & Cephalosporin) 3- Oral Liquid section (Non Antibiotic) 4- Dry powder for oral suspension section(Non Antibiotic, Antibiotic & Cephalosporin) 5- Liquid Inject able section (Vial and Ampoule) (Non Antibiotic,) 6- Dry powder inject able section (Cephalosporin) 7- Cream/ Ointment / Gel (General) 8- Eye Drops (General) 9- Tulle Dressing (General).
	Remarks of Evaluator	
	Previous decision	Registration Board in its 288th meeting decided as under: Deferred for confirmation of approval status of reference regulatory authorities and generic status.
	Evaluation BY PEC AD(PEC-XII)	Firm provide the evidence of Me-too product. Neurobion Injection of M/s.Martin Dow (001485). Product is registered in the name of M/s. P&G Health Germany GmbH (approved in Germany).
	Decision: Approved with innovator's specificatins	
41.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrail Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ossemin-D 830 mg +400 IU Tablets
	Composition	Each Film Coated Tablet Contains: Ossein Mineral Complex……..830mg Corresponding to : Calcium……..177.6mg* Phosphorus……82.2mg* Residual Mineral Salts……24.9mg Collagen ……224mg Other Proteins……66.4mg Trace elements…….FI, Mg, Fe, Zn, Cu, and Ni. *Corresponding to approximately 440mg Hydroxyapatite. Vitamin D……400 IU
	Diary No. Date of R& I & fee	Dy.No 4417, 06-02-2018, Rs. 20,000/-, 06-02-2018
	Pharmacological Group	Calcium supplement + Vitamin D
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	30's, 100's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Osnate-D Tablet of M/s AGP Limited
	GMP status	GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP

		compliance at the time of inspection.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 290th meeting decided as under: • Evidence of availability of atomic absorption spectrophotometer • Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	1. Firm provide the copy of GMP inspection report dated 10-07-2019, in which it is mentioned by the area FID that firm has atomic absorption Spectrophotometer. 2. Firm provide the evidence of Me-too product Osnate-D Tablet registered in the name of M/s. AGP Limited (Reg.no. 055948)
	Decision: Approved with innovator's specificatins	
42.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrail Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ossemin-D 250mg+400 IU/5ml Suspension
	Composition	Each 5ml Contains: Ossein Mineral Complex……250mg Corresponding to : Calcium……..53.5mg* Phosphorus……24.8mg* Residual Mineral Salts……7.5mg Collagen ……67.5mg Other Proteins……20 mg Trace elements…….FI, Mg, Fe, Zn, Cu, and Ni. *Corresponding to approximately 133mg Hydroxyapatite. Vitamin D……400 IU
	Diary No. Date of R& I & fee	Dy.No 4416, 06-02-2018, Rs. 20,000/-, 06-02-2018
	Pharmacological Group	Calcium supplement + Vitamin D
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	60ml, 120ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Osmin-D3 Suspension of Himont Pharma
	GMP status	GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 290th meeting decided as under: • Evidence of availability of atomic absorption spectrophotometer Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	1. Firm provide the copy of GMP inspection report dated 10-07-2019, in which it is mentioned by the area FID that firm has atomic absorption Spectrophotometer. 2. Firm provide the evidence of Me-too product Osmin – D3 Suspension registered in the name of M/s. Himont Pharmaceuticals (Reg.no. 064857)
	Decision: Approved with innovator's specificatins	
43.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrail Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ossemin-D 400mg+400 IU/5ml Suspension

	Composition	Each 5ml Contains: Ossein Mineral Complex……..400mg Corresponding to : Calcium……..85.6mg* Phosphorus……39.6mg* Residual Mineral Salts……12mg Collagen ……108mg Other Proteins……32mg Trace elements…….FI, Mg, Fe, Zn, Cu, and Ni. *Corresponding to approximately 212mg Hydroxyapatite. Vitamin D……400 IU
	Diary No. Date of R& I & fee	Dy.No 4411, 06-02-2018, Rs. 20,000/-, 06-02-2018
	Pharmacological Group	Calcium supplement + Vitamin D
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	60ml, 120ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Osnate-D suspension of AGP Limited
	GMP status	GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 290th meeting decided as under: • Evidence of availability of atomic absorption spectrophotometer • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	1. Firm provide the copy of GMP inspection report dated 10-07-2019, in which it is mentioned by the area FID that firm has atomic absorption Spectrophotometer. 2. Firm provide the evidence of Me-too product Osnate-D Suspension registered in the name of M/s. AGP Limited (Reg.no. 070854)
	Decision: Approved with innovator's specificatins	
44.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrail Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ossemin 250mg/5ml Suspension
	Composition	Each 5ml Contains: Ossein Mineral Complex……..…250mg Corresponding to : Calcium……..53.5mg* Phosphorus……24.8mg* Residual Mineral Salts……7.5mg Collagen ……67.5mg Other Proteins……20 mg Trace elements…….FI, Mg, Fe, Zn, Cu, and Ni. *Corresponding to approximately 133mg Hydroxyapatite.
	Diary No. Date of R& I & fee	Dy.No 4412, 06-02-2018, Rs. 20,000/-, 06-02-2018
	Pharmacological Group	Calcium supplement
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	60ml, 120ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Osmin suspension of Himont Pharma

	GMP status	GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 290th meeting decided as under: • Evidence of availability of atomic absorption spectrophotometer • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	1. Firm provide the copy of GMP inspection report dated 10-07-2019, in which it is mentioned by the area FID that firm has atomic absorption Spectrophotometer. 2. Firm provide the evidence of Me-too product Osmin Suspension registered in the name of M/s. Himont Pharmaceuticals (Reg.no. 064854)
	Decision: Approved with innovator's specificatins	
45.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrail Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ossemin 400mg/5ml Suspension
	Composition	Each 5ml Contains: Ossein Mineral Complex……..400mg Corresponding to : Calcium……..85.6mg* Phosphorus……39.6mg* Residual Mineral Salts……12mg Collagen ……108mg Other Proteins……32mg Trace elements…….FI, Mg, Fe, Zn, Cu, and Ni. *Corresponding to approximately 212mg Hydroxyapatite.
	Diary No. Date of R& I & fee	Dy.No 4414, 06-02-2018, Rs. 20,000/-, 06-02-2018
	Pharmacological Group	Calcium supplement
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	60ml, 120ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	OMC suspension of Genix Pharma
	GMP status	GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 290th meeting decided as under: • Evidence of availability of atomic absorption spectrophotometer • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	1. Firm provide the copy of GMP inspection report dated 10-07-2019, in which it is mentioned by the area FID that firm has atomic absorption Spectrophotometer. 2. Firm provide the evidence of Me-too product OMC Suspension registered in the name of M/s. Genix Pharma (Reg.no. 067652)
	Decision: Approved with innovator's specificatins	

46.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd., Plot No. 13-14, Sector 15, Korangi Industrail Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ossemin 500mg/5ml Suspension
	Composition	Each 5ml Contains: Ossein Mineral Complex……..500mg Corresponding to : Calcium……..107mg* Phosphorus……49.5mg* Residual Mineral Salts……15mg Collagen ……134.9mg Other Proteins……40mg Trace elements…….FI, Mg, Fe, Zn, Cu, and Ni. *Corresponding to approximately 265 mg Hydroxyapatite.
	Diary No. Date of R& I & fee	Dy.No 4415, 06-02-2018, Rs. 20,000/-, 06-02-2018
	Pharmacological Group	Calcium supplement
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	60ml, 120ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Esegrow Forte suspension of Barret Hodgson
	GMP status	GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 290th meeting decided as under: • Evidence of availability of atomic absorption spectrophotometer • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation BY PEC AD(PEC-XII)	1. Firm provide the copy of GMP inspection report dated 10-07-2019, in which it is mentioned by the area FID that firm has atomic absorption Spectrophotometer. 2. Firm provide the evidence of Me-too product Esegrow Forte Suspension registered in the name of M/s. Barrett Hodgson (Reg.no. 067652) which could not be verified.
	Decision: Deferred for evidence of applied formulation already appoved by DRAP.	
47.	Name and address of manufacturer / applicant	M/s Amson Vaccines & Pharma (Pvt) Ltd. Plot No. 154, Insdustrial Triangle, Kahuta Road, Islamabad Pakistan.
	Brand Name + Dosage Form + Strength	Osso-D Suspension 60ml / 120ml
	Composition	Each 5ml Contains Ossien Mineral Complex (Microcystalline Hydroxyapatite complex)…400mg + Vitamin D … 400IU
	Diary No. Date of R&1 & fee	Duplicate dossier
	Pharmacological Group	Minerals And Electrolytes
	Type of Form	Form-5
	Finished product and specification	AMSON SPECS
	Pack size and demanded price	60ml /120ml in PET bottle/AS per policy of DRAP
	Approval status of product in reference regulatory authorities	--
	Me too status	Osnate D Suspension AGP Limited (Reg.no.070854)
	Remarks of the evaluator	
	Previous Decision	Registration Board in its 289th meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.

	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me Too product Osnate D suspension by M/s. AGP Limited (Reg.no. 070854)
	Decision: Deferred for the evidence of purchase of Atomic Absorption Spectrophotometer.	
48.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Oscom-D Tablets
	Diary No. Date of R& I & fee	Each tablet contains:- Ossein Mineral Complex….830mg Vitamin D ……400IU
	Composition	Dy No. 793: 16-08-2012, Rs.8000/- 15-8-2012 Rs.12,000/- 17-07-2014
	Pharmacological Group	(Mineral supplements)
	Type of Form	Form 5
	Finished product Specification	Firm has claimed Mfg specs
	Pack size & Demanded Price	3x10's: As Per SRO
	Approval status of product in Reference Regulatory Authorities.	…….
	Me-too status	Bonmin tablet by S.J. & G Fazul Ellahie
	GMP status	Last inspection report 03-08-2016 Stated grant of additional section and renewal of DML.
	Previous remarks of the Evaluator.	International availability is not confirmed
	Previous decision(s)	Deferred for submission of complete composition of ossein mineral complex and confirmation of availability of atomic absorption spectrophotometer (M-267). Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-277). Registration Board deferred the case for further delibration. (M-285)
	Evaluation by PEC	Evaluation by PEC Firm has submitted following documents: • Last GMP inspection report dated 10-3-2017 confirms presence of atomic absorption and also recommended grant of additional section. • Approval status in reference regulatory authorities could not be confirmed • Detailed formulation as Each tablet contains Vitamin D……..400 IU Ossein Mineral Complex……..830mg Corresponding to Calcium……..177.6mg Phosphorous….82.2mg Residual Mineral Salt……24.9mg Collagen…….224mg Other proteins……..66.4mg Trace elements F, Mg, Fe, Zn, Cu, Ni. Corresponding to approximately 440mg hydroxyapatite "Ossopan 600mg Film coated tablet approved in ANSM France". Firm has submitted GMP inspection report dated 04-06-2018 confirming satisfactory compliance to GMP
	Previous Decision	Registration Board in its 286th meeting decided as under: Deferred for evidence of approval of applied formulation in Reference Regulatory Authorities/Agencies which were adopted by the Registration Board.
	Evaluation by PEC AD(PEC-XII)	1. Firm provide the evidence of Me-too product

		Bonmin Tablet Registered in the name of M/s. S.J. &G. Fazul Ellahie (Reg.no.070532).
	Decision: Approved with innovator's specificatins	
49.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Oscom Tablets 830mg
	Composition	Each tablet contains:- Ossein Mineral Complex…….830mg
	Diary No. Date of R& I & fee	Dy.#782 (16-8-2012), Rs.8000/-, 15-8-2012, Rs.12,000/-, 17-07-2014
	Pharmacological Group	Mineral supplements
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	3x10's, As Per SRO
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Osnate-800 tablet by AGP Ltd
	GMP status	Firm has submitted GMP inspection report dated 04-06-2018 confirming satisfactory compliance to GMP.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for submission of complete composition of ossein mineral complex and confirmation of availability of atomic absorption spectrophotometer. (M-267)
	Evaluation by PEC	• Detailed formulation as Each tablet contains Ossein Mineral Complex……..830mg Corresponding to Calcium……..177.6mg Phosphorous….82.2mg Residual Mineral Salt……24.9mg Collagen…….224mg Other proteins……..66.4mg Trace elements F, Mg, Fe, Zn, Cu, Ni. Corresponding to approximately 440mg hydroxyapatite. "Ossopan 600mg Film coated tablet approved in ANSM France". Firm has submitted GMP inspection report dated 04-6-2018 confirming satisfactory compliance to GMP.
	Previous Decision	Registration Board in its 286th meeting decided as under: Deferred for evidence of approval of applied formulation in Reference Regulatory Authorities/Agencies which were adopted by the Registration Board.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-too product Osnate 800 Tablet Registered in the name of M/s. AGP Ltd. (Reg.no.009087).
	Decision: Approved with innovator's specificatins	
50.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Cal C Sachet
	Composition	Each Sachet Contains: Calcium Lactate……. 3.24gm Calcium Carbonate……0.300gm
	Diary No. Date of R& I & fee	Dy. No 31029-A 14-09-2018 Rs.20,000/- 14-09-2018
	Pharmacological Group	Mineral supplements
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's; Rs. 75/-

		25's; Rs. 187.5/- 50's; Rs. 375/-
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Calc-M-Forte Sachet of M/s Medimarker's, Hyderabad (Reg.#048612)
	GMP status	Inspection conducted on 19th Dec., 2017 & 2nd Mar, 2018. Renewal of DML and grant of additional sections. Panel recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Previous Decision	Registration Board in its 285th meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting
	Evaluation by PEC AD(PEC-XII)	Evidence of Me-Too product provided by the firm,is not verifiable.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
51.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Cal C 1000 Sachet
	Composition	Each Sachet Contains: Calcium Lactate…….578gm Calcium Carbonate…….327gm Calcium Gluconate…….422mg"
	Diary No. Date of R& I & fee	Dy.No 31029-B dated 14-09-2018 Rs.20,000/- Dated 14-09-2018
	Pharmacological Group	Mineral supplements
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's; Rs. 75/- 25's; Rs. 187.5/- 50's; Rs. 375/-
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	N/A
	GMP status	Inspection conducted on 19th Dec., 2017 & 2nd March, 2018 Renewal of DML and grant of additional sections. Panel recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Previous Decision	Registration Board in its 285th meeting decided as under: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved

		by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Evaluation by PEC AD(PEC-XII)	Firm did not provide the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
52.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Cal Vit Sachet
	Composition	Each Sachet Contains: Calcium Lactate……..1000mg Calcium Carbonate……..327mg Vitamin C…….500mg
	Diary No. Date of R& I & fee	Dy.No 31029-C (14-09-2018) Rs.20,000/- 14-09-2018
	Pharmacological Group	Mineral supplements
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's; Rs. 75/- 25's; Rs. 187.5/- 50's; Rs. 375/-
	Approval status of product in Reference Regulatory Authorities.	……
	Me-too status	Calwell Sachet of M/s Well & Well Pharma (Reg.#068899)
	GMP status	Inspection conducted on 19th Dec., 2017 & 2nd March, 2018 Renewal of DML and grant of additional sections. Panel recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.
	Previous Decision	Registration Board in its 286th meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC AD(PEC-XII)	Me Too product mentioned by the firm has different composition
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
53.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Cal Vit Plus Sachet
	Composition	Each Sachet Contains: Calcium Lactate……1gm Calcium Carbonate……600mg Vitamin C…….1000mg
	Diary No. Date of R& I & fee	Dy.No 31029-D dated 14-09-2018 Rs.20,000/- Dated 14-09-2018
	Pharmacological Group	Mineral supplements
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's; Rs. 75/- 25's; Rs. 187.5/- 50's; Rs. 375/-
	Approval status of product in Reference Regulatory Authorities.	N/A

	Me-too status	CXT-3 2.6 g Sachet of M/s Wnsfeild Pharmaceutical (Reg.#075591)
	GMP status	Inspection conducted on 19th Dec., 2017 & 2nd March, 2018 Renewal of DML and grant of additional sections. Panel recommends renewal of DML and grant of additional sections. Panel recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Previous Decision	Registration Board in its 286th meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-too product CXT-3 2.6g Sachet Registered in the name of M/s. Wnsfield Pharmaceuticals Hattar (Reg.no.075591**).**
	Decision: Approved with innovator's specificatins	
54.	Name and address of manufacturer /Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Vitacal Plus Sachet
	Composition	Each Sachet Contains: Calcium Carbonate…….0.327gm Calcium Lactate……..1gm Ascorbic Acid……..100mg
	Diary No. Date of R& I & fee	Dy.No 31029-E dated 14-09-2018 Rs.20,000/- Dated 14-09-2018
	Pharmacological Group	Mineral supplements
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	Pack size not submitted, Rs.134.2/-; Pack size not submitted, Rs.335.5/-; Pack size not submitted, Rs.671/-.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Max-V Sachet by M/s Alliance Pharma (Reg#043770)
	GMP status	Inspection conducted on 19th Dec., 2017 & 2nd March, 2018. Renewal of DML and grant of additional sections. Panel recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name & name of firm as submitted reference is of different composition.
	Previous Decision	Registration Board in its 286th meeting decided as under: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

	Evaluation by PEC AD(PEC-XII)	Me Too product mentioned by the frim has different composition.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
55.	Name and address of Manufacturer / Applicant	M/s Islam Pharmaceuticals,7 km, Pasrur Road, Sialkot
	Brand Name +Dosage Form +Strength	Calcim Sachet 1000/500/327 mg
	Composition	Each Sachet Contains: Calcium Lactate gluconate…1000mg Vitamin C…500mg Calcium Carbonate…327mg
	Diary No. Date of R&I & fee	DyNo.29193;31-08-2018; Rs. 20,000/-
	Pharmacological Group	Calcium + Vitamin Supplement
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	High-C 1000 Sachet of Werrick Pharmaceuticals
	GMP status	New License (letter issuance date: 29th August 2018)
	Remarks of Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Previous Decision	Registration Board in its 285th meeting decided as under: Deferred for evidence of approval status of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-too product High-C 1000 Sachet Registered in the name of M/s. Werrick Pharmaceuticals, Islamabad (Reg.no.016036).
	Decision: Approved with innovator's specificatins	
56.	Name and address of manufacturer / Applicant	Zeta Pharmaceuticals Plot # 494-A, Sunder Industrial Estate, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Ze-Cal Sachet
	Composition	Each sachet contains: Calcium lactate gluconate…….1000mg Vitamin C…… 500mg Calcium carbonate……. 327mg
	Diary No. Date of R& I & fee	Dy No. 28150: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Calcium supplement
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Innovator's specs
	Pack size & Demanded Price	10's, Rs. 73.00/-
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Calwell Sachet by Well & Well Pharma (Pvt) Ltd., Islamabad Reg. No. 68899
	GMP status	The firm has granted Additional Section (Sachet, General) on the basis of inspection dated 28.05.2018
	Remarks of the Evaluator.	• Old Form 5 • Proof of International availability of the FPP with same compositions is needed • Complete Testing procedure is needed
	Previous Decision	Registration Board in its 285th meeting decided as under: Deferred for evidence of approval of applied formulation in

		reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-too product Calwell Sachet Registered in the name of M/s. Well & well Pharmaceuticals, Islamabad (Reg.no.068899).
	Decision: Approved with innovator's specificatins	
57.	Name and address of manufacturer / Applicant	Zeta Pharmaceuticals Plot # 494-A, Sunder Industrial Estate, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Ze-Cal Plus Sachet
	Composition	Each sachet contains: Calcium lactate Glycerophosphate …….373.3mg Calcium carbonate……. 156.7 Calcium pentothenate……. 15mg Vitamin C……..100mg Vitamin B1…….15mg Vitamin B2…….15mg Vitamin B6…….10mg Vitamin B3…….50mg
	Diary No. Date of R& I & fee	Dy No. 28151: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Calcium Supplement + Vitamins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Innovator's specs.
	Pack size & Demanded Price	20's, Rs. 230/-
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	The firm has granted Additional Section (Sachet, General) on the basis of inspection dated 28.05.2018
	Remarks of the Evaluator.	• Old Form 5 • The firm has revised the composition without submission of fee. • Proof of International availability and me-too product with same compositions is needed
	Previous Decision	Registration Board in its 285th meeting decided as under: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by Registration Board • Submission of fee for revision of formulation.
	Evaluation by PEC AD(PEC-XII)	• Firm did not provide the Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm • Fee is required for revision of formulation.
	Decision: Deferred for submission of following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Submission of fee for revision of formulation.**	
58.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12-A, Sector 5, I-5, New Serveyno-276, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Biomin Plus tablets
	Composition	Each film coated tablet contains: Thiamine mononitrate……..…50mg

		Pyridoxine hydrochloride...…...…100mg Cyanocobalamine …….……100mg Paracetamol……...……250mg
	Diary No. Date of R& I & fee	Dy. No.1301; 23-09-2016; Rs.20,000/- (23-09-2016)
	Pharmacological Group	Vitamin B + analgesic and anti-pyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10x10's; Rs.190.00/-
	Approval status of product in Reference Regulatory Authorities	…..
	Me-too status (with strength and dosage form)	……
	GMP status	Last GMP inspection conducted on 06-03-2018 & report concludes that firm is considered to be operating at satisfactory level of compliance with GMP guidelines.
	Remarks of the Evaluator	Evidence of approval of applied formulation in applied strength in reference regulatory authorities/ agencies. Evidence of generic/me-too already approved with DRAP.
	Previous Decision	Registration Board in its 284th meeting decided as under: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	Firm did not provide the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
59.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12-A, Sector 5, I-5, New Serveyno-276, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	B-C-Plex injection 2ml
	Composition	Each 2ml ampoule contains: Thiamine mononitrate.....…….10mg Riboflavin…….....……..02mg Pyridoxine…….....…05mg Nicotinamide…….....……..75mg Pantothenic acid.....……...05mg
	Diary No. Date of R& I & fee	Dy. No.1298; 23-09-2016; Rs.20,000/- (23-09-2016)
	Pharmacological Group	Vitamin B compounds
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	2ml x 25's; Rs.72.50/-
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	Last GMP inspection conducted on 06-03-2018 and the report concludes that the firm is considered to be operating at satisfactory level of compliance with GMP guidelines.
	Remarks of the Evaluator	Evidence of approval of applied formulation in the applied strength in reference regulatory authorities/ agencies. Evidence of generic/me-too already approved with DRAP.

	Previous Decision	Registration Board in its 284th meeting decided as under: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	Firm did not provide the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the evidence of applied formulation/drug in already adopted refrence regulatory authorities	
60.	Name and address of manufacturer / Applicant	Simz Pharmaceuticals (Pvt) Ltd., 574-575, Sunder Industrial Estate, Raiwind Road, Lahore Contract manufactured by Friends Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Sunday Injection 5mg/1ml
	Composition	Each ml contains:- Cholecalciferol (vitaminD3)……5mg (vitamin-D analogue)
	Diary No. Date of R& I & fee	Dy No. 9399 31-7-2013 PKR 50000/- (31-7-2013)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1ml ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3GOOD (ANSM France approved)
	Me-too status	Vitamin D3injection by Ameer Pharma
	GMP status	
	Remarks of the Evaluator	Reminder 02-05-2018 Letter 04-4-2018 •Latest GMP inspection report of the manufacturer which should have been conducted within a period of last 1 year. •Description of container closure has not been submitted. •Detail of already registered products on contract manufacturing. •Evidence of approval of manufacturing facility / section of the manufacturer by Licensing division •The application on Form 5 has been submitted by M/s Friends Pharma, while the applicant is M/s Simz Pharma.
	Previous Decision	Registration Board in its 284th meeting decided as under: Registration Board deferred the case for further deliberation
	Evaluation by PEC AD(PEC-XII)	Deficiencies already communicated to the firm, further product is approved in ANSM France and in Me-Too 600,000 IU(15mg) of cholecalciferol has used according to the Registered product Data.
	Decision: Deferred for submission of followings: **• Latest GMP inspection report of the manufacturer which should have been conducted within a period of last 1 year.** **• Description of container closure has not been submitted.** **• Detail of already registered products on contract manufacturing.** **• Evidence of approval of manufacturing facility / section of the manufacturer by Licensing division** **• The application on Form 5 has been submitted by M/s Friends Pharma, while the applicant is M/s Simz Pharma.**	

61.	Name and address of manufacturer / Applicant	M/s Pharmatec Pakistan (Pvt) Ltd., D-86/A, S.I.T.E, Karachi
	Brand Name +Dosage Form + Strength	Osselex-F Suspension
	Diary No. Date of R& I & fee	Dy No. 149: 18-8-2014 PKR 20,000/-: 12-8-2014
	Composition	Each 5ml contains: Vitamin D……400IU Ossein Mineral Complex….400mg (corresponding to) Calcium…..85.59mg Phosphorous…….39.61mg Residual Mineral salts…….12mg Collagen……107.95mg Other proteins……32mg Trace elements (F, Mg, Fe, Zn, Cu & Ni) corresponds to app 212mg Hydroxyapatite
	Pharmacological Group	Mineral complex with vitamin D
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Osnate D suspension by AGP
	GMP status	Last inspection report dated 30-04-18 with the remarks level of gmp is rated as good. "GMP Certificate issued on 15-12-2017"
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities is not provided.
	Previous Decision	Registration Board in its 284th meeting decided as under: Registration Board deferred the case for further deliberation.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-Too product Osnate-D Suspension registered in the M/s. AGP Ltd (R.No.070854)
	Decision: Deferred for the evidence of availability of Atomic Absorption spectrophotometer.	
62.	Name and address of manufacturer / Applicant	M/s. Brookes Pharma (Pvt) Ltd, Plot No. 58-59 Sector No. 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Mincal-D Tablet
	Composition	Each tablet contains: Ossein Mineral complex…830mg Vitamin d…….400 IU
	Diary No. Date of R& I & fee	Dy.No.398; Rs.20,000/- 07-05-2014 (Duplicate dossier)
	Pharmacological Group	Minerals & Vitamins
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	30's/ as per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status (with strength and dosage form)	Osam-D Tablet Of M/s Getz Pharma
	GMP status	Last inspection was conducted on 15-07-2019 with the following remarks: Based on the above observations the panel unanimously recommends the firm for the grant of GMP Certificate for export purpose.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Previous Decision	Registration Board in its 283rd meeting decided as under: Deferred for evidence of approval of applied formulation in

		reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-Too product Osam-D registered in the name of M/s. Getz Pharma, Karachi (Reg.no.061106)
	Decision: Deferred for the evidence of availability of Atomic Absorption Spectrophotometer and complete formulation.	
63.	Name and address of manufacturer / Applicant	Mass Pharma (Pvt.) Ltd, 17 km Ferozpur road, Lahore
	Brand Name+Dosage Form + Strength	EEE-400 SOFT GELATIN CAPSULE 400MG
	Composition	Each Soft Gelatin Capsule Contains Alpha Tocopheryl Acetate …..…400mg
	Diary No. Date of R& I & fee	Dy No.26962; Dated: 29-12-2017
	Pharmacological Group	Fat Soluble Vitamin ,Antioxidant
	Type of Form	Form 5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	3x10's: Rs. 500/= per Pack
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (EVION) (as provided by the firm)
	Me-too status	Zescap 400mg capsule of Zafa Pharmaceutical Laboratories (Pvt) Ltd. (drug infosis)
	GMP status	Date of inspection: 11-09-2017. Purpose of inspection: Routine GMP Conclusion: GMP complaint
	Previous remarks of the Evaluator.	Evidence of approval status of applied formulation in reference agencies.
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.(M-279)
	Evaluation by PEC	The approval status in TGA, Australia submitted by the firm is in Vitamin E 400 IU softgel capsule.
	Previous Decision	Registration Board in its 283rd meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting as submitted reference is not verifiable.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-Too product Zescap 400mg soft Gelatin Capsule registered in the name of M/s. Zafa Pharmaceuticals (Reg.no.030626) *1000mg is the UL of vitamin E as per (CRN &US IoM)
	Decision: Deferred for the evidence of of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting.	
64.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medbionta injection
	Composition	Each 10 ml ampoule contains: Ascorbic acid … 500mg Dexpanthenol …… 25mg Nicotinamide ……. 100mg Vitamin B6 …… 15mg Vitamin B2 …… 10mg Vitamin A ……. 10,000IU Vitamin B1 ….. 50mg Vitamin E ….. 5mg
	Diary No. Date of R& I & fee	Dy. No. 6352, 15-06-2017, Rs. 20,000/- (15-06-2017)
	Pharmacological Group	Vitamin supplement

	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Multibionta Infusion Inj. of M/s Merck (Reg.# 004158)
	GMP status	Last GMP inspection conducted on 04-03-2020, and report concludes that M/s Mediate Pharmaceuticals P vt Ltd Karachi was considered to be operating at an acceptable level of compliance of GMP guidelines as on today.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Upon communication of above observation firm has referred to following product: "Multibionta Solution for infusion 10 ml Ampoule" of M/s"Merck Serono Ltd." https://myhealthbox.eu/en/medicine/multibionta/4201734 • The above cited reference of product and weblink submitted by firm could not be verified from any reference regulatory authorities
	Previous Decision	Registration Board in its 283rd meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting as submitted reference could not be verified.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-Too Multibionta Solution for Infusion registered in the name of M/s. Martin Dow Marker Limited (Reg.no.004158)
	Decision: Deferred for the evidence of of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting.	
65.	Name and address of manufacturer /Applicant	M/s Glitz Pharma , Plot No 265,Industrial Triangle, KahutaRoad, Islamabad
	Brand Name +Dosage Form + Strength	Chaien Syrup
	Composition	Each 5 ml of syrup contains: Pizotifen (as hydrogen maleate)…….0.25 mg Thiamine hydrochloride……0.875 Riboflavin phosphate…….1.31mg Pyridoxine hydrochloride……..0.77mg Nicotinamide……5.25mg
	Diary No. Date of R& I & fee	Dy. No.7436; 08-07-2015; Rs.20,000/- (06-07-2015)
	Pharmacological Group	Vitamin
	Type of Form	Not available
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	60ml, 90 ml, 120 ml & 240 ml; As per policy of MOH.
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Mosegor-V syrup of M/s Novartis Pharma.
	GMP status	Last inspection report dated 16-01-2019, with the following conclusion: Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were

		declared/approved by the Registration Board in its 275th meeting as submitted reference is not verifiable.
	Previous Decision	Registration Board in its 283rd meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting as submitted reference is not verifiable
	Evaluation by PEC AD(PEC-XII)	Me Too product mentioned by the firm has different composition
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
66.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals.124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Evilar 600mg Soft Gel Capsule
	Composition	Each Soft Gel Capsule Contains: Alpha tocopheryl acetate ..…600mg
	Diary No. Date of R& I & fee	Dy.No 19253 dated 28-05-2018 Rs.20,000/- 25-05-2018
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specification	Manufacture specs.
	Pack size & Demanded Price	100's; Rs. 720/-
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Zescap 600mg capsule Of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd. (Reg.#030627)
	GMP status	New section granted on 25-06-2018
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared /approved by the Registration Board in its 275th meeting.
	Previous Decision	Registration Board in its 283rd meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting as submitted reference is not verifiable.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-Too Product Zescap 600mg Capsule (Reg.no. 030627) registered in the name of M/s. Zafa Pharmaceutical Laboratories, Karachi. *1000mg is the UL of vitamin E as per (CRN &US IoM)
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatoryauthorities/agencies which were adopted by the Registration Board in its 275th meeting.	
67.	Name and address of manufacturer / Applicant	M/s Mafins Pharma A-5 S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Betofox Tablet
	Composition	Each film coated tablet contains: Vitamin B1……100mg Vitamin B6…….100 mg Vitamin B12…..200 mcg
	Diary No. Date of R& I & fee	Dy.No.277, 15-02-2017, Rs.20,000/-
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Spectra Tablets By Global Islamabad Reg.#. 066598
	GMP status	Last GMP Inspection dated 5-10-17 with conclusive

		remarks ofgood cGMP compliance.
	Remarks of Evaluator	● Latest GMP inspection report (which should have been conducted within the period of last one year). ● Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board.
	Previous Decision	Registration Board in its 282nd meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Evaluation by PEC AD(PEC-XII)	• Firm provide the evidence of Me-Too product Spectra Tablet registered in the name of M/s. Global Pharmaceuticals (Reg.no.066598) • Latest GMP inspection report (which should have been conducted within the period of last three years).
	Decision: Deferred for the submission of latest GMP inspection report (which should have been conducted within the period of last three year).	
68.	Name and address of manufacturer / Applicant	M/s Focus & Rules pharmaceuticals (Pvt.) Ltd 44-industrial triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Actibone capsules
	Composition	Each capsule contains:- Vit D3…0.005 mg Calcium Citrate…500mg Magnesium Citrate……..100 mg
	Diary No. Date of R& I & fee	30-4-2015 Dy.No.3095 Rs.12,000/- (21-4-15) Rs.8000/- (14 jun-2011)
	Pharmacological Group	Vitamin and Mineral Formulation
	Type of Form	Form-5
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	20, 10's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Evidence of approval of applied formulation in reference regulatory authorities missing. Provided reference of Natural factors, calcium and magnesium can't be verified.
	Me-too status	Evidence of applied formulation/drug already approved by DRAP missing, Provided reference of GNC natural Pakistan can'tbe verified.
	GMP status	Latest GMP inspection dated 25/1/2018 showing Fair cGMP compliance
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 282nd meeting decided as under: Deferred for following: ● Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. ● Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Application will be re-checked for submission of fee deposit date.
	Evaluation by PEC AD(PEC-XII)	Firm did not provide Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

69.	Name and address of manufacturer / Applicant	M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Step- D Tablet
	Composition	Each film coating tablet contains Vitamin D……400IU Ossien Mineral complex…..830mg Corresponding to Calcium……177.6mg Phosphorous…….82.2mg Residual Mineral Salt……24.9mg Collagen…….224mg Other proteins……....66.4mg Trace elements F, Mg, Fe, Zn, Cu, Ni. Corresponding to approximately 440mg hydroxyapatite
	Diary No. Date of R& I & fee	Dy.No.2925; 12-04-2017; Rs.20,000/- (10-04-2017)
	Pharmacological Group	Minerals and Electrolytes
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	3 x10's ; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Osam-D Tablet Of M/s Getz Pharma
	GMP status	Certificate of GMP Issued on 19-10-2019
	Remarks of the Evaluator	1st letter: 19th February, 2018 ● Reminder letter: 17th April, 2018 ● Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared /approved by Registration Board in its 275th meeting ● Evidence of presence of Atomic Absorption Spectrophotometer verified by FID
	Previous Decision	**Registration Board in its 282nd meeting decided as under:** ● Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared /approved by the Registration Board in its 275th meeting. ● Evidence of presence of Atomic Absorption Spectrophotometer verified by FID.
	Evaluation by PEC AD(PEC-XII)	• Firm provide the evidence of Me-Too product Osam-D registered in the name of M/s. Getz Pharma, Karachi (Reg.no.061106). • Evidence of presence of Atomic Absorption Spectrophotometer verified by FID is still required.
	Decision: Deferred for the evidence of availability of Atomic Absorption Spectrophotometer.	
70.	Name and address of manufacturer / Applicant	M/S Mediate Pharmaceuticals (Pvt) Ltd. Plot No #150-151 Sector 24 Korangi, Industrial Area Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Osin- D Suspension
	Composition	Each 5ml contains: Ossein Hydroxyapatite Compound (Anhydrous)….400mg Equivalent to : Calcium…85.59mg Phosphorus….39.61mg Residual Mineral Salt…12mg Collagen….107.95mg Other Protein…32mg Vitamin D..400IU

		(Fi, Mg, Fe, Zn, Cu, Ni)
	Diary No. Date of R& I & fee	Dy.No.2211; 31-10-2016; Rs.20,000/- (31-10-2016)
	Pharmacological Group	Minerals and Electrolytes
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	As per SRO ;As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Osnate- D Suspension Of M/s AGP
	GMP status	Last GMP inspection conducted on 04-03-2020, and report concludes that M/s Mediate Pharmaceuticals P vt Ltd Karachi was considered to be operating at an acceptable level of compliance of GMP guidelines as on today.
	Remarks of the Evaluator	● 1st letter: 15th February 2018 ● Reminder letter: 07th March, 2018 ● Latest GMP inspection report (which should have been conducted within the period of last one year). ● Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by Registration Board in its 275th meeting ● Evidence of presence of Atomic Absorption Spectrophotometer verified by FID.
	Previous Decision	Registration Board in its 282nd meeting decided to defer the case on the basis of following reason: ● Latest GMP inspection report (which should have been conducted within period of last one year). ● Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting ● Evidence of presence of Atomic Absorption Spectrophotometer verified by FID.
	Evaluation by PEC AD(PEC-XII)	• Firm provide the evidence of Me-Too product Osnate-D Suspension by M/s. AGP Limited (Reg.no.070854) • Evidence of presence of Atomic Absorption Spectrophotometer verified by FID.
	Decision: Deferred for the evidence of purchase of Atomic Absorption Spectrophotometer.	
71.	Name and address of manufacturer / Applicant	M/s. Mediate Pharmaceuticals, 150-151, Sector 24, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Osin-D Tablet
	Composition	Each film coated tablet contains: Ossein Mineral Complex…… 830mg Equivalent to: Calcium…177.6mg* Phosphorus….82.2mg Residual Mineral Salt…24.9mg Collagen….224mg Other Protein…66.4mg (Fi, Mg, Fe, Zn, Cu, Ni) *Corresponding to approximately 440mg Hydroxyapatite Vitamin D…..400IU
	Diary No. Date of R& I & fee	Dy. No. 2210, 31-10-2016 , Rs.20,000/- (31-10-2016)
	Pharmacological Group	Minerals and Electrolytes
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	3x10's, As per SRO
	Approval status of product in Reference	Wellesse Calcium & Vitamin D3 Suspension, US

	Regulatory Authorities.	
	Me-too status	Osam D by Getz Pharmaceuticals
	GMP status	Last GMP inspection conducted on 04-03-2020, and report concludes that M/s Mediate Pharmaceuticals P vt Ltd Karachi was considered to be operating at an acceptable level of compliance of GMP guidelines as on today.
	Remarks of the Evaluator.	● 1st letter: 15th February 2018 ● Reminder letter: 07th March, 2018 ● Latest GMP inspection report (which should have been conducted within the period of last one year). ● Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by Registration Board in its 275th meeting ● Evidence of presence of Atomic Absorption Spectrophotometer verified by FID.
	Previous Decision	Registration Board in its 282nd meeting decided to defer the case on the basis of following reason**:** ● Latest GMP inspection report (which should have been conducted within the period of last one year). ● Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting ● Evidence of presence of Atomic Absorption Spectrophotometer verified by FID.
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me-Too product Osam-D registered in the name of M/s. Getz Pharma, Karachi (Reg.no.061106) Evidence of availability of atomic absorption spectrophotometer is required
	Decision: Deferred for the evidence of purchase of Atomic Absorption Spectrophotometer.	
72.	Name and address of manufacturer / Applicant	M/s Danas Pharma. 312-Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Cynovit 500mcg Injection
	Composition	Each 2ml ampoule contains: Cyanocobalamin (vitamin b12)…..500mcg
	Diary No. Date of R& I & fee	Dy. No.788; 20-06-2017; Rs.20,000/- (15-6-2017)
	Pharmacological Group	Vitamin b12
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2mlx25's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Cyanocob 250 Injection Each ml contains:- Cyanocobalamin (Vitamin B12)…….250mcg Pack size 10ml, 50ml, 100ml
	GMP status	The firm was granted GMP certificate based on inspection conducted on 03-10-2017.
	Remarks of the Evaluator.	Firm has sterile liquid injection (General and steroidal ampoule, vials) section Approval in RRA could not be confirmed. Me-too product has different pack size than the applied product
	Previous Decision	Registration Board in its 282nd meeting decided to defer the case on the basis of following: ● Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration

		number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board.
	Evaluation by PEC AD(PEC-XII)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required, as the provided Me-Too product is not verifiable. • Latest GMP inspection report (which should have been conducted within the period of last three year).
	Decision: Deferred for submission of followings: • **Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** • **Latest GMP inspection report (which should have been conducted within the period of last three year).**	
73.	Name and address of manufacturer / Applicant	M/s Danas Pharma. 312-Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Neuvita Tablet
	Composition	Each Film Coated Tablet contains: Thiamine HCl (Vitamin B1)……100mg Pyridoxine HCl (Vitamin B6)……100mg Cyanocobalamin (Vitamin B12)……200mcg
	Diary No. Date of R& I & fee	3338, 19-05-2017, 18-05-2017, 20,000/-
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Neurobion of Neurobedoxin of schazoo labs
	GMP status	The firm was granted GMP certificate based on inspection conducted on 03-10-2017.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authority & me-too reference could not be verified.
	Previous Decision	Registration Board in its 281st meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting and evidence of me-too status.
	Evaluation by PEC AD(PEC-XII)	• Firm provide the evidence of Me-Too product which has different composition. • Latest GMP inspection report (which should have been conducted within the period of last three year).
	Decision:Deferred for submission of followings: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Latest GMP inspection report (which should have been conducted within the period of last three year).**	
	Name and address of manufacturer / Applicant	M/s. Sharex Labs, Sadiqabad
	Brand Name +Dosage Form + Strength	Cynoplex Injection
	Composition	Each 2ml contains:- Vitamin B1 BP ….. 10mg Vitamin B2 BP ….. 2mg

		Vitamin B6 BP ….. 5mg Nicotinamide BP …. 75mg Dexpanthanol BP ….. 5mg
	Diary No. Date of R& I & fee	Dy# 3271 (08-3-2011); Rs.8,000/- Form-5 Dy #1087 (29.05.2014) Rs. 12,000/- (14-03-2013)
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specification	--
	Pack size & Demanded Price	Pack size / 2ml x 25s Rs. 90/-
	Approval status of product in Reference Regulatory Authorities.	--
	Me-too status	Amroplex injection of M/s Amros, Karachi (Reg.#042164)
	GMP status	GMP inspection dated 29-03-2017 concluding satisfactory GMP compliant status
	Previous remarks of the Evaluator.	Deferred in 261st meeting for the submission of following i. Inspection report ii. Commitment as per decision of board iii. Finished product specification is incomplete. iv. Fee Rs. 8000/- and 12000/- is Photocopy v.Approval status in reference country and Pakistan
	Previous decision(s)	Deferred in 264th meeting for review of formulation and evidence of submission of Fee of Rs.12,000/-
	Evaluation by PEC	● The applied formulation is approved in Austria with slight different composition. (MultiVit B-Forte injection) as under: "Each 2ml ampoule contains Vitamin B1 … 11mg Vitamin B2 … 3.8mg Vitamin B6 … 5mg Nicotinamide 110mg Dexpanthenol … 6 mg
	Previous Decision	Registration Board in its 280th meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies as approved by the Registration Board in its 275th meeting as submitted reference is of different composition.
	Evaluation by PEC AD(PEC-XII)	• Me-Too product Amroplex Injection has different composition. • Latest GMP inspection report (which should have been conducted within the period of last three year).
	Decision:Deferred for submission of followings: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies as approved by the Registration Board in its 275th meeting** • **Latest GMP inspection report (which should have been conducted within the period of last three year).**	
74.	Name and address of manufacturer / Applicant	The Searle company limited F-39 Site Karachi Pakistan.
	Brand Name +Dosage Form + Strength	Frutum tablets
	Composition	Each tablet contains: Zinc Oxide eq to Zinc…..22.5mg Vitamin A acetate eq to Vitamin A…..5000IU Vitamin B1……2.25mg Vitamin B2……2.6mg Vitamin B6…….3mg Vitamin B12…….9mcg Vitamin C……90mg Vitamin D……..400IU

		Vitamin E Acetate 50% eq to Vitamin E……30IU Nicotinamide…….20mg Biotin…….150mcg Calcium…..162mg Phosphorus…….125mg Copper…..3mg Folic Acid…..400mcg Ferrous Fumarate eq to Iron……18mg Potassium Idodide eq to Iodine….150mcg Magnesium Oxide eq to Magnesium…..100mg Manganese Sulphate monohydrate eq.to Manganese ……7.5mg Calcium-D Pantothenate eq to Pantothenic Acid..10mg Potassium Sulphate eq toPotassium……..7.5mg
	Diary No. Date of R& I & fee	Dy. No.170; 27-1-2017; Rs.20,000/- (26-1-2017)
	Pharmacological Group	Vitamin & minerals
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	30's, As per DPC
	Approval status of product in Reference Regulatory Authorities.	Provided Reference could not be confirmed.
	Me-too status	Provided Reference could not be confirmed
	GMP status	Last inspection report 30-01-2019, with the conclusion that the firm for continous improvement and people met, it is concluded that the firm is operating at a Good level of GMP compliance.
	Remarks of the Evaluator.	International Reference in RRA and me-too status could not be confirmed.
	Previous Decision	Registration Board in its 279th meeting decided as under: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	Firm did not provide the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
75.	Name and address of manufacturer / Applicant	Mass Pharma (Pvt.) Ltd, 17 km Ferozpur road, Lahore
	Brand Name +Dosage Form + Strength	DEE 200K SOFT GELATIN CAPSULE 200,000 IU
	Composition	Each Soft Gelatin Capsule Contains; Vitamin D3 (Cholecalciferol)……200,000IU
	Diary No. Date of R& I & fee	Diary No.26960; 29-12-2017; Rs: 20,000/-
	Pharmacological Group	Fat Soluble Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	1x1's: Rs. 300/= per Pack
	Approval status of product in Reference Regulatory Authorities.	FDA (CALCITRIOL - LIFEEXTENSION) EMA (FULTIUM-D3)
	Me TOO Status	Sunny D Of Scotmann Solar-D Of Crystolite Pharmaceuticals Pakistan Dx3 Of Macter Pharma

		Dneed Of Spectrum Healthcare
	GMP status	Date of inspection: 11-09-2017. Purpose of inspection: Routine GMP Conclusion: GMP complaint
	Remarks of the Evaluator.	Evidence of Me too is required as the provided evidence is not verifiable
	Previous Meeting	Registration Board in its 279th meeting decided as under: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC AD(PEC-XII)	Me-Too provided by the firm is not verifiable
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
76.	Name and address of manufacturer / Applicant	Mass Pharma (Pvt.) Ltd, 17 km Ferozpur road, Lahore
	Brand Name +Dosage Form + Strength	VARIENCE SOFT GELATIN CAPSULE
	Composition	Each Soft Gelatin Capsule Contains Ferrous gluconate BP……..….250mg Maganese Sulfate Monohydrate USP…….0.2mg Copper Sulphate BP……..…….….0.2mg Vitamin C (Ascorbic acid), USP……..……50mg Folic Acid USP…..……..…..1mg Vitamin B12 (Cyanocobalamin), USP…..7.5mcg
	Diary No. Date of R& I & fee	Diary No: 26953, 29-12-2017: Rs: 20,000/-
	Pharmacological Group	Multivitamin (Nutrition Supplement)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	3x10's: Rs. 200/= per Pack
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed (FDA (SANGOBION) **EMA (** FORCEVAL) as provided by the firm)
	Me-too status	Sangobion of Merck Private Ltd.
	GMP status	Date of inspection: 11-09-2017. Purpose of inspection: Routine GMP Conclusion: GMP complaint
	Remarks of the Evaluator.	
	Previous Decision	*Registration Board in its 279th meeting decided as under:* Deferred for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were declared/approved by Registration Board in its 275th meeting.
	Evaluation by PEC AD(PEC-XII)	Me-Too provided by the firm in not verifiable
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
77.	Name and address of manufacturer / Applicant	Mass Pharma (Pvt.) Ltd, 17 km Ferozpur road, Lahore
	Brand Name +Dosage Form + Strength	VARIENCE-Z SOFT GELATIN CAPSULE
	Composition	Each Soft Gelatin Capsule Contains Zinc (as Zinc Sulfate), USP……..22.5mg Vitamin E (dl-Alpha Tocopheryl Acetate), USP.30 IU Vitamin C (Ascorbic Acid), USP……....500mg Folic Acid, USP……150mcg

		Vitamin B1 (Thiamine Mononitrate), USP…...15mg Vitamin B2 (Riboflavin), USP……..15mg Nicotinamide, BP……..100mg Vitamin B6 (Pyridoxine Hydrochloride), USP...20mg Vitamin B12 (Cyanocobalamin), USP……...12mcg Pantothenic Acid (as Calcium D-Pantothenate), USP….20mg
	Diary No. Date of R& I & fee	Diary No: 26954, 29-12-2017: Rs: 20,000/-
	Pharmacological Group	Multivitamin (Nutrition Supplement)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	2x10's :Rs. 300/= per Pack
	Approval status of product in Reference Regulatory Authorities	FDA (POLYBION-Z) EMA **(** FORCEVAL-Z)
	Me-too status	Polybion of Merck Privte Ltd.
	GMP status	Date of inspection: 11-09-2017. Purpose of inspection: Routine GMP Conclusion: GMP complaint
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 279th meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Evaluation by PEC AD(PEC-XII)	Me-Too provided by the firm is not verifiable
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
78.	Name and address of manufacturer / Applicant	M/s Perfect Pharma (Pvt) Ltd. 5-km, Manga Road, Riawind, Lahore.
	Brand Name +Dosage Form + Strength	VeerVit Syrup
	Composition	Diary No: 25379, 20-12-2017, Rs: 20,000/-
	Diary No. Date of R& I & fee	Each 5ml contains Thiamine hydrochloride..……..5mg Riboflavin……..1.66mg Pyridoxine……..1mg Cyanocobalamin……10mcg Ascorbic acid……75mg D-Pantothenol……..……...2.5mg Inositol…….5mg Nicotinamide……...20mg Lycine monohydrate (as HCl)….35mg
	Pharmacological Group	Vitamin preparation/ amino acid
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	120ml: Rs: 65.00/-
	Approval status of product in Reference Regulatory Authorities	Wellcosine by GSK Australia (The reference provided by the firm could not be confirmed)
	Me-too status	Wellcosine Syrup by M/s GSK (Reg#006662)
	GMP status	Last inspection report dated 06-10-2016 & 29-10-2016, the panel recommended the resumption /renewal /additional section for Liquid section (General), cream/ ointment section (general) and external preparation section (repacking) but the panel did not recommend resumption/renewal of tablet (general / psychotropic) and capsule (general) section.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.

		• GMP inspection report is older than 1 year.
	Previous Decision	Registration Board in its 278th meeting decided as under: Deferred for submission of latest GMP inspection report conducted within a period of last 1 year by DRAP.
	Evaluation by PEC AD(PEC-XII)	• Firm provide the evidence the evidence of Me Too product Wellcosine Syrup by M/s. GSK (Reg.no. 006662) • Latest GMP inspection report (which should have been conducted within the period of last three year).
	Decision: Approved.	
79.	Name and address of manufacturer / Applicant	M/s Inventor Pharma, Plot No. K/196, S.I.T.E, (SHW) Phase-II, Karachi
	Brand Name +Dosage Form + Strength	Invit Injection 2000mcg/2ml
	Composition	Diary No: 15231, 15/09/2017, Rs: 20,000/-
	Diary No. Date of R& I & fee	Each 2ml ampoule contains:- Vitamin B12 (Cyanocobalamin)…2000mcg
	Pharmacological Group	Antianemic Preparation
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2mlx25's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Not confirmed
	Me-too status	Not Confirmed
	GMP status	10-06-2017; New License
	Remarks of the Evaluator.	• Approval status of applied formulation in Reference Regulatory Authorities not confirmed. • Me-too status not confirmed from available database.
	Previous Decision	Registration Board in its 277th meeting decided as under: • Evidence of applied formulation/drug already approved by DRAP (generic / me too status) alongwith registration number, brand name & name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board
	Evaluation by PEC AD(PEC-XII)	Firm did not provide the Evidence of applied formulation/drug already approved by DRAP (generic / me too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
80.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals, Karachi.
	Brand Name +Dosage Form + Strength	Safecare-D tablet
	Composition	Each tablet contains: Cholecalciferol (Vit D3)….. 50 mg
	Diary No. Date of R& I & fee	Dy. No.341; 14-03-2016; Rs.20,000/- (10-03-2016)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1's x 3 ml; as per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Not verifiable
	GMP status	Last inspection report dated 04-03-2019 with the following conclusion: All the observations pointed out during inspection were discussed with the management of the firm and they were

		committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its meeting shall be submitted. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm shall be submitted.
	Previous Decision	Registration Board in its 276th meeting decided as under: Deferred for following: i. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. ii. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Evaluation by PEC AD(PEC-XII)	Firm did not provide the Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for the evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
81.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories Pvt. Ltd. 313, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	ONC-D tablet
	Composition	Each film coated tablet contains: Vitamin D…….400IU Ossein mineral complex…`…830mg eq.to Calcium…….. 177.6mg Phosphorous……82.2mg Resid.mineral salts…. 24.9mg Collagen ……224mg Other proteins ……66.mg Trace elements F,Mg,Fe,Ni,Cu,calculated on anhydrous basis
	Diary No. Date of R& I & fee	Dy. No. 514; 25-03-2016; Rs.20,000/- (24-03-2016)
	Pharmacological Group	Vitamins, Minerals
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's ; As decided by Ministry of Health
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Bonmin Tablet by M/s. S.J. & G.Fazal Elahi Pvt Ltd, Karachi. (Reg. No. 070532)
	GMP status	Last inspection conducted on 11-01-2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Medizan Labs pvt Ltd, the panel unanimously recommends the renewal of DML No.00572.
	Previous Remarks of the Evaluator.	• Evidence of approval of applied formulation by reference regulatory authority shall be submitted. • Copy of invoice has been submitted as evidence of

		availability of atomic absorption spectrophotometer. • Last inspection report conducted within last one year by DRAP shall be submitted.
	Previous Decision of Registration Board	Registration Board in its 273rd meeting deferred for submission of latest GMP inspection report conducted within last 1 year by DRAP.
	Evaluation PEC	• Firm has submitted latest GMP inspection report conducted on 20-11-2017 concluding acceptable level of GMP compliance. • Evidence of approval of applied formulation by reference regulatory authority shall be submitted
	Previous Decision	Registration Board in its 276th meeting decided as under: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board
	Evaluation by PEC AD(PEC-XII)	Firm provide the evidence of Me Too product Bonmin Tablet Registered in the name of M/s. M/s. S J & G Fazal Elahi Pvt Ltd, Karachi. (Reg. No. 070532)
	Decision: Deferred for the evidence of purchase of Atomic Absorption Spectrophotometer.	
82.	Name and address of manufacturer / Applicant	M/s. Winthrox Laboratories Plot # K-219-A, SITE, Super Highway Phase II, Karachi
	Brand Name +Dosage Form + Strength	Womic-D Tablet 830mg+400IU
	Diary No. Date of R& I & fee	Diary No: 521 , 17/11/2016 , Rs. 20,000/-
	Composition	Each Tablet contains: Ossein MineralComplex…830mg Vitamin D……..400 I.U
	Pharmacological Group	Mineral + Vitamin
	Type of Form	Form-5
	Finished Product Specification	Mfg.
	Pack size & Demanded Price	As per SRO / Pack size as per SRO
	Approval status of product in Reference Regulatory Authorities.	Wellese Calcium and Vitamin D3 Tablet by Botanical Laboratories, USA.
	Me-too status	Bonmin Tablet by M/s. S J & G Fazal Elahi, Karachi.
	GMP status	09-10-2018 Routine GMP Inspection "overall GMP compliance level is rated as good."
	Remarks of Evaluator	Evidence of international availability provided by firm could not be confirmed in reference regulatory authority.
	Previous Decision	Registration Board in its 275th meeting decided as under: Deferred for submission of following: • Evidence of approval in reference regulatory authorities. • Evidence of availability of atomic absorption spectrophotometer
	Evaluation by PEC AD(PEC-XII)	• Firm provide the evidence of Me Too product Bonmin Tablet Registered in the name of M/s. S J & G Fazal Elahi Pvt Ltd, Karachi. (Reg. No. 070532) • Evidence of availability of atomic absorption spectrophotometer is required.
	Decision: Deferred for confirmation of availability of Atomic absorption spectrophotometer	

Case No.01: Routine Applications (Human) for local manufacturing

83.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Onzaflox 3/25mg Capsules
	Diary No. Date of R& I & fee	Dy.No 40013 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Capsule Contains: Olanzapine……3mg Flouxetine as HCl.…25mg
	Pharmacological Group	SSRI/Thienobenzodiazepine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Symbyax 3mg/25 mg Capsules by Ms/ Eli Lilly, USA (USFDA approved).
	Me-too Status	Olanco Capsules by Genome Pharma. (Reg. # 079388)
	GMP Status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator.	
	Decision: Approved.	
84.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Onzaflox 6/25mg Capsules
	Diary No. Date of R& I & fee	Dy.No 40014 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Capsule Contains: Olanzapine……6mg Flouxetine as HCL…25mg
	Pharmacological Group	SSRI/Thienobenzodiazepine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	SYMBYAX capsule by M/s Eli Lilly and Company. (USFDA Approved)
	Me-too Status	Olanzo–F 6/25 Capsule by M/s Regal Pharma, Reg No.81974
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
85.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Onzaflox 12/25mg Capsules
	Diary No. Date of R& I & fee	Dy.No 40015 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Capsule Contains: Olanzapine……..12mg Flouxetine as HCL…..25mg
	Pharmacological Group	Form 5
	Type of Form	USP
	Finished Product Specification	As per SRO
	Pack Size & Demanded Price	SYMBYAX capsule 12/25 by M/s Eli Lilly and Company. (USFDA Approved)
	Approval Status of Product in Reference Regulatory Authorities	Olanzo – F 12/25 Capsule by M/s Regal Pharmaceuticals, Reg No. 81975
	Me-too Status	Form 5
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	

86.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Tranex 500mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40000 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each film coated tablet contains: Tranexamic Acid…500mg
	Pharmacological Group	Anti- fibrinolytic agent
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Menstralite 500mg Film coated tablet by M/s Waymade Plc trading as Sovereign Medical (MHRA Approved
	Me-too Status	Traumax tablet (250mg&500mg) by M/s Siza International (Pvt) Ltd, Reg. no. 24787
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
87.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Prebalin 150mg Capsule
	Diary No. Date of R& I & fee	Dy.No 40006 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Capsule Contains: Pregabalin…150mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LYRICA (pregabalin) Capsules 150mg by M/s PF Prism (USFDA Approved)
	Me-too Status	Zeegap 150mg Capsules by M/s Hilton (Reg#047361)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
88.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Prebalin 100mg Capsule
	Diary No. Date of R& I & fee	Dy.No 40005 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Capsule Contains: Pregabalin…100mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	MFG Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LYRICA (pregabalin) Capsules 100mg by M/s PF Prism (USFDA Approved)
	Me-too Status	Zeegap 100mg Capsules by M/s Hilton (Reg#047360)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
89.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Prebalin 75mg Capsule
	Diary No. Date of R& I & fee	Dy.No 40004 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Capsule Contains: Pregabalin……75mg
	Pharmacological Group	Antiepileptic

	Type of Form	Form 5
	Finished Product Specification	MFG Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LYRICA (pregabalin) Capsules 75mg by M/s PF Prism CV (USFDA Approved)
	Me-too Status	Zeegap 75mg Capsules by M/s Hilton (Reg#047359)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
90.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Rovas 5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40007 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium…5mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Rosulin Tablets 5mg tablet by M/s ' Highnoon Laboratories, Reg. no. 48373
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved innovator's specifications.	
91.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Rovas 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40008 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium…..10mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Rosulin Tablets 5mg tablet by M/s Highnoon Labs, Reg.#048372
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
92.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Rovas 20mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40009 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as calcium.…20mg
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too Status	Rosulin Tablets 5mg by M/s Highnoon Labs, Reg.no. 48371
	GMP Status	Same as stated above

	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
93.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Amlosar 5/160mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40011 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan……..160mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Exforge 5/160mg film-coated tablets by M/s Novartis Pharma, USFDA Approved..
	Me-too Status	Amsart 5/160mg Tablet by M/s Genetics Pharmaceutical (Pvt) Ltd, Reg. No. 84098
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
94.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Amlosar 10/160mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40012 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Valsartan……..160mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Exforge 10/160mg film-coated tablets by M/s Novartis Pharma, USFDA Approved..
	Me-too Status	Amsart 10/160mg Tablet by M/s Genetics Pharmaceutical (Pvt) Ltd, Reg. No. 84097
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
95.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Amlosar 5/80mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40010 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…80mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Exforge 5/80mg film-coated tablets by M/s Novartis Pharma, TGA Australia Approved..
	Me-too Status	Amsart 5/80mg Tablet by M/s Genetics Pharmaceutical (Pvt) Ltd, Reg. No. 84099
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	

96.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	Trapamol 37.5mg/325mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40001 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Tramadol……37.5mg Paracetamol……325mg
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved
	Me-too Status	Tramal Plus tablet by M/s Searle Company Ltd, Reg No.77129
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
97.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	S-Met 50/500mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40002 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate……50mg Metformin HCL ……500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/500 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53403
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
98.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif
	Brand Name +Dosage Form + Strength	S-Met 50/1000mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40003 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate……50mg Metformin HCL ……1000mgs
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) by M/s MSD, USFDA Approved.
	Me-too Status	Sitaglip-Plus Tablet 50/1000 by M/s Maple Pharmaceuticals (Pvt) Ltd, Reg. No. 53404
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
99.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medlofenac SR 100mg Tablet

	Diary No. Date of R& I & fee	Dy.No 40755 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Sustained Release Tablet Contains: Diclofenac Sodium…100mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Dicloflex Retard 100 mg prolonged release tablet by M/s Dexcel Pharma Ltd. M**HRA** approved
	Me-too Status	Sintral SR Tablets 100mg of M/s Neomedix (R.# 081413)
	GMP Status	DML was issued to the firm dated 26/02/2018. Sections: Tablet general, capsule general, Sachet General, Capsule Cph, Dry powder suspension general, Dry powder Suspension Ceph, Dry Powder Injection Ceph.
	Remarks of the Evaluator.	
	Decision: Approved.	
100.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medlucinol 80/80 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40754 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each sugar coated tablet contains: Hydrated Phloroglucinol…80mg Trimethylphloroglucinol…80mg
	Pharmacological Group	Drugs for functional Gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	PHLOROGLUCINOL/TRIMETHYLPHLOROGLUCINOL ACINO 62,233 mg/80 mg, comprimé enrobe by M/s Acino, ANSM France Approved.
	Me-too Status	Spasrid tablet 80mg/80mg of M/s Barrett Hodgson (R.#034743)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved innovator's specifications.	
101.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medriva 3mg Capsule
	Diary No. Date of R& I & fee	Dy.No 40758 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Capsule Contains: Rivastigmine as Hydrogen Tartrate…..…3mg
	Pharmacological Group	Acetylcholinesterase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nimvastid (1.5 mg, 3 mg, 4.5 mg, and 6 mg) capsule, EMA Approved.
	Me-too Status	Rivamine 3mg Capsule by M/s CCL Pharma Reg. No. 048029
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
102.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medoxib 60mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40752 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Etoricoxib as monohydrate…….60mg

	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ARCOXIA (30mg, 60mg, 90mg, 120mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Etoria 60mg Table of M/s Hygeia Pharma, (Reg.# 080818)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved innovator's specifications.	
103.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medsartan-H 50/12.5 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40757 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…….50mg Hydrochlorothiazide……12.5mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar Comp (50/12.5mg, 100/12.5mg, 100/25mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Sartan –H Tablets 50/12.5mg by M/s Barrett Hodgson Pakistan (Pvt) Ltd, Reg. No. 24252
	GMP Status	Same as above
	Remarks of the Evaluator.	
	Decision: Approved.	
104.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medfenacin 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40759 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…10mg (Eq. to Solifenacin…7.5mg)
	Pharmacological Group	Muscarinic antagonist
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vesicare® (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too Status	Solifen Tablet 10mg by M/s GetzPharma, Reg. No. 61203
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved innovator's specifications.	
105.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medsetron 8mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40753 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Ondansetron as HCL Dihydrate…8mg
	Pharmacological Group	Serotonin 5-HT3 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in	Ondansetron 8mg film coated tablets by M/s Milpharm Limited

	Reference Regulatory Authorities	MHRA Approved.
	Me-too Status	Oniron 4mg Tablets by Genome Pharma. (Reg. # 068375)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
106.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medlans 30mg Capsule
	Diary No. Date of R& I & fee	Dy.No 40750 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Capsule Contains: Lansoprazole as Enteric Coated Pellets…30mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Lansoprazole (15mg, 30mg) gastro resistant capsule by M/s Consilient, MHRA Approved.
	Me-too Status	Leazole 30mg Capsules of M/s Leads Pharma (Reg.#035891)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	**Source of pellets:** M/s Vision Pharma
	Decision: Approved.	
107.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medosamide 100mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40756 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Pharmacological Group	Anticonvulsive
	Type of Form	Form 5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vimpat 100mg film coated tablet by M/s UCB Inc, USFDA Approved.
	Me-too Status	Lacolep 100mg tablet by M/s Hilton Pharma (Reg # 073858)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
108.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medvastatin-EZ 10/10 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40761 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Ezitimibe…….10mg Atorvastatin as Calcium Trihydrate…10mg
	Pharmacological Group	Lipid lowering agent/antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	USFDA Approved.
	Me-too Status	Lipiget EZ Tablet by Getz
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	

109.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medtrimazole 500mg Vaginal Tablet
	Diary No. Date of R& I & fee	Dy.No 40762 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Vaginal Tablet Contains: Clotrimazole..…500mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MYCOHYDRALIN 500 mg, vaginal tablet by M/s Bayer Healthcare SAS, **ANSM** approved
	Me-too Status	CANESTTEN-VAGINAL TAB 500mg by M/s Bayer (Imported) Reg No. 7293
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
110.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medtrazole 100mg Capsule
	Diary No. Date of R& I & fee	Dy.No 40760 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Capsule Contains: Itraconazole Pellets 22.5%...100mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	SPORANOX capsule 100mg by M/s Jannsen Pharms, USFDA Approved.
	Me-too Status	Rolac 100mg Capsules of Sami Pharmaceuticals, Reg.No. 24491.
	GMP Status	Same as stated above
	Remarks of the Evaluator.	**Source of pellets:** M/s Vision Pharma
	Decision: Approved with innovator's specifications.	
111.	Name and address of manufacturer / Applicant	M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Medflucan 150mg Capsule
	Diary No. Date of R& I & fee	Dy.No 40751 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Capsule Contains: Fluconazole…150mg
	Pharmacological Group	Anti Fungal
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diflucan (50mg, 150mg) hard capsules by M/s Pfizer Limited, MHRA Approved.
	Me-too Status	Diflucan 150mg Cap by M/s Pfizer, Reg. No. 11828
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
112.	Name and address of manufacturer / Applicant Contract manufacturing	**Applicant:** M/s Helix Pharma (PVT) Ltd, Hakimson House,A/56, SITE Manghopir road, Karachi. **Manufacturer:** M/s Mediate Pharmaceutical (pvt) ltd. Plot no. 150-151, sector 24 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Cefolix Injection 500mg IV/IM (Powder for solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 43202 dated 18/12/2018 (Rs. 20,000/- 04/12/2018 +

		30,000/- dated 06/02/2019)
	Composition	Each vial contains: Ceftazidime as pentahydrate……..500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×1's price as per PRC
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 500mg IM/IV by M/s Biocef,Reg. no. 82750
	GMP Status	Last inspection report of M/s Mediate pharma dated 20/07/2018 shows that satisfactory compliance to GMP was observed. Section available M/s Helix pharma, Inspection date 16/01/2020.the panel Recommended Resumption of product in OSD and Oral liquid sections. Working of HVAC ducting and installation of air showers was in progress in Ampoule/infusion/ophthalmic/otic sections.
	Remarks of the Evaluator.	Detail of products being manufactured for M/s Helix pharma on contract manufacturing: Total number of sections: 08 Total number of products already being manufactured: 09 Alternate brand name: Helixime
	Decision: Approved.	
113.	Name and address of manufacturer / Applicant Contract manufacturing	**Applicant:** M/s Helix Pharma (PVT) Ltd, Hakimson House,A/56, SITE Manghopir road, Karachi. **Manufacturer:** M/s Mediate Pharmaceutical (pvt) ltd. Plot no. 150-151, sector 24 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Cefolix Injection 1000mg IV/IM (Powder for solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 43203 dated 18/12/2018 (Rs. 20,000/- dated 04/12/2018 + 30,000/- dated 06/02/2019)
	Composition	Each vial contains: Ceftazidime as pentahydrate……..1000mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×1's price as per PRC
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 1000mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82749
	GMP Status	Last inspection report of M/s Mediate pharma dated 20/07/2018 shows that satisfactory compliance to GMP was observed. Section available M/s Helix pharma, Inspection date 16/01/2020.the panel Recommended Resumption of product in OSD and Oral liquid sections. Working of HVAC ducting and installation of air showers was in progress in Ampoule/infusion/ophthalmic/otic sections.
	Remarks of the Evaluator.	Detail of products being manufactured for M/s Helix pharma on contract manufacturing: Total number of sections: 08 Total number of products already being manufactured: 09

		Alternate brand name: Helixime
	Decision: Approved.	
114.	Name and address of manufacturer / Applicant Contract manufacturing	**Applicant:** M/s Helix Pharma (PVT) Ltd, Hakimson House,A/56, SITE Manghopir road, Karachi. **Manufacturer:** M/s Mediate Pharmaceutical (pvt) ltd. Plot no. 150-151, sector 24 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Cefolix Injection 250mg IV/IM (Powder for solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 43201 dated 18/12/2018 (Rs. 20,000/- dated 04/12/2018 + 30,000/- dated 06/02/2019)
	Composition	Each vial contains: Ceftazidime as pentahydrate……..250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×1's price as per PRC
	Approval Status of Product in Reference Regulatory Authorities	CEFTAZIDIME PANPHARMA CHILDREN AND INFANTS 250 mg powder for solution for injection by M/s PANPHARMA Approved.
	Me-too Status	Fortez Injection 250mg IM/IV by M/s Biocef (Pvt)Ltd.,Reg. no. 82751
	GMP Status	Last inspection report of M/s Mediate pharma dated 20/07/2018 shows that satisfactory compliance to GMP was observed. Section available
	Remarks of the Evaluator.	Last inspection report of M/s Mediate pharma dated 20/07/2018 shows that satisfactory compliance to GMP was observed. Section available M/sHelix pharma, Inspection date 16/01/2020.the panel Recommended Resumption of product in OSD and Oral liquid sections. Working of HVAC ducting and installation of air showers was in progress in Ampoule/infusion/ophthalmic/otic sections.
	Decision: Approved.	
115.	Name and address of manufacturer / Applicant Contract manufacturing	**Applicant:** M/s Helix Pharma (PVT) Ltd, Hakimson House,A/56, SITE Manghopir road, Karachi. **Manufacturer:** M/s Mediate Pharmaceutical (pvt) ltd. Plot no. 150-151, sector 24 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Heliphen Injection 250mg IV (powder for solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 43198 dated 18/12/2018 (Rs. 20,000/- dated 04/12/2018 + 30,000/- dated 19/02/2019)
	Composition	Each vial contains: Ceftriaxone as sodium……..250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×1's price as per PRC
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone (250mg & 1gm) powder for solution for injection by M/s Villerton Invest SA, MHRA Approved.
	Me-too Status	Unixone Injection 250mg IM by M/s Caliph Pharmaceuticals (Pvt.) Ltd, Reg. no. 82556
	GMP Status	Last inspection report of M/s Mediate pharma dated 20/07/2018 shows that satisfactory compliance to GMP was observed. Section available M/s Helix pharma, Inspection date 16/01/2020.the panel Recommended Resumption of product in OSD and Oral liquid sections. Working of HVAC ducting and installation of air

		showers was in progress in Ampoule/infusion/ophthalmic/otic sections.
	Remarks of the Evaluator.	Detail of products being manufactured for M/s Helix pharma on contract manufacturing: Total number of sections: 08 Total number of products already being manufactured: 09 Alternate brand name: Helixone
	Decision: Approved.	
116.	Name and address of manufacturer / Applicant Contract manufacturing	**Applicant:** M/s Helix Pharma (PVT) Ltd, Hakimson House,A/56, SITE Manghopir road, Karachi. **Manufacturer:** M/s Mediate Pharmaceutical (pvt) ltd. Plot no. 150-151, sector 24 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Heliphen Injection 1gm IV (powder for solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 431200 dated 18/12/2018 (Rs. 20,000/- dated 04/12/2018 + 30,000/- dated 19/02/2019)
	Composition	Each vial contains: Ceftriaxone as sodium……..1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×1's price as per PRC
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone (250mg & 1gm) powder for solution for injection by M/s Villerton Invest SA, MHRA Approved.
	Me-too Status	Unixone Injection 1gm IM by M/s Caliph Pharmaceuticals (Pvt.) Ltd, Reg. no. 82555
	GMP Status	Last inspection report of M/s Mediate pharma dated 20/07/2018 shows that satisfactory compliance to GMP was observed. Section available M/s Helix pharma, Inspection date 16/01/2020.the panel Recommended Resumption of product in OSD and Oral liquid sections. Working of HVAC ducting and installation of air showers was in progress in Ampoule/infusion/ophthalmic/otic sections.
	Remarks of the Evaluator.	Detail of products being manufactured for M/s Helix pharma on contract manufacturing: Total number of sections: 08 Total number of products already being manufactured: 09 Alternate brand name: Helixone
	Decision: Approved.	
117.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	I Rose Injection
	Diary No. Date of R& I & fee	Dy.No 42382 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each 5ml Ampoule contains: Iron sucrose eq to Elemental iron…100mg
	Pharmacological Group	Antianemic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Venofer Injection M/s Vifor (MHRA Approved).
	Me-too Status	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)

	GMP Status	M/s Rotex Pharma, Last inspection report dated 19/09/2018, the panel approved 16 new/additional sections except Gel preparations/product, Cream/Ointment (General) and Topical (steroid). Seraph pharma, GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision: Approved.	
118.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vidot Injection 5mg/1ml IM
	Diary No. Date of R& I & fee	Dy.No 42383 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each 1ml ampoule contains: Cholecalciferol (Vit D3)…5mg (200,000 IU)
	Pharmacological Group	Vitamin D3 analogue
	Type of Form	Form-5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml, oral solution in ampoule and Vitamin D3 Good 200,000 IU / 1 ml, solution for injection IM in ampoule by Bouchara-Recordati. ANSM Approved.
	Me-too Status	ORA-D3 Injection by Ameer & Adnan Pharmaceuticals (Pvt) Ltd. Reg. No. 78639.
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision: Approved with innovator's specifications.	
119.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hisone 100mg Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 42384 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Hydrocortisone sodium Succinate eq to Hydrocortisone…100mg
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solu-Cortef Act-O-Vial (100mg,250mg,500mg) powder for injection by M/s Pfizer, MHRA Approved.
	Me-too Status	Cortizone 100mg Inj. by M/s Vision Pharma Reg.No.081898
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision: Approved.	
120.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hisone 250mg Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 42385 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains:

		Hydrocortisone sodium Succinate eq to Hydrocortisone…250mg
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solu-Cortef Act-O-Vial (100mg,250mg,500mg) powder for injection by M/s Pfizer, MHRA Approved.
	Me-too Status	Cortizone 250mg Injection by M/s Vision Pharmaceuticals, Reg. No. 81899
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision: Deferred for confirmation of section in M/s Rotex Pharma Pvt Ltd .	
121.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ceropenim 500mg Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 42386 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Meropenem as trihydrate (as a mixture of sodium carbonate)…500mg
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Meronem IV (meropenem as trihydrate) powder for solution for injection (500mg, 1g) by M/s Pfizer, MHRA Approved.
	Me-too Status	Meroget Powder for Solution for Infusion or Injection 500mg/vial by M/sGetz Pharma, Karachi, Reg. No. 83174
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision: Approved.	
122.	Name and address of manufacturer / Applicant	**Applicant:** M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad **Manufactured By:** M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ceropenim 1g Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 42386 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Meropenem as trihydrate (as a mixture of sodium carbonate)…1g
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Meronem IV (meropenem as trihydrate) powder for solution for injection (500mg, 1g) by M/s Pfizer, MHRA Approved.
	Me-too Status	Meroget Powder for Solution for Infusion or Injection 1g/vial by M/sGetz Pharma, Karachi, Reg. No. 83175
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Number of products already being manufactured: 00 Number of approved sections: 07
	Decision: Approved.	
123.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad

	Brand Name +Dosage Form + Strength	Droncef Injection 500mg IV Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41787 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark Pharmaceutical, Reg. No. 69751
	GMP Status	GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Remarks of the Evaluator.	
	Decision: Approved.	
124.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Droncef Injection 250mg IV Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41788 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 250mg Inj. by M/s WelMark Pharma Reg.No.069750
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
125.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mictarin Gel 2% w/w
	Diary No. Date of R& I & fee	Dy.No 41786 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each gram of contains: Miconazole……20mg (2% w/w)
	Pharmacological Group	Anti-fungal
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	DAKTARIN Oral Gel 20mg/g by M/s Janssen-Cilag Limited, MHRA Approved.
	Me-too Status	Myzoge Oral Gel 20mg/g by M/s Nabiqasim Industries (Pvt) Ltd, Reg. No. 34465
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
126.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Onsoft 8mg/4ml Injection IV

	Diary No. Date of R& I & fee	Dy. No. 40956 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each 4ml Ampoule contains: Odnansetron as HCl dihydrate….. 8mg
	Pharmacological Group	Selective serotonin 5-HT3 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ondansetron 8mg/4ml solution for injection (MHRA approved)
	Me-too Status	Ondansetron –Sandoz 8mg / 4ml solution for injection by M/s Novartis (Reg#066121)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	Ampoule General Section available (biolabs)
	Decision: Approved.	
127.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Zolid 600mg.300ml Infusion
	Diary No. Date of R& I & fee	Dy. No. 43541 dated 21/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial of 300ml contains: Linzolid…….600mg
	Pharmacological Group	Quinolone antibiotic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Linezolid 2 mg/ml solution for infusion bag by M/s Mylan, MHRA Approved.
	Me-too Status	Hilid Injection 600mg/300ml Infusion vial by M/s Hilton, Reg. No. 55624
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
128.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Ceflet 400mg Capsule
	Diary No. Date of R& I & fee	Dy. No. 40944 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Eachc capsule contains: Cefixime as trihydrate …400mg
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO

	Approval Status of Product in Reference Regulatory Authorities	Suprax (cefixime as trihydrate) 400mg capsule by M/s Lupin ltd, USFDA approved.
	Me-too Status	Xalfocin 400mg Capsule by M/s Martin Dow (Reg. # 080646)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved.	
129.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Ceflet for Suspension (100mg/5ml)
	Diary No. Date of R& I & fee	Dy. No. 40945 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	EACH 5ML (Reconstituted) CONTAINS: Cefixime as trihydrate …….100mg
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved.	
130.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Ceflet for Suspension (200mg/5ml)
	Diary No. Date of R& I & fee	Dy. No. 43540 dated 21/12/2018 Fee Rs. 50,000/-
	Composition	EACH 5ML (Reconstituted)CONTAINS: Cefixime as trihydrate…200mg
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Xerak Oral Dry Powder Suspension (200mg/5ml) by M/s CKD, Reg. No. 81788
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017.

		Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved.	
131.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Moxilet 400mg/250ml Infusion IV
	Diary No. Date of R& I & fee	Dy. No. 40953 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each vial of 250ml contains: Moxifloxacin as Hydrochloride…… 400mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Avelox 400 mg/250 ml solution for infusion by M/s Bayer PLC, MHRA Approved
	Me-too Status	Moxilox 400mg Infusion by M/s Spencer Karachi (Reg.#075988)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
132.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Keto 30mg Ampoule IM/IV
	Diary No. Date of R& I & fee	Dy. No. 40950 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each Ampoule of 1ml contains: Ketorolac Tromethamine…30mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ketorolac trometamol 30mg/1ml ampoule Solution for Injection by M/s Beacon Pharmaceuticals Limited, MHRA Approved.
	Me-too Status	Torapan Injection 30mg by M/s AL-HAMEED AGENCIES, Reg. No. 25295
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved.	

133.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Irolet Injection 100mg/5ml IM/IV
	Diary No. Date of R& I & fee	Dy. No. 40955 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each 5ml Ampoule contains: Iron sucrose eq to Elemental iron…100mg
	Pharmacological Group	Antianemic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Venofer Injection M/s Vifor (MHRA Approved).
	Me-too Status	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved.	
134.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Esozole 40mg Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40952 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial Contains: Esomeprazole as Sodium……40mg (Lyophilized powder of Esomeprazole sodium)
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nexium IV 40mg/vial injection by M/s ASTRAZENECA PHARMS (USFDA approved)
	Me-too Status	Esold 40mg/vial Injection of M/s Weather Folds Pharmaceutical, Reg No. 74824
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.	
135.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Cefzone 250mg Injection IM
	Diary No. Date of R& I & fee	Dy. No. 40948 dated 06/12/2018 Fee Rs. 50,000/-

	Composition	Each vial of dry substance contains: Ceftriaxone Sodium eq to Ceftriaxone…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 250mg Injection IM by M/s WelMark Pharmaceutical, Reg. No. 69750
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved.	
136.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Cefzone 500mg Injection IM
	Diary No. Date of R& I & fee	Dy. No. 40947 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each vial of dry substance contains: Ceftriaxone Sodium eq to Ceftriaxone…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection by M/s WelMark Pharmaceutical, Reg. No. 69751
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved.	
137.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Cefzone 1g Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40946 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each vial of dry substance contains: Ceftriaxone Sodium eq to Ceftriaxone…1g
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in	Ceftriaxone powder for injection (250mg, 500mg, 1000mg,

	Reference Regulatory Authorities	2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 1000mg Injection by M/s WelMark Pharmaceutical, Reg. No. 69752
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved.	
138.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Omezole 40mg Injection IV
	Diary No. Date of R& I & fee	Dy. No. 40951 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each vial vontains: Omeprazole as Sodium…40mg (Lyophilized powder)
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.	
139.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Mecowin 500mcg Ampoule IV/IM
	Diary No. Date of R& I & fee	Dy. No. 40954 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each ampoule of 1ml contains: Mecobalamin…….500mcg
	Pharmacological Group	Coenzyme Type Vitamin B12
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	PMDA Approved
	Me-too Status	Mexamine 500mcg/ml Injection of M/s Asian Continental (Pvt.) Ltd, Karachi(Reg. # 057864)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing

		License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
140.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	D-Let Injection 5mg/ml
	Diary No. Date of R& I & fee	Dy. No. 40949 dated 06/12/2018 Fee Rs. 50,000/-
	Composition	Each 1ml ampoule contains: Cholecalciferol (Vitamin D3)……200,000IU (5mg)
	Pharmacological Group	Vitamin D3 analogue
	Type of Form	Form-5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml, oral solution in ampoule and Vitamin D3 Good 200,000 IU / 1 ml, solution for injection IM in ampoule by Bouchara-Recordati. ANSM France Approved.
	Me-too Status	ORA-D3 Injection by Ameer & Adnan Pharmaceuticals (Pvt) Ltd. Reg. No. 78639.
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
141.	Name and address of manufacturer / Applicant	**Applicant:** M/s Winlet Pharmaceuticasl, 30-km, Lakisa Lahore-Sargodha road, Sargodha. **Manufacturer:** M/s Biolabs (pvt) Ltd., Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Lorno 8mg for Injection IV/IM
	Diary No. Date of R& I & fee	Dy. No. 43539 dated 21/12/2018 Fee Rs. 50,000/-
	Composition	Each Vial contains: Lornoxicam……8mg (Lyopilized powder)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 8 mg powder and solvent for solution for injection by M/s Takeda Austria GmbH, (Austria Approved)
	Me-too Status	Viltaz Injection 8mg/2ml by Wilshire (Reg. No. 077112)
	GMP Status	**Biolabs:** Last GMP inspection was conducted on 23-04-2019 and the report concludes a reasonably acceptable GMP compliance. **Winlet Pharma:** The firm is granted New Drug Manufacturing License based on inspection Dated 05-12-2017. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	

	Decision: Deferred for following: **a. Confirmation whether application is by lyophilization process or powder filling.** **b. Registration status of M/s Biolab for same formulation.**	
142.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (pvt) ltd. Plot Number 129, Sundar Industrial Estate (P.I.E) Raiwind Road Lahore.
	Brand Name +Dosage Form + Strength	Lakill Syrup 10mg/ml
	Diary No. Date of R& I & fee	Dy. No. 44265 dated 28/12/2018 fee Rs, 20,000/-
	Composition	Each ml contains: Lacosamide…….10mg
	Pharmacological Group	Anticonvulsive
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	100ml,120ml, 200ml Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	VImpat syrup 10mg/ml by M/s UCB INC, USFDA Approved.
	Me-too Status	Lalap syrup 10mg/ml by Genix Pharma (Reg #089376)
	GMP Status	GMP certificate issued on the basis of inspection conducted on 08/11/2018. Firm has informed that the applicant firm has 4 approved sections and they have no product already registered on contract manufacturing.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
143.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (pvt) ltd. Plot Number 129, Sundar Industrial Estate (P.I.E) Raiwind Road Lahore.
	Brand Name +Dosage Form + Strength	Risplax Oral Solution 1mg/ml
	Diary No. Date of R& I & fee	Dy. No. 44282 dated 28/12/2018 fee Rs, 20,000/-
	Composition	Each ml contains: Risperidone……..1mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Risperidone 1 mg/ml oral solution by M/s Milpharm Limited, MHRA Approved.
	Me-too Status	Buzon Oral Solution 1mg/1ml by M/s Nabi Qasim, R#042141
	GMP Status	GMP certificate issued on the basis of inspection conducted on 08/11/2018.
	Remarks of the Evaluator.	
	Decision: Approved.	
144.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (pvt) ltd. Plot Number 129, Sundar Industrial Estate (P.I.E) Raiwind Road Lahore.
	Brand Name +Dosage Form + Strength	Cobwim 1000mcg Injection IM
	Diary No. Date of R& I & fee	Dy. No. 44259 dated 28/12/2018 fee Rs, 20,000/-
	Composition	Each ampoule of 1ml contains: Cyanocobalamin…….1000mcg
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	B12>>Ankermann<<1000 µgsolution for injection by Wörwag Pharma GmbH (Germany Approved)
	Me-too Status	Cyanocobalamin Injection by Amaan Pharma (Reg#094555)
	GMP Status	GMP certificate issued on the basis of inspection conducted on 08/11/2018.
	Remarks of the Evaluator.	Alternate brand name: Coyancowim 1000mcg Injection
	Decision: Approved.	

145.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Aferol-D 70mg/70mcg Tablet
	Diary No. Date of R& I & fee	Dy.No 41522 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Uncoated Tablet Contains: Alendronate Acid as alendronate sodium Trihydrate……70mg Cholecalciferol……70mcg
	Pharmacological Group	Bisphosphonates , vitamin
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	FOSAMAX PLUS D tablet 70mg/70mcg) by M/s Merck, USFDA Approved.
	Me-too Status	Osteopor-D Tablet of M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad. (Reg.# 068878)
	GMP Status	Last inspection report dated 19/09/2018, the panel approved 16 new/additional sections except Gel preparations/product, Cream/Ointment (General) and Topical (steroid).
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
146.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ceropenim 1000mg Injection IV
	Diary No. Date of R& I & fee	Dy.No 42387 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Meropenem trihydrate eq to Meropenem…1000mg
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Meronem IV (meropenem as trihydrate) powder for solution for injection (500mg, 1g) by M/s Pfizer, MHRA Approved.
	Me-too Status	Meroget Powder for Solution for Infusion or Injection 1000mg/vial by M/sGetz Pharma, Karachi, Reg. No. 83175
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
147.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ceropenim 500mg Injection
	Diary No. Date of R& I & fee	Dy.No 42386 dated 11-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Vial Contains: Meropenem as trihydrate…500mg (as trihydrate to be confirmed from dossier)
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Meronem IV (meropenem as trihydrate) powder for solution for injection (500mg, 1g) by M/s Pfizer, MHRA Approved.
	Me-too Status	Meroget Powder for Solution for Infusion or Injection 500mg/vial by M/sGetz Pharma, Karachi, Reg. No. 83174
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	

148.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Deox 250mg/5ml Liquid Suspension
	Diary No. Date of R& I & fee	Dy.No 41118 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Ursodeoxycholic Acid…250mg
	Pharmacological Group	Bile-acid
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ursofalk 250mg/5ml Suspension by M/s Dr Falk Pharma UK Ltd, MHRA Approved.
	Me-too Status	Urso Suspension 250mg/5ml by M/s AGP (Reg. No. 076152)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
149.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Exor-H Tablet
	Diary No. Date of R& I & fee	Dy.No 41520 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…..10mg Valsartan……160mg Hydrochlorthiazide……..12.5mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Amlodipine Besylate, Valsartan and Hydrochlorothiazide (10mg/160/12.5) by M/s LUPIN LTD, USFDA Approved.
	Me-too Status	EXFORGE HCT 10/160/12.5MG FILM COATED TABLETS by M/s Novartis, Reg. No. 69550
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
150.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hexalor 2.5mg/5ml Liquid Syrup
	Diary No. Date of R& I & fee	Dy.No 41093 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Desloratadine…2.5mg
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	30mlm, 60ml, 120ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Aerius For Children Syrup desloratadine 2.5mg/5mL oral liquid bottle by M/s Bayer Australia Ltd (TGA approved)
	Me-too Status	Desora 0.5mg/ml syrup by M/s S.J&G.FazulEllahie,(R.#055192)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
151.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hi-Pride 200mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41576 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Uncoated Tablet Contains:

		Amisulpride…200mg
	Pharmacological Group	Benzamides
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	10's, 20's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solian (50mg, 100mg, 200mg) uncoated tablet by M/s Sanofi, MHRA Approved.
	Me-too Status	Ampisol 200mg Tablet by M/s Sami Karachi, Reg. No. 76059
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
152.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hi-Pride 400mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41577 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Uncoated Tablet Contains: Amisulpride…400mg
	Pharmacological Group	Benzamides/Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	10's, 20's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Solian 400mg Film Coated tablet by M/s Sanofi, MHRA Approved.
	Me-too Status	Amiride Tablet 400mg by M/s Shrooq Pharma, Reg. No. 63103
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
153.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	IPC 100mg/5ml Syrup
	Diary No. Date of R& I & fee	Dy.No 41103 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Iron III Polysaccharide Complex Eq. to Elemental Iron…100mg
	Pharmacological Group	Hematinic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	30ml, 60ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Niferex Elixir by M/s Tillomed Lab (MHRA Approved)
	Me-too Status	NuIron syrup by M/s Hiranis, Reg. No. 76507
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
154.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	IPS 40mg/15ml Syrup
	Diary No. Date of R& I & fee	Dy.No 41107 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 15ml Contains: Elemental Iron as Iron Protein Succinylate…40mg
	Pharmacological Group	Antianemic (iran deficiency anemia)
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	60ml, 120ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ferplex 40mg oral solution by M/s Italfarmaco Spain Ferrocur Effik, CIMA Spain Approved
	Me-too Status	Fero-slim Syrup by M/s Fynk Pharmaceuticals (Reg#062725)

	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
155.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Isodil 10mg/10ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40242 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 10ml Ampoule Contains: Isosorbide Dinitrate…10mg
	Pharmacological Group	Vasodilators used in cardiac diseases (Organic nitrates)
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	1's, 10's, 50's, 100's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Isoket 1 mg/ml concentrate for solution for injection or infusion (10mg/10ml, 50mg/50ml, 100mg/100ml) Ampoule by M/s Norgine Pharmaceuticals Limited, MHRA Approved.
	Me-too Status	Isosornite Injection 10mg/10ml by M/s Akson Pharmaceuticals Pvt Ltd, Reg. No. 81637
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
156.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Jevomet Plus 50/850 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41521 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin HCL……850mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	VELMETIA 50/850 film coated tablet by M/s MSD, TGA Australia Approved.
	Me-too Status	S-Gliptin Plus 50mg+850mg Tablet by M/s Barret Hodgson, Reg. No. 81619
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
157.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Kalset 1mcg Injection IV
	Diary No. Date of R& I & fee	Dy.No 40184 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 1ml Ampoule Contains: Calcitriol…1mcg
	Pharmacological Group	Form 5
	Type of Form	USP
	Finished Product Specification	1's, 10's, 25's, Price as per SRO
	Pack Size & Demanded Price	Calcitriol 1µg/ml Injection by M/s Akorn, Inc.(USFDA Approved)
	Approval Status of Product in Reference Regulatory Authorities	Aksobone Injection1µg/ml by M/s Akson pharmaceuticals Pvt Ltd (Reg#081638)
	Me-too Status	Form 5
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	

158.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
		Kelac 30mg/ml Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 40142 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 1ml Ampoule Contains: Ketorolac Tromethamine…30mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's, 10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ketorolac trometamol 30mg/ml ampoule Solution for Injection by M/s Beacon Pharmaceuticals Limited, MHRA Approved.
	Me-too Status	Torapan Injection 30mg by M/s AL-HAMEED AGENCIES, Reg. No. 25295
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
159.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ketostil Tablet
	Diary No. Date of R& I & fee	Dy.No 41591 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each film coated tablet contains: α-Ketoanalogue to DL-isoleucine (Calcium-salt)…67mg α-Ketoanalogue to isoleucine (Calcium-salt)…101mg α-Ketoanalogue to phenylalanine (Calcium-Salt)…68mg α-Ketoanalogue to valine (Calcium-Salt)…86mg α-hydroxyanalogue to DL-methionine (Calcium-Salt)...59mg L-lysine acetate...105mg L-threonine...53mg L-tryptophan...23mg L-histidine...38mg L-tyrosine...30mg Total nitrogen content per tablet....36mg Calcium content per tablet...1.25mmol = 50mg
	Pharmacological Group	Calcium and analogue of essential amino acids
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As pe rSRO
	Approval Status of Product in Reference Regulatory Authorities	KETOSTERIL by Fresenius Kabi, Germany.(Bfarm approved)
	Me-too Status	Ketoalfa Tablets M/s Genome Pharmaceuticals
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
160.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Kolmax 200mg/5ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40150 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 5ml Ampoule Contains: Dopamine Hydrochloride…200mg
	Pharmacological Group	Adrenergic and dopaminergic agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 10's, 50's, 100's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Dopamine Hydrochloride 40mg/ml Concentrate for Solution for Infusion by M/s Mercury Pharma International Ltd (MHRA

		Approved)
	Me-too Status	Dopamine 200mg Injection by M/s LC&PW. (Reg.# 005935)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
161.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lamsy 125mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41515 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Terbinafine as HCL…125mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Terbinafine 125mg Tablets by M/s Dr. Reddy's Laboratories, MHRA Approved.
	Me-too Status	Logirid Tablet 125mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80846
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
162.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lamsy 250mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41514 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Terbinafine as HCL…250mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Lamisil® Tablets 250mg by M/s NOVARTIS PHARMACEUTICALS UK LIMITED, MHRA Approved.
	Me-too Status	Logirid Tablet 250mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80847
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
163.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lemoxol 80mg/ml Injection IM
	Diary No. Date of R& I & fee	Dy.No 40249 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 1ml Ampoule Contains: Artemether…80mg
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	1's, 6's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO approved formulation
	Me-too Status	Artesinate Injection of M/S Gray's Pharmaceuticals, Reg. No. 72458
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	

164.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Levitra 100mg/ml Liquid Syrup
	Diary No. Date of R& I & fee	Dy.No 41102 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 1ml Contains: Levetiracetam…100mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30ml, 60ml, 120ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	LEVETIRACETAM (Levetiracetam100mg/ml) solution; oral By M/s TARO. USFDA Approved.
	Me-too Status	Levotam Oral solution 100mg/ml By M/s Platinum, Karachi. (Reg.# 070837)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
165.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Levitra 500mg/5ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40125 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 5ml Ampoule Contains: Levetiracetam…..500mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 10's, 5's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Keppra 500 mg/5ml concentrate for solution for infusion by M/s UCB Pharma S.A
	Me-too Status	Eplipsa 500mg/5ml Injection by M/s Helix, Reg. No. 75918
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
166.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Levopray 50mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41594 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Levosulpride…50mg
	Pharmacological Group	Antipsychotic
	Type of Form	From 5
	Finished Product Specification	MFg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved.
	Me-too Status	Vesulpid Tablets 50mg by M/s Martin Dow Pharmaceutical (Pakistan) Ltd, Reg. No. 41012
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The product approved in reference ecountry is uncoated while the applied product is film coated, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
167.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Linomycin 600mg/2ml Injection IM/IV

	Diary No. Date of R& I & fee	Dy.No 40166 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 2ml Vial Contains: Lincomycin as HCL…600mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Lincocin 600mg/2ml injection by M/s Pfizer, USFDA Approved.
	Me-too Status	Leemed 600mg Injection by M/s Medley Pharmaceuticals Wah Cantt, Reg. No. 79210
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
168.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lonax 50mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41588 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…50mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar (12.5mg, 25mg, 50mg, 100mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Acozar 50mg Tablet by M/s AGP, Reg. No. 82245
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
169.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lonax-H Tablet 50/12.5mg
	Diary No. Date of R& I & fee	Dy.No 41513 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…….50mg Hydrochlorothiazide……12.5mg
	Pharmacological Group	antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10’s, 20’s, 28’s, 14’s, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar Comp (50/12.5mg, 100/12.5mg, 100/25mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Sartan –H Tablets 50/12.5mg by M/s Barrett Hodgson Pakistan (Pvt) Ltd, Reg. No. 24252
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
170.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lorin 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41528 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Lisinopril as Dihydrate…10mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 14's,20's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Lisinopril tablets (2.5mg, 5mg, 10mg, 20mg) by M/s Mylan, MHRA Approved.
	Me-too Status	Veskor Tablets 10mg by M/s Raazee, Reg. No. 24064
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
171.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lyca 3.35gm/ml Liquid Syrup (ref solution)
	Diary No. Date of R& I & fee	Dy.No 41080 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Lactulose…3.35gm
	Pharmacological Group	Ammonium detoxicant, laxative, osmotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Laevolac **10 g/15 ml** oral solution by M/s Fresenius Kabi Austria GmbH, MHRA Approved.
	Me-too Status	Lactusure Syrup 3.35mg/5ml by M/s Medisure Laboratories Pakistan, Reg. No.
	GMP Status	Same as stated above
	Remarks of the Evaluator.	As per submitted undertaking, Lactulose will be imported from China, submit, GMP certificate of manufacturer, stability studies of 03 batches conducted under the conditions of Zone IV-A and as Lactulose is imported then the fee Rs. 100,000/- should be submitted.
	Decision: Deferred for the submission of GMP certificate of manufacturer of Lactulose, Stability studies of 03 batches according to the conditions of zone IV-A and differential fee.	
172.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Maximus 10mg/2ml Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 40151 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 2ml Ampoule Contains: Metoclopramide HCL…10mg
	Pharmacological Group	Antiemetic/ Dopamine D2 Receptor Antagonists
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	10×2ml ampoule, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	METOCLOPRAMIDE 10mg/2ml Solution for Injection by M/s Advanz Pharma, MHRA Approved.
	Me-too Status	Metanil Injection 10mg/2ml by M/s Dosaco Laboratories, Reg. No. 25510
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
173.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mesotek 200mcg Tablet
	Diary No. Date of R& I & fee	Dy.No 41556 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Misoprostol (as HPMC dispersion).…200mcg
	Pharmacological Group	Prostaglandin
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specification

	Pack Size & Demanded Price	3's, 10's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cytotec 200mcg by M/s GD Searle (USFDA approved)
	Me-too Status	Miso 200mcg tablet M/s Global Pharmaceuticals, Reg. No. 66326
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
174.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Milli 1mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 40149 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each Ampoule Contains: Milrinone…1mg
	Pharmacological Group	Inotropic agent & vasodilator
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Milrinone 1mg/ml Solution for injection/infusion (10mg/10ml ampoule) by M/s Wockhardt UK Ltd, MHRA Approved.
	Me-too Status	Milron Injection 1mg/1m (10ml) by M/s Atco Laboratories Limited, Reg. No. 53459
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The product approved in reference country contains Milrinone as Lactate while the applied product contains Milrinone, clarify or otherwise submit revised formulation with equivalency factor along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "Milrinone" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
175.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mirlep 15mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41566 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Mirtazapine…15mg
	Pharmacological Group	Anti-depressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Mirtazapine (15mg, 30mg) Film-coated Tablets by M/s Accord Healthcare Limited, MHRA Approved.
	Me-too Status	Tazemir 15mg Tablet of M/s Lisko Pakistan Ltd (Reg.#058172)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
176.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	MTX 15mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41575 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Meloxicam…15mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack Size & Demanded Price	10;s, 20's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Mobic tablet (7.5mg, 15mg) uncoated by M/s Boehringer, USFDA Approved.
	Me-too Status	MIWS 15 mg Tablets of M/s Weather folds (Reg.#078489)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
177.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Nizox 100mg/5ml Dry Suspension
	Diary No. Date of R& I & fee	Dy.No 40129 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 5ml reconstituted Suspension Contains: Nitazoxanide…100mg
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alini for Oral Suspension (100mg/5ml reconstituted) by M/s Romark, USFDA Approved.
	Me-too Status	Nitranex 100mg/5ml Suspension by M/s Nexus Pharma R.No.081596
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
178.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Noori 1mg/ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40207 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 4ml Ampoule Contains: Norepinephrine as Bitartrate monohydrate …4mg
	Pharmacological Group	Alpha-adrenoceptor agonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's. 5's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Noradrenaline (Norepinephrine) 1 mg / ml Concentrate for solution for infusion (4mg/4ml Ampoule, 8mg/8ml ampoule, by M/s Laboratoire Aguettant, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm could not be confirmed.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
179.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Nuroject Injection IM/IV
	Diary No. Date of R& I & fee	Dy.No 40211 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 3ml Ampoule Contains: Vitamin B1…100mg Vitamin B6…100mg Vitamin B12……100mcg
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	5's, 25's, Price as per SRO

	Approval Status of Product in Reference Regulatory Authorities	Neurobion solution for Injection 3ml by M/s Merck Selbstmedikation GmbH (Germany Approved)
	Me-too Status	Neurolina Injection 3ml by M/s Alina Combine (Reg#076143)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
180.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Olmax 5/20 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41525 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……5mg Olmesartan Medoxomil……20mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	20's price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sevikar film-coated tablets (20mg/5mg, 40mg/5mg, 40mg/10mg) by M/s DAIICHI SANKYO UK Limited, MHRA Approved.
	Me-too Status	Omsana-AM 5/20 Tablet by M/s HiltonPharma (Pvt.) Limited, Reg. No. 58557
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
181.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Olmax 5/40 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41526 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……5mg Olmesartan Medoxomil……40mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	20's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sevikar film-coated tablets (20mg/5mg, 40mg/5mg, 40mg/10mg) by M/s DAIICHI SANKYO UK Limited, MHRA Approved.
	Me-too Status	Omsana-AM 5/40 Tablet by M/s Hilton Pharma, Reg. No. 58558
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
182.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Olmax 10/20 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41527 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate……10mg Olmesartan Medoxomil……20mg
	Pharmacological Group	Antihypertensive
	Type of Form	From 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sevikar film-coated tablets (20mg/5mg, 40mg/5mg, 40mg/10mg) by M/s DAIICHI SANKYO UK Limited, MHRA Approved.
	Me-too Status	Omsana-AM 10/20 Tablet by M/s HiltonPharma (Pvt.) Limited, Reg. No. 58559

	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
183.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Orexa 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41561 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Olanzapine…10mg
	Pharmacological Group	Neuroleptic
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Olanzapine Actavis 10 mg Film-coated Tablets (PL 30306/0166) MHRA Approved.
	Me-too Status	Olanzpine 10 mg Tablets. By: Akson Pharmaceuticals Pvt Ltd. Mirpur. (Reg.#081661)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
184.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Orexa 5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41559 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Olanzapine…5mg
	Pharmacological Group	Neuroleptic
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Olanzapine Actavis 5 mg Film-coated Tablets, from Actavis Group Iceland. PL 30306/0164, MHRA Approved.
	Me-too Status	Olanzapine-Sandoz 5mg Tablets. By Novartis Pharma, Karachi. (Reg#064040)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
185.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ossorin-D Liquid Suspension
	Diary No. Date of R& I & fee	Dy.No 41078 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Ossein Mineral Complex (i.e. Hydroxyapatite Compound)…400mg Vitamin D3…400 iu Calcium……..85.59mg Phosphorus….39.61mg Collagen……..107.95mg Residual mineral salts…….12mg Other proteins….32mg Trace elements F, Mg, Fe, Zn, Cu, Ni Complete composition
	Pharmacological Group	Mineral complex/vitamin
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	60ml, 120ml, price as per SRO

	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Osnate-D suspension by M/s AGP Limited, Reg. No. 70854
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Evidence of purchase of Atomic absorption spectrophotometer. evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of availability of Atomic absorption spectrophotometer.**	
186.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Panamol 120mg/5ml Liquid Suspension
	Diary No. Date of R& I & fee	Dy.No 41061 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Paracetamol…120mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	60ml, 90ml, 120ml, 450ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Care Infant Paracetamol 120mg/5ml Suspension by M/s Thornton and Ross Limited, MHRA Approved
	Me-too Status	Nendol 120mg/5ml Suspension by M/s Nenza Pharmaceuticlas, Reg. No. 59344
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
187.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Panamol Forte 250mg/5ml Liquid Suspension
	Diary No. Date of R& I & fee	Dy.No 41086 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Paracetamol…250mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	60ml, 100ml, 450ml, 120ml, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paracetamol 250mg/5ml Oral Suspension by M/s Pinewood Laboratories Limited, MHRA Approved.
	Me-too Status	Nendol 250mg/5ml Suspension by M/s Nenza Pharmaceuticlas, Reg. No. 59345
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
188.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	PZT-M Liquid Syrup
	Diary No. Date of R& I & fee	Dy.No 41101 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Pizotifen as Hydrogen Maleate…0.25mg
	Pharmacological Group	To be checked in dossier
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	60ml, 120ml, Price as per SRO

	Approval Status of Product in Reference Regulatory Authorities	SANOMIGRAN Elixir 0.25mg/5ml by M/s PHOENIX LABS, MHRA Approved.
	Me-too Status	Pizotifen syrup 0.25mg/5ml by M/s English Pharmaceutical Industries, Reg. No. 20337
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
189.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	QTP 25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41596 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Captopril…….25mg
	Pharmacological Group	ACE inhibitors,
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, 30's, 100's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Captopril 25mg Tablets by M/s Tillomed Laboratories Ltd (MHRA Approved)
	Me-too Status	Capoten 25mg tablet by M/s Squibb Khi (Reg#006156)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
190.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rantec 50mg/2ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40187 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 2ml Ampoule Contains: Ranitidine HCl……50mg
	Pharmacological Group	Histamine-2 Blocker
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ranitidine 50mg/2ml Solution for Injection and Infusionby M/s Alliance Pharmaceuticals Limited, MHRA Approved.
	Me-too Status	Anzol 50mg/2ml ampoule Injection of M/s Indus Pharma (Reg.# 024110)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The product approved in reference country contains Ranitidine as HCl while the applied product contaisn Ranitidine HCl, clarify or submit revised formulation with correct equivalency factor along with the submission of requisite fee.
	Decision: Deferred for following: **a. submission of evidence of approval of applied formulation containing "Ranitidine HCl" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.** **b. Ranitidine containing products have been deferred by Registration Board due to safety matters.**	
191.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Relive 400mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41523 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Sevelamer Hydrochloride…400mg
	Pharmacological Group	Drugs for treatment of hyperkalemia and hyperphosphatemia
	Type of Form	Form 5
	Finished Product Specification	Mfg specs

	Pack Size & Demanded Price	30's,price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Renagel (400mg, 800mg) Film Coated Tablets by M/s Genzyme Corporation (USFDA Approved)
	Me-too Status	Renavel Tablets 400mg by M/s Genome pharmaceuticals (Reg#073228)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
192.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rivas 6mg Capusle
	Diary No. Date of R& I & fee	Dy.No 41115 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Capsule Contains: Rivastigmine as Hydrogen Tartrate Eq. to Rivastigmine…6mg
	Pharmacological Group	Acetylcholinesterase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 28's, 60's, pric3e as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Nimvastid (1.5 mg, 3 mg, 4.5 mg, and 6 mg) capsule, EMA Approved.
	Me-too Status	Riveme 6mg Capsule of M/s Genix Karachi (Reg.#079954)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
193.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rocucure 10mg/ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40215 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each ml Contains: Rocuronium Bromide…10mg
	Pharmacological Group	Muscle relaxants, peripherally acting agents (Other quaternaryammonium compounds)
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, 25's (5ml ampoule), Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	bromide 10mg/ml solution for injection/ infusion (5ml ampoule) by M/s Ibigen Srl, MHRA Approved
	Me-too Status	Esmeron inj. 50mg/5ml (ampoule) by M/s OBS (Reg#021154)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
194.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ronex 1g/5ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40141 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 5ml Ampoule Contains: Piracetam…1gm
	Pharmacological Group	Nootropic / Corical Myoclonus
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, 12's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Couldnot be confirmed
	Me-too Status	Piractim Injection 1gm/5ml ampoule M/s Global Reg. No. 32039
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference

		regulatory authorities/agencies as adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
195.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ronex 400mg Capsule
	Diary No. Date of R& I & fee	Dy.No 41072 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Capsule Contains: Piracetam……400mg
	Pharmacological Group	Nootropic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	20's, 30's, 60's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
196.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Roprin 75mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41516 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Enteric Coated Tablet Contains: Aspirin…75mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 30's, 60's, 100's price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Boots Aspirin 75 mg Gastro-resistant tablets by M/s The Boots Company PLC, MHRA Approved.
	Me-too Status	Disprime Tablets 75mg enteric coated tablet by M/s Prime Laboratories (Pvt.) Ltd, Reg. No. 80184
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
197.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rotacam 20mg Capsule
	Diary No. Date of R& I & fee	Dy.No 41122 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Capsule Contains: Piroxicam…20mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 15's, 20's, 30's, 40's, 50's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	FELDENE 20mg CAPSULES by M/s Pfizer Limited. MHRA approved
	Me-too Status	FELDEN 20MG CAP by Pfizer Karachi. (Reg#006349)
	GMP Status	Same as stated above

	Remarks of the Evaluator.	
	Decision: Approved.	
198.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rotfol 1% Injection
	Diary No. Date of R& I & fee	Dy.No 40212 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	each 20ml Ampoule Contains: Propofol……200mg
	Pharmacological Group	Anesthetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×20ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diprivan 10 mg/ml (1%) (20ml Ampoule, 50ml vial)emulsion for injection or infusion by M/s Aspen Pharma Trading Ltd, MHRA Approved.
	Me-too Status	Fresofol 1% Injection (20ml) by M/s Medipak (Reg#027384)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
199.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rovi 5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41582 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Amlodipine as Besylate …5mg
	Pharmacological Group	Selective calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	NORVASC® (amlodipine besylate) (2.5mg, 5mg, 10mg) Tablets for oral administration. USFDA approved
	Me-too Status	NORVASC 5MG TAB by M/s Pfizer, Reg. No. 11825
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
200.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Rovinate 50mg/ml Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 40183 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 1ml Ampoule Contains: Dimenhydrinate…50mg
	Pharmacological Group	Antiemetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	25×1ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Dimenhydrinate Injection of Fresenius Kabi, USFDA Approved.
	Me-too Status	Corinate 50mg/ml Inj. of Asian continental (Reg#057863)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
201.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Scanlux 200mg/100ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40210 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018

	Composition	Each 100ml Contains: Ciprofloxacin as HCL…200mg
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's (100ml), Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ciprofloxacin as lactate (2mg/ml) solution for infusion (100ml vial) by M/s Consilient Health ltd, MHRA Approved
	Me-too Status	Lawrcip Injection 200mg/100ml by M/s Lawrence Pharma (Pvt.) Ltd, Reg. No. 71167
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The firm has submitted the revised formulation containing Lactic Acid as per the reference product and submitted Rs. 5000/- vide challan number 2017891 dated 05/03/2020.
	Decision: Approved.	
202.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	S-C-S Advance Liquid Suspension
	Diary No. Date of R& I & fee	Dy.No 41108 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 10ml Contains: Sodium Alginate……1000mg Potassium Hydrogen Carbonate…200mg
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	120ml price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Gaviscon Advance Oral suspension 1000mg/200mg per 10ml by M/s Reckitt Benckiser Healthcare (UK) Ltd, MHRA Approved
	Me-too Status	Gesecon Advance 1000/200 syrup by M/s Winthrox Karachi, Reg. No. 74951
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
203.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Spasgo-Plus Injection
	Diary No. Date of R& I & fee	Dy.No 40167 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 4ml Ampoule Contains: Phloroglucinol hydrated…40mg Trimethyl phloroglucinol…0.04mg
	Pharmacological Group	Drugs for functional Gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	6×4ml ampoule, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Phloroglucinol/Trimethylphloroglucinol Arrow 40 mg / 0.04 mg per 4 ml, solution for injection by M/s GENERIC ARROW, ANSM France
	Me-too Status	Anafortan Plus Injection 40mg/0.04mg (4ml ampoule) by M/s Ali Gohar Pharmaceuticals (Pvt) Ltd, Reg. No. 24503
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
204.	**Name and address of manufacturer / Applicant**	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Spasmed Tablet
	Diary No. Date of R& I & fee	Dy.No 41517 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018

	Composition	Each Sugar Coated Tablet Contains: Hydrated Phloroglucinol 80mg Corresponding to anhydrous Phloroglucinol…62.233mg Trimethyl Phloroglucinol…80mg
	Pharmacological Group	Drugs for functional Gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	20's, 30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	PHLOROGLUCINOL/TRIMETHYLPHLOROGLUCINOL ACINO 62,233 mg/80 mg, comprimé enrobe by M/s Acino, ANSM France Approved.
	Me-too Status	Spasrid tablet 80mg/ 80 mg of M/s Barrett Hodgson (R.# 034743)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
205.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tenlo Liquid Syrup 5mg/5ml
	Diary No. Date of R& I & fee	Dy.No 41062 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Loratadine Hydrochloride…5mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30ml, 60ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Loratadine 5 mg/ 5 ml syrup (solution) by M/s Generics [UK] Limited t/a Mylan, MHRA Approved.
	Me-too Status	Loroking Syrup 5mg/5ml by M/s Medicraft Pharmaceuticals (Pvt) Ltd,, Reg. No. 49041
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
206.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tenormax 100mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41594 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Atenolol……..100mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 14's, 20's, 30's, 100's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	ATENOLOL TABLETS BP (100mg, 50mg, 25mg) by M/s Accord-UK ltd, MHRA Approved.
	Me-too Status	SYNAROME TABLETS 100mg by M/s MUBARAK SONS, Reg. No. 10671
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
207.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Topmac 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41565 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Memantine Hydrochloride…10mg
	Pharmacological Group	Anti-dementia drugs

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ebixa (10mg, 20mg) film-coated tablets by M/s H. Lundbeck A/S, EMA approved.
	Me-too Status	Namentec 10mg Tablet of M/s Pharmatec (R # 075937)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
208.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Torivas-E 10/20mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41557 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Ezetimibe……..10mg Atorvastatin as Calcium Trihydrate…...20mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Atozet 10mg/10mg Film coated Tablets, Merck Sharp & Dohme Ltd. UK (MHRA Approved) (atorvastatin as calcium trihydrate+Ezetimib)
	Me-too Status	Atorax-E Tablets 10mg M/s. Dyson Research Laboratories (Pvt) Ltd, Lahore, Reg. No. 78838
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
209.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Trimax 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41519 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Cetirizine Dihydrochloride…10mg
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 20's, 100's, /;price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Zirtek tablet 10mg film coatd tablet by M/s UCB Pharma Ltd, MHRA approved
	Me-too Status	Serzine 10mg Tablets of M/s Qintar pharmaceuticals, Reg. No. 30644
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
210.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tropex 18mcg Rotacaps
	Diary No. Date of R& I & fee	Dy.No 41138 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Rotacap Contains: Tiotropium as Bromide Monohydrate…18mcg
	Pharmacological Group	Anticholinergics
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	15's, 20's, Price as per SRO
	Approval Status of Product in	Spiriva® 18 microgram Capsules for Inhalation by M/s

	Reference Regulatory Authorities	Boehringer Ingelheim International GmbH MHRA approved
	Me-too Status	Tyo Rotacaps 18mcg by M/s Scilife Reg. No. 82188
	GMP Status	Same as stated above
	Remarks of the Evaluator.	proof of availability of manufacturing facility for dry powder inhaler capsules,
	Decision: Deferred for confirmation whether manufacturing facility of dry powder inhaler capsules as decided by Registration Board.	
211.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ulbin 1g/5ml Liquid Suspension
	Diary No. Date of R& I & fee	Dy.No 41136 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Sucralfate……1g
	Pharmacological Group	Other drugs for peptic ulcer and gastro-esophageal reflux disease (GERD)
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	60ml, 120ml, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Antepsin® 1g/5ml Oral Suspension by M/s Chugai Pharma UK Limited, MHRA approved
	Me-too Status	Gastromed Oral Suspension 1gm/5ml by M/s Aries Pharmaceuticals (Pvt) Ltd. Reg. No. 82601
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
212.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Uric 80mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41552 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Febuxostat…80mg
	Pharmacological Group	Antigout Agent
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Urolic (40mg, 80mg) film coated tablet by M/s TAKEDA PHARMS USA, USFDA Approved.
	Me-too Status	Febuxin 80mg tablet by M/s AGP, Karachi (Reg. No. 081105)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
213.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vifor 100mg/5ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40132 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 5ml Ampoule Contains: Iron Sucrose Eq. to Elemental Iron…100mg
	Pharmacological Group	Antianemic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Venofer Injection M/s Vifor (MHRA Approved).
	Me-too Status	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	

	Decision: Approved.	
214.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vigain 500mg Oral Sachet
	Diary No. Date of R& I & fee	Dy.No 40240 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each Sachet Contains: Vigabatrin…500mg
	Pharmacological Group	Antiepileptic belongs to gamma amino acids and Derivatives.
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 14's, as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sabril 500mg film coated tablet by M/s Aventis Pharma Limited MHRA approved
	Me-too Status	Seizril 500mg Tablet of M/s Nabiqasim, Reg. No. 81564
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
215.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vilda Plus 50/500 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41555 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Vildagliptin……..50mg Metformin Hydrochloride…500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, 14's, 28's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	GALVUMET 50/500 film coated tablet. TGA Australia approved approved
	Me-too Status	Galvus met 50mg/500mg tablets by M/s Novartis,. Reg. No. 78106
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Approved in TGA with shelf life of 18 months
	Decision: Approved with innovator's specifications with a shelf life of 18 months.	
216.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Viscon Liquid Suspension
	Diary No. Date of R& I & fee	Dy.No 41059 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 10ml Contains: Sodium Alginate……..500mg Calcium Carbonate…..160mg Sodium bicarbonate…..267mg
	Pharmacological Group	antacid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Gaviscon Cool Liquid (250/80/133.5mg per 5ml) oral suspension by M/s Reckitt Benckiser Healthcare (UK) Ltd, MHRA Approved.
	Me-too Status	Ul-Nil Suspension (250/80/133.5mg per 5ml) by M/s Z-JANS Pharmaceuticals, Reg. No. 52470
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

217.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Volden k 50mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41586 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Diclofenac Potassium…50mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diclofenac Potassium 50mg Film Coated Tablets by M/s Accord Healthcare Limited, MHRA Approved.
	Me-too Status	NOREX TABLETS 50mg tablets by M/s Alen Pharmaceuticals (Pvt) Ltd, Reg. No. 3172
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
218.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Vorit 200mg Injection IV
	Diary No. Date of R& I & fee	Dy.No 40244 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each Vial Contains: Voriconazole…200mg
	Pharmacological Group	Antimycotics
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vfend 200mg vial powder for solution for injection by M/s Pfizer Europe MA EEIG, EMA Approved
	Me-too Status	Vivid Injection 200mg by M/s 'S.J & G, Reg. No. 70582
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of manufacturing facility as per dosage form of the products.	
219.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	V-Zol 200mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41573 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Voriconazole…200mg
	Pharmacological Group	Antimycotics
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vfend (50mg, 200mg) film coated tbalet by M/s Pfizer Europe MA EEIG, EMA Approved.
	Me-too Status	Vorif tablets of M/s Ferozsons Laboratories (Reg. # 069765)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
220.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Xanthik 100mg/5ml Liquid Syrup
	Diary No. Date of R& I & fee	Dy.No 41094 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each 5ml Contains: Doxofylline…100mg
	Pharmacological Group	Anti- histamine

	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	60ml, 120ml, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Doxofillina ABC 200 mg / 10 ml Syrup by M/s ABC Farmaceutici SpA – Corso Vittorio (Italian Medicine Agency (AIFA) Italy Approved)
	Me-too Status	Unifyline Syrup 100mg/ 5ml by M/s Platinum Pharmaceuticals (Reg.# 047180)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
221.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Zolnic 4mg/100ml Injection
	Diary No. Date of R& I & fee	Dy.No 40153 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 100ml Injection Contains: Zoledronic Acid as Monohydrate…4mg
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Zoledronic Acid Injection 4mg/100ml (Vial) by Apotex Pty Ltd (TGA Approved)
	Me-too Status	Kedronico Injection 4mg/100ml by Novartis Reg. # 072551
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
222.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Zoltranz 3mg/3ml Injection IV
	Diary No. Date of R& I & fee	Dy.No 40145 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 3ml Ampoule Contains: Ibandronate Sodium Monohydrate Eq. to Ibandronic Acid…3mg
	Pharmacological Group	Bone resorption inhibitor
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ibandronate sodium 3mg/3ml vial by M/s Sun Pharm, USFDA Approved.
	Me-too Status	Ibro injection 3mg/3ml by M/s Regal Pharmaceuticals (Reg#082004)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
223.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	Solitam Tablet 6/0.4mg
	Diary No. Date of R& I & fee	Dy.No 39609 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each Modified Release Tablet Contains: Solifenacin …6mg Tamsulosin…0.4mg
	Pharmacological Group	Antimuscarinic/alpha adrenergic blocker
	Type of Form	Form 5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in	MHRA Approved.

	Reference Regulatory Authorities	
	Me-too Status	Tasolin-S tablet by M/s Getz Pharma, Reg. No. 89374
	GMP Status	Last inspection report dated 02/08/2018. Satisfactory level of GMP compliance. Firm should focus on the observations and comply with them on priority. • More climatic chambers required as existing one were near to saturation • Separate equipments for dispensing of steroidal products are required. Dedicated SS cabinets can be installed for proper palcemnet of dispensing equipments in the area. • SS cabinets are required for proper storage of unifroms in change room.
	Remarks of the Evaluator.	stability data required as per directions of 278th meeting of registration Board.
	Decision: Deferred for submission of stability studies as per directions of 278th meeting of Registration Board.	
224.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	Rivarox 2.5 Tablet
	Diary No. Date of R& I & fee	Dy.No 42466 dated 12-12-2018 Rs.20,000/- Dated 11-12-2018
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…2.5mg
	Pharmacological Group	anticoagulant
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xarelto of M/s Bayer healthcare approved by EMA
	Me-too Status	Xarelto 2.5mg Tablet by M/s. Bayer Pakistan (Reg#074794)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The firm has revised the forumualtion from Dispersible tablet to Film coated tablet as per the reference product without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation as per the reference product.	
225.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	Ramel Tablet 8mg
	Diary No. Date of R& I & fee	Dy.No 42465 dated 12-12-2018 Rs.20,000/- Dated 11-12-2018
	Composition	Each Film Coated Tablet Contains: Ramelteon…8mg
	Pharmacological Group	Non Barbiturate hypnotic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, 20's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	ROZEREM 8mg tablet by M/s TAKEDA PHARMS USA, USFDA Aprroved.
	Me-too Status	Xerom tablet 8mg by M/s Helix Pharma, Reg. No. 89373
	GMP Status	Same as stated above
	Remarks of the Evaluator.	stability data is required as per the directions of Registration Board in its 278th meeting.
	Decision: Deferred for submission of stability studies as per directions of 278th meeting of Registration Board.	
226.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	Olopta Nasal Spray 665mcg

	Diary No. Date of R& I & fee	Dy.No 42464 dated 12-12-2018 Rs.20,000/- Dated 11-12-2018
	Composition	Eah 100µl (spray) contains: Olopatadine HCl…665mcg
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, 20's, 30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	PATANASE nasal psray (0.665MG/SPRAY) by M/s Novartis, USFDA Approved
	Me-too Status	Olonase 0.6% nasal spray by Sante Pharma, Reg. No. 097084
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Stability data as per the directions of Registration Board in its 251st meeting later amended in 278th meeting.
	Decision: Deferred for submission of stability studies as per directions of 278th meeting of Registration Board.	
227.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	Velflex Gel 2.32% w/w
	Diary No. Date of R& I & fee	Dy.No 42463 dated 12-12-2018 Rs.20,000/- Dated 11-12-2018
	Composition	Each Film Coated Tablet Contains: Diclofenac diethylamine…23.3mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Innovator;s
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Me too and approval status in RRAs could not be confirmed.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
228.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nebihil 20mg Tablets
	Diary No. Date of R& I & fee	Dy.No 43240 dated 19-12-2018 Rs.20,000/- Dated 10-12-2018
	Composition	Each Tablet Contains: Nebivolol HCl `…20mg
	Pharmacological Group	Anti Hypertensive
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Inspection date 10/07/2019, good level of gmp compliance.
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status)**	

	alongwith registration number, brand name and name of firm • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
229.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Metzid 5mg/500mg Tablet
	Diary No. Date of R& I & fee	Dy.No 43895 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each Film Coated Tablet Contains: Glipizide…5mg Metformin HCL…500mg
	Pharmacological Group	Anti diabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GLIPIZIDE AND METFORMIN HYDROCHLORIDE Film coated tablets, (2.5mg/250mg, 2.5mg/500mg, 5mg/500mg) by M/s TEVA PHARMS, USFDA Aprroved.
	Me-too Status	Ordiab 5/500 Tablet by M/s Nabiqasim Industries Reg. No. 53133
	GMP Status	Based on the areas inspected, the people met and considering the findings of inspection M/s Jaens Pharmaceuticals (pvt.) ltd., is operating satisfactory. Overall hygienic condition of the firm was satisfactory at the time of inspection however, they were advised to continue improvements in production and quality control, they agreed."
	Remarks of the Evaluator.	
	Decision: Approved.	
230.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Metzid 2.5mg/500mg Tablet
	Diary No. Date of R& I & fee	Dy.No 43894 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each Film Coated Tablet Contains: Glipizide…2.5mg Metformin HCL…500mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GLIPIZIDE AND METFORMIN HYDROCHLORIDE Film coated tablets, (2.5mg/250mg, 2.5mg/500mg, 5mg/500mg) by M/s TEVA PHARMS, USFDA Aprroved.
	Me-too Status	Ordiab 2.5/500 Tablet by M/s Nabiqasim Industries (Pvt) Ltd, Reg. No. 53132
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
231.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Glyzine Tablets 4mg/30mg
	Diary No. Date of R& I & fee	Dy.No 43893 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each Tablet Contains: Glimepiride……..…4mg Pioglitazone as HCL…30mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	DUETACT (2mg/40mg, 4mg/30mg) Uncoated tablets by M/s TAKEDA PHARMS USA, USFDA Approved
	Me-too Status	Piozer-G 4/30mg tablet of M/s Hilton Pharma (Reg. # 050691)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The firm has revised the formulation from Film coated to Uncoated and submitted fee Rs. 5,000/- vide challan number 0824893 dated 04/033/2020.
	Decision: Approved.	
232.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Glyzine Tablets 2mg/30mg
	Diary No. Date of R& I & fee	Dy.No 43892 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each Tablet Contains: Glimepiride……2mg Pioglitazone as HCL…30mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	DUETACT (2mg/40mg, 4mg/30mg) Uncoated tablets by M/s TAKEDA PHARMS USA, USFDA Approved
	Me-too Status	Piozer-G 2/30mg tablet of M/s Hilton Pharma (Reg. # 050690)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The firm has revised the formulation from Film coated to Uncoated and submitted fee Rs. 5,000/- vide challan number 0824892 dated 04/033/2020.
	Decision: Approved.	
233.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Clida Gel 1%
	Diary No. Date of R& I & fee	Dy.No 43888 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gram contains: Clindamycin Phospate eq to Clindamycin…1% 10mg
	Pharmacological Group	Antiinfectives for treatment of acne
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	RESIDERM 1%w/w GEL by M/s Crawford Healthcare Limited (MHRA Approved)
	Me-too Status	Clindacin Gel 1%w/w by M/s Sante (Reg#067485)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Relevant section is not confirmed.
	Decision: Deferred for confirmation of approval of relevant/required manufacturing facility.	
234.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Lozid-H 100mg/25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 43891 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…….100mg Hydrochlorothiazide……25mg
	Pharmacological Group	antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in	Cozaar Comp (50/12.5mg, 100/12.5mg, 100/25mg) film coated

	Reference Regulatory Authorities	tablet by M/s MSD,
	Me-too Status	Diu-Tansin Forte Tablets 100/25mg by M/s PharmEvo Ltd, Reg. No. 34426
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
235.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Lozid-H 50mg/12.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 43890 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each Film Coated Tablet Contains: Losartan Potassium……..50mg Hydrochlorothiazide……12.5mg
	Pharmacological Group	antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar Comp (50/12.5mg, 100/12.5mg, 100/25mg) film coated tablet by M/s MSD,
	Me-too Status	Sartan –H Tablets 50/12.5mg by M/s Barrett Hodgson Pakistan (Pvt) Ltd, Reg. No. 24252
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
236.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Glomet Plus Tablet 15mg/850mg
	Diary No. Date of R& I & fee	Dy.No 43889 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each Film Coated Tablet Contains: Pioglitazone as HCL……15mg Metformin HCL……850mg
	Pharmacological Group	antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ACTOPLUS MET (15mg/500mg, 15mg/850mg) film coated tablet TAKEDA PHARMS USA, USFD AApproved.
	Me-too Status	PioGet-M 15mg/850mg Tablet of Platinum Pharmaceuticals, Reg. No. 55728
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
237.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Jusidic Eye Drops
	Diary No. Date of R& I & fee	Dy.No 43887 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gm contains: Fusidic acid…1%
	Pharmacological Group	Anti-biotic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Fucithalmic 1%w/w viscous eye drops, MHRA Approved
	Me-too Status	Fusitek Eye Drops 1% by M/s Invotek Pharma, Reg. No. 26957
	GMP Status	Same as stated above

		Ear/Eye Drops (General/Steroidal) section approved.
	Remarks of the Evaluator.	The firm has revised the formulation from 1% w/v to 1% w/w without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation.	
238.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Pizid 5mg Tablets
	Diary No. Date of R& I & fee	Dy.No 43885 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each Film Coated Tablet Contains: Glipizide…5mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Minodiab 5 mg Tablets by M/s Pfizer, MHRA Approved.
	Me-too Status	GLIBENESE 5mg tablet by M/s Pfizer, Reg. No. 2793
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
239.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Sisul Cream, 1%
	Diary No. Date of R& I & fee	Dy.No 43886 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Composition	Each gram contains: Silver Sulfadiazine…1% (w/w)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Silvadene Cream 1% of USFDA approved
	Me-too Status	Quench 1% Cream by Ferozsons (Reg. No. 013090)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Relevant section is not confirmed.
	Decision: Deferred for confirmation of approval of relevant/required manufacturing facility.	
240.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Ersan 300mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44004 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Composition	Each Film Coated Tablet Contains: Irbesartan…300mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Aprovel (75mg, 150mg, 300mg) film coated tablet by M/s Sanofi Aventis, MHRA Approved.
	Me-too Status	Gooday-H Tablets 300mg, by M/s Wilson, Reg No. 75367
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
241.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Ersan 75mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44003 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018

	Composition	Each Film Coated Tablet Contains: Irbesartan…75mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Aprovel (75mg, 150mg, 300mg) film coated tablet by M/s Sanofi Aventis, MHRA Approved.
	Me-too Status	Gooday-H Tablets 300mg, by M/s Wilson, Reg No. 75366
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
242.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Lozid 100mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44002 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…100mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar (12.5mg, 25mg, 50mg, 100mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Acozar 100mg Tablet by M/s AGP, Reg. No. 82246
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
243.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Lozid 50mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44001 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…50mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar (12.5mg, 25mg, 50mg, 100mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Acozar 50mg Tablet by M/s AGP, Reg. No. 82245
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
244.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Lozid 25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44000 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…25mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar (12.5mg, 25mg, 50mg, 100mg) film coated tablet by M/s MSD, MHRA Approved.

	Me-too Status	Pixan-25 Tablet by M/s Medipak, Reg. No. 23943
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
245.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Metzid 2.5mg/250mg Tablet
	Diary No. Date of R& I & fee	Dy.No 43999 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Composition	Each Film Coated Tablet Contains: Glipizide……..2.5mg Metformin HCL…...250mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GLIPIZIDE AND METFORMIN HYDROCHLORIDE Film coated tablets, (2.5mg/250mg, 2.5mg/500mg, 5mg/500mg) by M/s TEVA PHARMS, USFDA Aprroved.
	Me-too Status	Ordiab 2.5/500 Tablet by M/s Nabiqasim Industries (Pvt) Ltd, Reg. No. 53132
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
246.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Ersan-H 300mg/25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44007 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Composition	Each Film Coated Tablet Contains: Irbesartan…….300mg Hydrochlorothiazide…25mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	CoAprovel 300mg/25mg film-coated tablets by M/s Sanofi, MHRA Approved.
	Me-too Status	Irecon – H Tablet 300mg/25mg tablets by M/s Barrett Hodgson, Reg. No. 76151
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
247.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Ersan-H 300mg/12.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44006 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Composition	Each Film Coated Tablet Contains: Irbesartan……300mg Hydrochlorothiazide…12.5mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	AVALIDE 3000mg/12.5mg Film Coated Tablet of Bristol-Myers Squibb, USFDA approved
	Me-too Status	ARBI-D 300/12.5mg Tablet of M/s PharmEvo (Reg#073771)
	GMP Status	Same as stated above

	Remarks of the Evaluator.	
	Decision: Approved.	
248.	Name and address of manufacturer / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Ersan-H 150mg/12.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44005 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018
	Composition	Each Film Coated Tablet Contains: Irbesartan…….150mg Hydrochlorothiazide…12.5mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	AVALIDE 150mg/12.5mg Film Coated Tablet of Bristol-Myers Squibb, USFDA approved
	Me-too Status	ARBI-D 150/12.5mg Tablet of M/s PharmEvo (Reg#073772)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
249.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Flutiderm Cream 0.05%
	Diary No. Date of R& I & fee	Dy.No 42677 dated 13-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each gram contains: Fluticasone Propionate…0.05% w/w
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10gm tube (1×1's), price Rs. 105/-
	Approval Status of Product in Reference Regulatory Authorities	Cutivate 0.05% w/w Cream by M/s GSK, MHRA Approved
	Me-too Status	Cutivate M Cream 0.05% w/w by M/s GSK, (Reg. # 058448)
	GMP Status	Last inspection report dated 04/09/2018, the firm has good GMP compliance on the day of inspection.Section available.
	Remarks of the Evaluator.	
	Decision: Approved.	
250.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Flutiderm Lotion 0.05%
	Diary No. Date of R& I & fee	Dy.No 42679 dated 13-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each gram contains: Fluticasone Propionate…0.05% w/w
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 200/- per 20ml bottle
	Approval Status of Product in Reference Regulatory Authorities	Cutivate lotion 0.05% by M/s Fougera Pharma of USFDA Approvede.
	Me-too Status	Ticovate Lotion by Saffron Pharma (Reg. No. 067826)
	GMP Status	Same as stated above Section available
	Remarks of the Evaluator.	
	Decision: Approved.	
251.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Furomet Cream 0.1%

	Diary No. Date of R& I & fee	Dy.No 42680 dated 13-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each gram contains: Mometasone Furoate…0.1% w/w
	Pharmacological Group	Anti-inflammatory, Antipruritic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 221/- per 15g tube, Rs. 95/- per 5g tube
	Approval Status of Product in Reference Regulatory Authorities	Momasone cream 0.1% by M/s Medis Pharma Pty Ltd TGA Australia Approved.
	Me-too Status	Hivate cream 0.1% by M/s Saffron Pharma, Reg. No. 46432
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
252.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Furomet Lotion 0.1%
	Diary No. Date of R& I & fee	Dy.No 42681 dated 13-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each ml contains: Mometasone Furoate…0.1% w/v
	Pharmacological Group	Anti-inflammatory, Antipruritic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	Rs. 100 per bottle of 20ml
	Approval Status of Product in Reference Regulatory Authorities	MOMETASONE-ZP mometasone furoate 0.1% w/w lotion bottle by M/s Medis Pharma Pty Ltd, TGA Australia Aprroved.
	Me-too Status	Momate 0.1% lotion by M/s Mexitech Pharma, Reg. No. 83744
	GMP Status	Same as stated above Section available
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
253.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Flutiderm Ointment 0.005%
	Diary No. Date of R& I & fee	Dy.No 42678 dated 13-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each gram contains: Fluticasone Propionate…0.005% w/w
	Pharmacological Group	Anti-inflammatory, Antipruritic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Rs. 65/- per 5g tube, Rs. 105/- per 10g tube
	Approval Status of Product in Reference Regulatory Authorities	Fluticasone propionate ointment 0.005% by M/s ACP Nimble, USFDA Approved.
	Me-too Status	Ticovate ointment 0.005% by M/s Saffron Pharma (Reg. No. 046434)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
254.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Pelipera ER 3mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41439 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each film coated extended release tablet contains: Paliperidone…3mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs

	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Paliris-XR Tablets 3mg by M/s Genome Pharmaceuticals (Pvt) Ltd. Reg. no. 079271
	GMP Status	Last inspection report dated 06-07th November, 2018, GMP compliance is found good as of today.
	Remarks of the Evaluator.	The reference product Invega, approved by USFDA is prolonged release tablet manufactured using OROS Push-Pull Technology. Therefore, Submit manufacturing method of applied formulation in line with reference product which is prepared by above mentioned technology along with the evidence of related instruments/equipments, however, the firm has not provided the evidence of availability of the said manufacturing requirements. The firm has revised the formulation from Paliperidone as palmitate to Paliperidone (as per the reference product) and submitted correct label claim of the applied product with the submission of fee Rs. 20,000/- vide challan number 2015467 dated 04/03/2020.
	Decision: Deferred for confirmation of manufacturing requirements as per rereference product	
255.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Pelipera ER 6mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41440 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each film coated extended release tablet contains: Paliperidone as Palmitate…6mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	MFG Spcs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	NVEGA® (paliperidone) Extended-Release Tablets (1.5mg, 3mg, 6mg, 9mg) by M/s Janssen Pharmaceuticals, Inc., USFDA Approved.
	Me-too Status	Avega 6mg Tablets by M/s Biogen Pharma, Reg No. 080370
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The reference product Invega, approved by USFDA is prolonged release tablet manufactured using OROS Push-Pull Technology. Therefore, Submit manufacturing method of applied formulation in line with reference product which is prepared by above mentioned technology along with the evidence of related instruments/equipments, however, the firm has not provided the evidence of availability of the said manufacturing requirements. The firm has revised the formulation from Paliperidone as palmitate to Paliperidone (as per the reference product) and submitted correct label claim of the applied product with the submission of fee Rs. 20,000/- vide challan number 2015466 dated 04/03/2020.
	Decision: Deferred for confirmation of manufacturing requirements as per rereference product	
256.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Medrol Tablets 450mg/35mg
	Diary No. Date of R& I & fee	Dy.No 41441 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Paracetamol……..450mg Orphenadrine citrate ……35mg
	Pharmacological Group	Skeletal muscle relaxant/Antipyretic&Analgesic

	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Norgesic tablets (uncoated) M/s iNova Pharmaceuticals Australia Pvt. Ltd. approved by TGA of Australia
	Me-too Status	Nuberol Tablet by M/s Searle Pakistan Ltd,, Reg. No. 20373
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The firm has revised the formulation containing the correct salt form of Orphenadrine citrate along with the submission of fee Rs. 20,000/- vide challan number 2015468 dated 04/03/2020.
	Decision: Approved with innovator's specifications.	
257.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Tacromed 0.03% Ointment
	Diary No. Date of R& I & fee	Dy.No 41436 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each gram contains: Tacrolimus as monhydrate…0.03% w/w
	Pharmacological Group	Agents for dermatitis, excluding corticosteroid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Protopic 0.03% ointment by M/s LEO Pharma A/S, MHRA Approved.
	Me-too Status	Imunol Ointment 0.03% by M/s Saffron Pharmaceuticals (Pvt) Ltd, Reg. No. 46443
	GMP Status	Same as stated above Semi Solid (cream/Ointment) Section (General)
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
258.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Ketomera 2% cream
	Diary No. Date of R& I & fee	Dy.No 41449 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each gram contains: Ketoconazole…2% w/w
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Daktarin Gold 2% Cream by M/s McNeil Products Limited, MHRA Approved.
	Me-too Status	Bizrole Cream 2 % by M/s Searle IV Solutions (Pvt.) Ltd, Reg. No. 78620
	GMP Status	Same as stated above Semi Solid (cream/Ointment) Section (General)
	Remarks of the Evaluator.	
	Decision: Approved.	
259.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Eramox 400mg Tablets
	Diary No. Date of R& I & fee	Dy.No 41445 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Moxifloxacin as Hcl…400mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs

	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Avelox 400 mg film-coated tablets by M/s Bayer plc, MHRA Approved.
	Me-too Status	G-Mox 400 mg Tablets by M/s Reliance Pharma, Reg. No. 72148
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
260.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Erapram 20mg Tablets
	Diary No. Date of R& I & fee	Dy.No 41443 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Escitalopram as Oxalate…20mg
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	CIPRALEX (5mg, 10mg, 20mg) film coated tablet by M/s H. Lundbeck A/S, MHRA Approved.
	Me-too Status	Sayset 20mg Tab. by M/s Sayyed Pharmaceuticals R No.070381
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
261.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Erapram 10mg Tablets
	Diary No. Date of R& I & fee	Dy.No 41442 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Escitalopram as Oxalate…10mg
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	CIPRALEX (5mg, 10mg, 20mg) film coated tablet by M/s H. Lundbeck A/S, MHRA Approved.
	Me-too Status	Esmak Tablets 10 mg by M/s Makson Pharma, Reg. No. 70006
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
262.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Calcera 0.005% cream
	Diary No. Date of R& I & fee	Dy.No 41437 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each gram contains: Calcipotriol as monohydrate…..0.005% w/w
	Pharmacological Group	antipsoriatics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Calcipotriol Cream 50 micrograms/g by M/s Sandoz Limited MHRA approved.
	Me-too Status	Calcipot Cream 0.005% w/w by M/s Valor Pharma R.No.69823
	GMP Status	Same as stated above Semi Solid Section (General) Semi Solid Section (Steroidal)
	Remarks of the Evaluator.	
	Decision: Approved.	

263.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Erazole 20mg Capsule
	Diary No. Date of R& I & fee	Dy.No 41438 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Capsule Contains: Omeprazole enteric coated pellets…20mg **Source of pellets:** M/s Vision Pharmaceuticals.
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Losec Capsule (20mg,40mg) by M/s Astra Zaneca (MHRA Approved)
	Me-too Status	Meprascot Capsules (20mg) by M/s Scotmann Pharmaceuticals (Reg#028238)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
264.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Eraoxib 60mg Tablets
	Diary No. Date of R& I & fee	Dy.No 41446 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each film coated Tablet Contains: Etoricoxib…60mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ARCOXIA (30mg, 60mg, 90mg, 120mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Etoria 60mg Table of M/s Hygeia Pharma (Reg.# 080818)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
265.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Med XR-300 Tablets
	Diary No. Date of R& I & fee	Dy.No 41447 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Extended Release Tablet Contains: Quetiapine as Fumarate…300mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alaquet XL (50mg, 150mg, 200mg, 300mg, 400mg) film coated prolonged-release tablets by M/s Generics [UK] Limited t/a Myla, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	

266.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Med XR 150 Tablets
	Diary No. Date of R& I & fee	Dy.No 41448 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…150mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alaquet XL (50mg, 150mg, 200mg, 300mg, 400mg) film coated prolonged-release tablets by M/s Generics [UK] Limited t/a Myla, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of approval of applied formulation already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
267.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Linkcin 600mg Injection
	Diary No. Date of R& I & fee	Dy.No 41286 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each 2ml ampoule contains: Linkomycin as HCL monohydrate…600mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LINCOCIN 600mg/2ml (Vial) solution for injection by M/s Pharmacia and Upjohn (USFDA Approved).
	Me-too Status	Lincin Injection 600mg/2ml by M/s Medisure, Reg. No. 73483
	GMP Status	Inspection date 18/07/2017, fair level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
268.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Pictam Injection
	Diary No. Date of R& I & fee	Dy.No 41278 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each 5ml contains: Piracetam…1g
	Pharmacological Group	Cerebral Stimulant
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	10's, 20's, 30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Neurotam Inj.1g/5ml ampoule by M/s Medisure, Reg.No.073480
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Evidence of approval of applied formulation and applied volume in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation and applied volume in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	

269.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Lacosin 50mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41269 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Pharmacological Group	Anticonvulsive
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	14's, 28's, 56's, 168's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vimpat (50, 100mg, 150mg, 200mg) film coated tablet by M/s UCB Inc, USFDA Approved.
	Me-too Status	Lacolep 100mg tablet by M/s Hilton Pharma (Reg # 073858)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
270.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Rifixin 550mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41268 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Rifaximin…550mg
	Pharmacological Group	Antibiotics (A07AA11)
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, 20's, 30's, 50's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	TARGAXAN 550 mg film-coated tablets by M/s Norgine Pharmaceuticals Ltd, MHRA Approved.
	Me-too Status	Xifaxa 550mg Tablet by M/s Brookes Pharma, Reg. No. 70438
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Form 5 is not attached with the dossier, submit duly signed and stamped Form 5.
	Decision: Deferred for submission of Form 5 duly signed and stamped.	
271.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	FC-Zole Infusion 200mg/100ml
	Diary No. Date of R& I & fee	Dy.No 41288 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each ml contains: Fluconazole…2mg
	Pharmacological Group	Anti-Fungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×100ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diflucan 2 mg/ml (200mg/100ml vial) solution for infusion by M/s Pfizer Limited (MHRA Approved)
	Me-too Status	Diflucan 2mg/ml IV infusion 50ml by M/s Pfizer (R.No.011830),
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Pack size of 100ml not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug with a filled volume of 100ml already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
272.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Cystin Sachet 200mg
	Diary No. Date of R& I & fee	Dy.No 41285 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018

	Composition	Each Sachet Contains: Acetylcysteine…200mg
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	Mfg spcs
	Pack Size & Demanded Price	30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Acetylcysteine 200 mg Powder for Oral Solution by M/s Colonis Pharma Limited, MHRA Approved
	Me-too Status	Fluimucil Sachets 200 by M/S Zambon Group Spa, R.No.021174
	GMP Status	Same as stated above Sachet section available
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
273.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Mazine 800mg Tablets
	Diary No. Date of R& I & fee	Dy.No 41264 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each delayed release tablet contains: Mesalazin…800mg
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ASACOL® HD (mesalamine) delayed-release tablets, for oral use. MHRA approved
	Me-too Status	Masacol 800mg Tablet by M/s Getz Pharma, Reg. No. 61348
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
274.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Etroxib 120mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41592 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Etoricoxib…120mg
	Pharmacological Group	NSAID
	Type of Form	Form 5D
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ARCOXIA (30mg, 60mg, 90mg,120mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	N/A
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Stability required
	Decision: Deferred for submission of stability studies of 3 batches according to the conditions of zone IV-A as per the directions given in 278th meeting of Registration Board.	
275.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Etroxib 90mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41296 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Etoricoxib…90mg
	Pharmacological Group	NSAID
	Type of Form	Form 5D
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO

	Approval Status of Product in Reference Regulatory Authorities	ARCOXIA (30mg, 60mg, 90mg,120mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	N/A
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Stability required
	Decision: Deferred for submission of stability studies of 3 batches according to the conditions of zone IV-A as per the directions given in 278th meeting of Registration Board.	
276.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Thiosid 4mg Capsule
	Diary No. Date of R& I & fee	Dy.No 41279 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each hard gelatin capsule contains: Thiocolchicoside…4mg
	Pharmacological Group	Muscle relaxant
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, 20's, 30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	IIOCOLCHICOSIDE Daiichi Sankyo 4 mg hard capsule ANSM Approved (repealed)
	Me-too Status	Myogen Capsules 4 mg by M/s Nimrall, (Reg.# 066700)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The product is approved in France but it has been repealed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
277.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Zedic Powder fpr oral suspension 250mg/5ml
	Diary No. Date of R& I & fee	Dy.No 41291 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each 5ml reconstituted suspension contains: Fusid Acid…250mg
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	90ml, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Fucidin 250 mg/5 ml Oral Suspension by M/s Leo Lab ltd, MHRA Approved.
	Me-too Status	Fumont Dry Suspension 250mg/5ml by M/s De Mont Research laboratories (Pvt) Ltd (Reg#084090)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
278.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Fiban Injection 12.5mg/50ml
	Diary No. Date of R& I & fee	Dy.No 41289 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each ml contains: Tirofiban (as HCl monohydrate)…0.25mg
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	AGGRASTAT (250 micrograms/ml) concentrate for solution for infusion 50ml vial by M/s Correvio (UK) Ltd (MHRA Approved)
	Me-too Status	Aggrastat Injection 0.25mg/ml 50ml vial by M/s Atco Labs (Reg#025299)

	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
279.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Miralax Plus Sachet
	Diary No. Date of R& I & fee	Dy.No 41294 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Sachet Contains: Macrogol 3350……13.125g Sodium Chloride…….0.3507g Sodium bicarbonate……0.1785g Potassium chloride……..0.0466g
	Pharmacological Group	Osmotic laxatives
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	MOVICOL 13.8g sachet, powder for oral solution by M/s Norgine limited, MHRA Approved.
	Me-too Status	Marfinal sachet 13.6g by M/s Martindow, Reg. no. 80647
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
280.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Egofin Tablet 1mg/100mg
	Diary No. Date of R& I & fee	Dy.No 41267 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Ergotamine tartarate……1mg Caffeine (anhydrous).....100mg
	Pharmacological Group	Ergot Alkaloid/ Xanthine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Bottle of 100 tablets, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cafergot tablet 1mg/100mg by M/s Sandoz, USFDA Approved.
	Me-too Status	Cafergot tablet (1mg/100mg) M/s Novartis Pharma Reg. No.0000511
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
281.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Desvin XR 100mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41272 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each extended release tablet contains: Desvenlafaxine as succinate monohydrate…..100mg
	Pharmacological Group	Anti-depressant
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	14's, 28's, 56's, 156's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Pristiq™ (desvenlafaxine) Extended-Release Tablets (50mg, 100mg) by M/s PF prism CV, USFDA Approved.
	Me-too Status	Desvel XR 100mg Tablet by M/s Hilton Pharma (Reg#070760)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

282.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Esoprox 500/20mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41301 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Enteric coated naproxen…..500mg immediate release esomeprazole magnesium….20mg
	Pharmacological Group	NSAId/PPI
	Type of Form	Form 5D
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	USFDA approved, vimovo
	Me-too Status	N/A
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Stability required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
283.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Trazo XR 100mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41262 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Trazodone HCL…100mg
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	14's, 20's, 28's, 30's, 50's, 56's, 60's, 100's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Desyrel (50mg, 100mg) film coated tablet by M/s Pragma Pharma (**USFDA**) was not discontinued or withdrawn for safety and efficacy reasons. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=018207 (Accessed on : 11-02-2020)
	Me-too Status	Deprel 100mg Tablets by M/s Adamjee (Reg # 010178)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
284.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Betin 24mg Tablets
	Diary No. Date of R& I & fee	Dy.No 41273 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Betahistine dihydrochloride…24mg
	Pharmacological Group	Anti vertigo
	Type of Form	Form 5
	Finished Product Specification	B.P
	Pack Size & Demanded Price	53×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Betahistine 24mg tablet by M/s Aurobindo Pharma-Milpharm ltd, MHRA Approved.
	Me-too Status	Stabler 24mg tablet by M/s Nabi Qasim Reg No. 83937
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	

285.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Meloci 7.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41266 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Meloxicam…7.5mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10, 14, 20, 28, 30, 50, 60, 100 500 (10×50), price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Mobic tablet (7.5mg, 15mg) uncoated by M/s Boehringer, USFDA Approved.
	Me-too Status	MIWS 7.5 mg Tablets of M/s Weather folds (Reg.#078486)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
286.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Actin 10mg Capsule
	Diary No. Date of R& I & fee	Dy.No 41280 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Capsule Contains: Acitretin…10mg
	Pharmacological Group	Antipsoriatics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	SORIATANE (acitretin) capsule (10mg, 25mg) by M/s Stiefel labs, USFDA Approved.
	Me-too Status	Acetin Capsules 10mg of M/s Genome Pharmaceuticals (Reg.# 064012)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approve.	
287.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Solif 5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41277 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…5mg
	Pharmacological Group	Muscarinic antagonist
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, 20's, 30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vesicare® (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too Status	Solifen Tablet 5mg by M/s GetzPharma, Reg. No. 61202
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
288.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Cinrog 1mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41276 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each film coated Tablet Contains: Cinitapride as hydrogen tartarate …1mg
	Pharmacological Group	gastroprokinetic agent and antiulcer agent

	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cidine 1 mg uncoated tablet by Almirall, SA (Spain Approved)
	Me-too Status	Cidine Tablets 1mg by M/s Highnoon Lab (Reg. # 052940)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The product approved in reference country is uncoated while the applied produt in film coated, clarification is required or otherwise revised formulation along with the submission of requisite fee should be submitted.
	Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
289.	Name and address of manufacturer / Applicant	M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore
	Brand Name +Dosage Form + Strength	Bacrid Injection 200mg/100ml
	Diary No. Date of R& I & fee	Dy.No 41287 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each 100ml contains: Ofloxacin (as HCl)…200mg
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Tarivid™ IV Infusion Solution 2mg/ml (50ml, 100ml, 200ml) by M/s Aventis Pharma Limited, MHRA Approved.
	Me-too Status	Lawrflox Inj. 200mg/100ml by M/s Lawrence Pharma R.No.71166
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
290.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Tafdin 30mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 42686 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Ampoule of 1ml Contains: Ephedrine as Sulphate…30mg
	Pharmacological Group	Indirect Acting Sympathomimetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ephedrine sulfate injection 30mg/ml by M/s Hospira, TGA Australia Approved.
	Me-too Status	EPHEDRINE INJ 30mg/ml by M/s PDH, Reg. No. 9260
	GMP Status	30-01-2018 & 09-04-2018. Renewal of DML and grant of additional sections. Panel recommends Renewal of DML and grant of additional sections.
	Remarks of the Evaluator.	The composition is not as per the product approved in reference country. The reference product contains 30mg of Ephedrine sulfate per ml while the applied product contains 30mg of Ephedrine as Sulfate per 1ml. Tablet (psychotropic) section approved.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Ephedrine as Sulfate" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.	

291.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xoclan 0.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42710 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Clonazepam……0.5mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Klonopil tablet (0.125mg, 0.25mg, 0.5mg, 1mg. 2mg) by M/s Roche, USFDA Approved
	Me-too Status	Cozepam 0.5mg Tablet by M/s Schazoo Pharma (Reg.#064716)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved.
	Decision: Approved.	
292.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xoclan 2mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42711 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Clonazepam…2mg
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Klonopil tablet (0.125mg, 0.25mg, 0.5mg, 1mg. 2mg) by M/s Roche, USFDA Approved
	Me-too Status	Cozepam 02mg Tablet by M/s Schazoo Pharma (Reg.#064715)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved.
	Decision: Approved.	
293.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xitonil 6mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42708 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Bromazepam…6mg
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Apo-bromazepam tablet (1.5mg, 3mg, 6mg) by M/s Apotex Inc. Health Canada Approved
	Me-too Status	Yazd 6mg Tablet By M/s. Wilshire Laboratories; Reg No. 65693
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved.
	Decision: Approved with innovator's specifications.	
294.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xulax 0.25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42704 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Alprazolam…0.25mg
	Pharmacological Group	Antidepressant
	Type of Form	Form 5

	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xanax 0.25mg by M/s Pfizer, MHRA Approved
	Me-too Status	Lydia 0.25mg Tab. by M/s. Wilshire Laboratories; R.No.065697
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved.
	Decision: Approved.	
295.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Phebrin 15mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 42688 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each ml Contains: Morphine Sulphate…15mg
	Pharmacological Group	opium alkaloids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Morphine Sulfate 15mg/ml (1ml ampoule) Solution for Injection by M/s Wockhardt UK Ltd, MHRA Approved
	Me-too Status	Qonza 15mg/1ml ampoule injection by M/s Wilshire Laboratories (Pvt) Ltd, Reg. No. 80060
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The applied product contains Morphine Sulfate while the reference product contains Morphine Sulfate as Pentahydrate, clarify or otherwise submit revised formulation along with master formula. Injectable (psychotropic) section approved.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Morphine Sulfate" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.	
296.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Phebrin 10mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 42687 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Ampoule of 1ml Contains: Morphine Sulphate…10mg
	Pharmacological Group	Natural opium alkaloids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Morphine Sulfate 10mg/ml (1ml ampoule) Solution for Injection by M/s Wockhardt UK Ltd, MHRA Approved
	Me-too Status	Morphine 10mg/1ml ampoule injection by M/s Neutro pharma, Reg. No. 65784
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The applied product contains Morphine Sulfate while the reference product contains Morphine Sulfate as Pentahydrate, clarify or otherwise submit revised formulation along with master formula. Injectable (psychotropic) section approved.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Morphine Sulfate" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.	

297.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Phebrin 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42699 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Morphine Sulphate…10mg
	Pharmacological Group	Natural opium alkaloids
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Morphine sulphate tablet (15mg, 30mg) by M/s Hikma, USFDA Approved.
	Me-too Status	Qonza 10mg Tablets by M/s Wilshire Laboratories (Pvt) Ltd, Reg. No. 71221
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved. The applied product contains "Morphine As Sulfate" while the reference product contains "Morphine Sulfate as Pentahydrate", clarify or otherwise submit revised formulation along with master formula and requisite fee
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Morphine Sulfate" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.	
298.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Phebrin 30mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42700 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Morphine Sulphate…30mg
	Pharmacological Group	Natural opium alkaloids
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Morphine sulphate tablet (15mg, 30mg) by M/s Hikma, USFDA Approved.
	Me-too Status	Qonza 30mg Tablets by M/s Wilshire Laboratories (Pvt) Ltd, Reg. No. 65704
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved. The applied product contains Morphine Sulfate while the reference product contains Morphine Sulfate as Pentahydrate, clarify or otherwise submit revised formulation along with master formula.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Morphine Sulfate" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.	
299.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xaltral 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42696 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Haloperidol…10mg
	Pharmacological Group	AntiPsychotics
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack Size & Demanded Price	10×5's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Haldol 10mg tablet by M/s Janssen-Cilag Pharma GmbH, AGES Austria Approved.
	Me-too Status	Hyrpridol Tablets 10Mg by M/s Global Pharmaceuticals, Reg. No. 37079
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved.
	Decision: Approved.	
300.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xaltral 5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42695 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Haloperidol…5mg
	Pharmacological Group	AntiPsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Haloperidol 5mg tablet by M/s Mylan, USFDA Approved.
	Me-too Status	Hyrpridol Tablets 5Mg by M/s Global Pharmaceuticals, Reg. No. 37078
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved.
	Decision: Approved.	
301.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Bupnar 0.6mg/2ml Injection
	Diary No. Date of R& I & fee	Dy.No 42685 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Ampoule (2ml) Contains: Buprenorphine as Hydrochloride……0.6mg
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
302.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xevan 2mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42698 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Lorazepam…2mg

	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Tavor tablet 2mg by /s Pfizer Germany Approved.
	Me-too Status	Veniti 2mg Tablet (Reg. 065694) of M/s. Wilshire Lab
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved.
	Decision: Approved.	
303.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xevan 1mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42697 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Lorazepam…1mg
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Tavor tablet 1mg by /s Pfizer Germany Approved.
	Me-too Status	Veniti 1mg Tablet (Reg. 065696) of M/s. Wilshire Lab
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved.
	Decision: Approved.	
304.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Panzin 25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42701 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each film coated Tablet Contains: Pentazocine Eq. to Base…25mg
	Pharmacological Group	Analgesic/Narcotic Antagonist
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Pentazocine Hydrochloride 25 mg Film-coated Tablets by M/s Generics [UK] Limited t/a Mylan, MHRA Approved.
	Me-too Status	Penfred Tablet (Pentazocine as hydrochloride) of M/s Friends Pharma, Reg. No. 60759
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet (psychotropic) section approved. The product approved in reference country is film coated while the applied product is uncoated, clarify or otherwise submit revised formulation along with master formula and requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
305.	Name and address of manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Xovitin 20mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42794 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Composition	Each Tablet Contains: Fluoxetine as HCl…20mg
	Pharmacological Group	SSRIs

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sarafem tablets (10mg, 15mg, 20mg) by M/s APIL, USFDA Approved
	Me-too Status	Futine 20 mg Tablet by M/s Wilshire Laboratories, Reg. No. 41772
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Tablet General section approved.
	Decision: Approved.	
306.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K.
	Brand Name +Dosage Form + Strength	Alfadol 2mcg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 39655 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each 1ml Ampoule contains: Alfacalcidol…2mcg
	Pharmacological Group	Vitamin D and analogues, ATC code A11CC03
	Type of Form	Form 5
	Finished Product Specification	BP Specs.
	Pack Size & Demanded Price	As Per SRO.
	Approval Status of Product in Reference Regulatory Authorities	One-Alpha Injection 2 micrograms/ml (0.5ml Ampoule & 1mlampoule) solution for injection BY, Leo Laboratories Limited, MHRA Approved.
	Me-too Status	BONAFIDE INJECTION 2 mcg/ml by M/s S.J. & G. FAZUL ELLAHIE (PVT) LTD. Reg. No. 55545
	GMP Status	Inspection date 13.02.2018, Good level of GMP compliance
	Remarks of the Evaluator.	
	Decision: Approved.	
307.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Aultasim 10mg Tablets
	Diary No. Date of R& I & fee	Dy.No 39654 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each Film Coated Tablet Contains: Simvastatin…10mg
	Pharmacological Group	HMG-CoA reductase inhibitor ATC-Code: C10A A01
	Type of Form	Form 5
	Finished Product Specification	USP Specs.
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Zocor® (10mg, 20mg, 40mg, 80mg) film-coated tablets BY Merck Sharp & Dohme Limited, MHRA Approved.
	Me-too Status	SIMPLACOR *10mg* TABLETS by M/s NOVARTIS PHARMA (PAK) LTD, reg. No. 26870
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
308.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Sumatriptan 50mg Tablet
	Diary No. Date of R& I & fee	Dy.No 39653 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each Film Coated Tablet Contains: Sumatriptan…50mg
	Pharmacological Group	Analgesics: Selective 5-HT1 receptor agonists. ATC code: N02CC01
	Type of Form	Form 5
	Finished Product Specification	BP

	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sumatriptan 50mg film-coated Tablets BY M/s Dr. Reddy's Laboratories (UK) Ltd, MHRA Approved.
	Me-too Status	Imigran *50mg* TABLETS M/s GlaxoSmithKline, Reg. No. 41158
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The applied product contains Sumatriptan 50mg while the reference product contains Sumatriptan as Succinate 50mg, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Sumatriotan" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product alingwith the susmission of requisite fee.	
309.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Loxo 60mg Tablets
	Diary No. Date of R& I & fee	Dy.No 39661 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each Film Coated Tablet Contains: Loxoprofen …60mg
	Pharmacological Group	Non steroidal anti-inflammatory drugs (NSAIDs)
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	*ROKIFEN film coated tablet 60mg(Japan)* BY M/s Ryukakusan Co., Ltd. PMDA Japan
	Me-too Status	Renox tablets of M/s Curative Pharmaceuticals, Rawalpindi (Reg.#039849)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
310.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Zolmiault 2.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 39659 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each Film Coated Tablet Contains: Zolmitriptan…2.5mg
	Pharmacological Group	selective serotonin receptor agonists/Anti-migrain preparation
	Type of Form	Form 5
	Finished Product Specification	USP SPECS.
	Pack Size & Demanded Price	As Per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Zomig tablets (2.5mg, 5mg) by M/s AstraZeneca Canada Inc. 1004 Middle gate Road Mississauga, Ontario, (USFDA Approved)
	Me-too Status	Engzol Tablet 2.5mg by M/s English Pharma. Reg. No.040153
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
311.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Zolmiault 5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41709 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Zolmitriptan…5mg
	Pharmacological Group	selective serotonin receptor agonists/Anti-migrain preparation
	Type of Form	Form 5

	Finished Product Specification	USP SPECS.
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Zomig tablets (2.5mg, 5mg) by M/s AstraZeneca Canada Inc. 1004 Middle gate Road Mississauga, Ontario, (USFDA Approved)
	Me-too Status	Engzol Tablet 5mg by M/s ENGLISH PHARMA. Reg. No. 41416
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
312.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Dimecrotic Acid 50mg Tablet
	Diary No. Date of R& I & fee	Dy.No 39658 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each Film Coated Tablet Contains: Dimecrotic Acid…50mg
	Pharmacological Group	Gastrointestinal drugs Cholagogues & hepatic preparations
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs
	Pack Size & Demanded Price	As Per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Hepadial *50mg* TABLETS(Hilton Pharma), Reg. No. 16850
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
313.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Aultreotide 0.1mg Injection
	Diary No. Date of R& I & fee	Dy.No 39657 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each ampoule of 1ml contains: Octreotide as acetate…0.1mg
	Pharmacological Group	Somatostatin and analogues ATC code: H01CB02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs.
	Pack Size & Demanded Price	As Per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Octreotide 100 micrograms/1ml ampoule solution for injection BY M/s Ranbaxy UK limited, MHRA Approved
	Me-too Status	Sandotide injection 0.1mg/ml M/s CCL Pharma, (Reg # 052284)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Clarification is required whether the API is from biological origin or synthetic along with the relevant documents.
	Decision: Deferred for submission of source of API whether biological or synthetic and requisite manufacturing facility.	
314.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Epri 50mg Tablet
	Diary No. Date of R& I & fee	Dy.No 39656 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Composition	Each Film Coated Tablet Contains: Eperisone HCL…50mg
	Pharmacological Group	Antispasmodics
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs.
	Pack Size & Demanded Price	As per SRO.

	Approval Status of Product in Reference Regulatory Authorities	Eperisone HCL (50mg, 100mg) film coated tablet, Aifa Italy Approved
	Me-too Status	Berelax 50mg Tablet by M/s Ray Pharma, Reg. no. 61084
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
315.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Artho 50mg Tablets
	Diary No. Date of R& I & fee	Dy.No 40877 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each delayed release Contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Arthrotec 50 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too Status	Prostol Tablets by M/s Flow Pharmaceutical (Pvt) Ltd, 17-KM Sheikhupura Road, Lahore, Reg. No. 026839
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Clarification is required since the composition of applied product is different from the reference product and is given in the following; Each film coated tablet contains: Diclofenac sodium…..50mg Misoprostol…….200mcg Moreover, Misoprostol requires special storage conditions 2-8^{0}C. Provide the evidence of presence of requisite storage facility or otherwise submit revised formulation as per the composition of reference product given in the following along with the submission of requisite fee; Each delayed release tablet contains: Diclofenac Sodium (enteric coated core)…..……50mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Decision: Deferred for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.	
316.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Artho 75mg Tablets
	Diary No. Date of R& I & fee	Dy.No 40868 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each delayed releaseTablet Contains: Diclofenac Sodium (enteric coated core)…..……75mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Arthrotec 75 modified-release tablets by M/s Pfizer, MHRA approved
	Me-too Status	Arsofin Tablets by M/s Martin Dow Pharmaceuticals (Pakistan) Ltd, Reg. no. 48013
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Clarification is required since the composition of applied product is different from the reference product and is given in the

		following; Each film coated tablet contains: Diclofenac sodium…..75mg Misoprostol…….200mcg Moreover, Misoprostol requires special storage conditions 2-8^{0}C. Provide the evidence of presence of requisite storage facility or otherwise submit revised formulation as per the composition of reference product given in the following along with the submission of requisite fee; Each delayed release tablet contains: Diclofenac Sodium (enteric coated core)…..……75mg Misoprostol (1% HPMC Dispersion)…..……..…200mcg
	Decision: Deferred for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.	
317.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Medo 400mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40871 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Midecamycin…400mg
	Pharmacological Group	macrolide
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
318.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Diart Sachet
	Diary No. Date of R& I & fee	Dy.No 40873 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Sachet Contains: Piperaquine Phosphate…..120mg Dihydroartemisinin……15mg
	Pharmacological Group	Antiprotozoals, antimalarials, artemisinin and derivatives, combinations, ATC code: P01BF05.
	Type of Form	Form 5
	Finished Product Specification	
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	TIMEQUIN SACHET 15/120 by M/s SAMI PHARMACEUTICALS (PVT) LTD, Reg No. 70787
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference

		regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation/drug in reference regulatory authorities adopted by Registration Board in 275th meeting or WHO approval status.	
319.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Atro 10/40 mg Tablets
	Diary No. Date of R& I & fee	Dy.No 40874 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Ezetimibe……...10mg Atorvastatin …..40mg
	Pharmacological Group	HMG-CoA reductase inhibitor and Other lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	Innovators Specs.
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	EZETIMIBE AND ATORVASTATIN CALCIUM (10mg/10mg, 20mg/10mg, 40mg/10mg, 80mg/10mg) film coated tablet by M/s Watson Labs, USFDA Approved.
	Me-too Status	Lytron Forte Tablet *10/40mg* TABLETS by M/s Maple pharma), Reg. No. 61266
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The applied formulation contains Atorvastatin as base while the product approved in reference country contains Atorvastatin as Calcium, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Atorvastatin (base)" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
320.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Atro 10/20 mg Tablets
	Diary No. Date of R& I & fee	Dy.No 40875 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Ezetimibe……...10mg Atorvastatin as calcium…..20mg
	Pharmacological Group	HMG-CoA reductase inhibitor and Other lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	Innovators Specs.
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	EZETIMIBE AND ATORVASTATIN CALCIUM (10mg/10mg, 20mg/10mg, 40mg/10mg, 80mg/10mg) film coated tablet by M/s Watson Labs, USFDA Approved.
	Me-too Status	Lytron Forte Tablet *10/20mg* TABLETS by M/s Maple pharma), Reg. No. 61265
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The applied formulation contains Atorvastatin as base while the product approved in reference country contains Atorvastatin as Calcium, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation containing "Atorvastatin (base)" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	

321.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Mebe 200mg Capsule
	Diary No. Date of R& I & fee	Dy.No 40872 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Capsule Contains: Mebeverine HCl (MR pellets)…200mg
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group, ATC-Code: A03AA04
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Aurobeverine MR 200mg capsule BY Milpharm Ltd., MHRA Approved.
	Me-too Status	Berrin 200 mg Capsules of M/s Focus &Rulz Pharmaceuticals, (Reg.#066660)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Source of pellets: not provided by the firm.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
322.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Neto 500mg Tablets
	Diary No. Date of R& I & fee	Dy.No 40876 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Nitazoxanide…500mg
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alinia 500mg film coated tablet by M/s Romark, USFDA Approved.
	Me-too Status	Nizonide 500mg Tablet by M/s AGP PvtLtd.Reg. No. 81101
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
323.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Aultatriptan 40mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41711 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Eletriptan Hydrobromide…40mg
	Pharmacological Group	selec-tive agonist at the 5-HT1B/D receptor. Antimigraine action
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Relpax (20mg, 40mg) film coated tablets BY M/s Pfizer USFDA Approved.
	Me-too Status	Relpax 40Mg Tablets by M/s Pfizer Reg. No. 39809
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
324.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Amlodiperin 8/5 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41710 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018

	Composition	Each Tablet Contains: Perindopril Erbumine…..…8mg Amlodipine as Besylate……5mg
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specs.
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Perindopril / Amlodipine 8/5mg Uncoated tablets by M/s Consilient, MHRA Approved.
	Me-too Status	Coversam 8/5mg tablet M/s Servier Research & Pharmaceuticals, Pakistan (Reg. # 065961)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
325.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Aultaskerin HCT 150/25 mg tablets
	Diary No. Date of R& I & fee	Dy.No 41708 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Aliskerin as hemihydrate…..150mg Hydrochlorothiazide…. ……25mg
	Pharmacological Group	Renin Inhibitor, Thiazide diuretics
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Tekturna hct Tablets (150mg/12.5mg, 150mg/25mg, 300mg/12.5mg, 300mg/25mg) by M/s Noden Pharma USFDA APPROVED
	Me-too Status	Rasilez Hct (150mg/25mg) Tablets by M/s Novartis Pharma (PVT) LTD), Reg No. 59292
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
326.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Aultaskerin 300mg Tablet
	Diary No. Date of R& I & fee	Dy.No 41707 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Film Coated Tablet Contains: Aliskerin as hemihydrate…..300mg
	Pharmacological Group	Renin Inhibitor, ATC Code. C09XA02
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Tekturna Tab.(150mg, 300mg) by Noden Pharma, USFDA approved
	Me-too Status	Rasilez 300 mg Tablets (Novartis Pharma), Reg. No. 52255
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
327.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Aultagab 300mg Capsule
	Diary No. Date of R& I & fee	Dy.No 41712 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Capsule Contains: Gabapentin…….300mg

	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Gabapentin 300mg Capsules. MHRA approved
	Me-too Status	Gababion 300mg Capsules of M/s Merck Marker (Reg.#045346)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
328.	Name and address of manufacturer / Applicant	M/s Otsuka Pakistan Ltd, No. F/4-9, Hub Industrial Trading Estate, Dist; Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Amiparen I.V Infusion
	Diary No. Date of R& I & fee	Dy. NO. 19595 dated 31/10/2017 Fee Rs. 20,000/-
	Composition	Each 100ml contains: L-Leucince……..1.40g L-isoleucine…..0.80g L-Valine……..….0.80g L-Lysine acetate…...1.48g L-Threonine…….0.57g L-Tryptophan……..0.20g L-Methionine……...0.39g L-Phenylalanine…..0.70g L-Cysteine……0.10g L-Tyrosine……...0.05g L-Arginine……...1.05g L-Histidine……..0.50g L-Alanine……0.80g Proline…….0.50g L-Serine.....0.30g Aminoacetic Acid…0.59g L-Aspartic Acid…..0.10g L-Glutamic acid….0.10g Water for injection….q.s
	Pharmacological Group	Amino acid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	500ml plastic (LDPE) bottle, Rs. 575/-
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	could not be confirmed with same composition and strength.
	GMP Status	Last inspection report dated 13/12/2017, the firm is found goo and compliant as per GMP requirement.
	Remarks of the Evaluator.	The firm had initially applied for 500ml glass bottle and then the firm applied for LDPE bottle. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in LDPE bottle with same strength, and filled volume.**	

329.	Name and address of manufacturer / Applicant	M/s Otsuka Pakistan Ltd, No. F/4-9, Hub Industrial Trading Estate, Dist; Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Kidmin I.V Infusion
	Diary No. Date of R& I & fee	Dy. NO. 19596 dated 31/10/2017 Fee Rs. 20,000/-
	Composition	Each 100ml contains: L-Leucince……..1.40g L-isoleucine…..0.90g L-Valine……..….1.00g L-Lysine acetate…..0.71g L-Threonine…….0.35g L-Tryptophan……..0.25g L-Methionine……...0.30g L-Phenylalanine…..0.50g L-Cysteine……0.10g L-Tyrosine……...0.05g L-Arginine……...0.45g L-Histidine……..0.35g L-Alanine……0.25g Proline…….0.30g L-Serine.....0.30g L-Aspartic Acid…..0.10g L-Glutamic acid….0.10g Water for injection….q.s
	Pharmacological Group	Amino acid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	100ml plastic (LDPE) bottle, Rs. 550/-
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed with same composition and strength.
	GMP Status	Last inspection report dated 13/12/2017, the firm is found goo and compliant as per GMP requirement.
	Remarks of the Evaluator.	Initially the product with filled volume of 200ml (which is already registered) in glass bottle was applied but now you have applied for 100ml in LDPe bottle, therefore, • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting andalready approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume. • Submit requisite fee for change in the filled volume.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm in LDPE bottle with same strength, and filled volume.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in LDPE bottle with same strength, and filled volume.** • **Submission of requisite fee for change in filled volume of the applied product.**	

Following duplicate dossiers were received from Reg-II section vide letter No.F.1-11/2019-Reg-II dated 24th Dec, 2019. The receiving of the following applications has been confirmed from the R&I section.		
330.	Name and address of manufacturer / Applicant	M/s Allmed (pvt) Ltd. Plot No. 590, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ganclovir 250mg capsule **(Duplicate dossier)**
	Diary No. Date of R& I & fee	Dy. No. 24914 fee rs. 20,000/- dated 12/10/2015

	Composition	Each capsule contains: Ganciclovir…… 250mg
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	60's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cytovene (250mg, 500mg) capsule by Roche (**USFDA** Approved) and discontinued for reasons other than safety and efficacy
	Me-too Status	GANVIR CAPSULES 250MG by M/s MISSION PHARMACEUTICALS, Reg. No. 47549
	GMP Status	GMP certificate issued on 21/01/2020 on the basis of inspection conducted on 01/01/2020.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications. Fee shall be verified as per procedure adopted in 285th Registration Board meeting.	

331.	Name and address of manufacturer / Applicant	M/s Allmed (pvt) Ltd. Plot No. 590, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ganclovir 500mg capsule **(Duplicate dossier)**
	Diary No. Date of R& I & fee	Dy. No. 24915 fee rs. 20,000/- dated 12/10/2015
	Composition	Each capsule contains: Ganciclovir…… 500mg
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	60's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cytovene (250mg, 500mg) capsule by Roche (**USFDA** Approved) and discontinued for reasons other than safety and efficacy
	Me-too Status	Could not be confirmed.
	GMP Status	GMP certificate issued on 21/01/2020 on the basis of inspection conducted on 01/01/2020.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
332.	Name and address of manufacturer / Applicant	M/s Allmed (pvt) Ltd. Plot No. 590, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Valgan 450mg tablet **(Duplicate dossier)**
	Diary No. Date of R& I & fee	Dy. No. 24913 fee rs. 20,000/- dated 12/10/2015
	Composition	Each film coated tablet contains: Valganciclovir as HCl…… 450mg
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	60's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Valcyte 450 mg film-coated tablets by M/s Roche Products Limited, MHRA Approved.
	Me-too Status	Valcyte tablets 450mg by M/s Rosch (Reg. # 052253)
	GMP Status	GMP certificate issued on 21/01/2020 on the basis of inspection conducted on 01/01/2020.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications. Fee shall be verified as per procedure adopted in 285th Registration Board meeting.	
333.	Name and address of manufacturer / Applicant	M/s Genix Pharma (pvt) ltd. 44,45-B Korangi Creek Road, Karachi.
	Brand Name +Dosage Form + Strength	Denide Ointment 0.05% **Duplicat dossier**
	Diary No. Date of R& I & fee	Dy. No. 6918 fee rs. 20,000/- dated 23/02/2018

	Composition	Each gram contains: Desonide……..0.5mg (0.05% w/w)
	Pharmacological Group	Topical corticosteroid
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10g, 15g, 60g, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Desowen 0.05% ointment by M/s Galderma labs, USFDA approved.
	Me-too Status	Stienoide Ointment 0.5mg/g by M/s Steifel Lab pvt ltd, Reg. No. 46988
	GMP Status	Last inspection report dated 16/02/2018 concludes satisfactory level of cGMP compoliance at the time of inspection.
	Remarks of the Evaluator.	Section available
	Decision: Approved with innovator's specifications. Fee shall be verified as per procedure adopted in 285th Registration Board meeting.	
334.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Examal Plus Tablet 80/480
	Diary No. Date of R& I & fee	Dy.No 40256 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each Tablet Contains: Artemether……80mg Lumefantrine…480mg
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too Status	R-Terine Forte Tab. of M/s Ardin Pharma, Reg.No.066814
	GMP Status	Last inspection report dated 4th June, 2018 show that the firm was performing at satisfactory GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
335.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Arisunate Dry Powder Injection 60mg
	Diary No. Date of R& I & fee	Dy.No 40257 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each Vial Contains: Artisunate…60mg
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too Status	Gen-M 60mg Injection of M/s Genix Pharma. Reg. No. 47630
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
336.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Aloran Syrup 5mg/5ml
	Diary No. Date of R& I & fee	Dy.No 40258 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 5ml contains: Loratadine…5mg
	Pharmacological Group	Antihistamine

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Loratadine 5 mg/ 5 ml syrup by M/s Generics [UK] Limited t/a Mylan, MHRA Approved.
	Me-too Status	Loroking Syrup 5mg/5ml by M/s Medicraft Pharmaceuticals (Pvt) Ltd,, Reg. No. 49041
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
337.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Artemet 80mg/ml Injection IM
	Diary No. Date of R& I & fee	Dy.No 40259 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each Ampoule of 1ml contains: Artemether…80mg
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too Status	Paluther injection 80mg imported by Rhone. Reg. No.14938
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
338.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Relizin Oral Solution 1mg/ml
	Diary No. Date of R& I & fee	Dy.No 40255 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each 5ml contains: Cetirizine dihydrochloride…5mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Benadryl Allergy Children's 1mg/ml Oral Solution by M/s McNeil Products Limited, MHRA Approved.
	Me-too Status	Cetrihit-S Syrup 5mg/5ml by M/s Unipharma, Reg. No. 81356
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
339.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Razolid 600mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40282 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each Film Coated Tablet Contains: Linezolid…60mg
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Linezolid 600 mg film-coated tablets by M/s Milpharm Limited, MHRA Approved.
	Me-too Status	Linzol Tablet 600 mg of M/s Regal pharma, Reg. No. 81957
	GMP Status	Inspection date 19/09/2018, The panel recommended issuance of

		GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
340.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Rakalong 60mg Tablet
	Diary No. Date of R& I & fee	Dy.No 40283 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Composition	Each Film Coated Tablet Contains: Dapoxetine as HCL…60mg
	Pharmacological Group	Other urologicals
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Priligy 60 mg film−coated tablets by M/s (A. Menarini Farmaceutica Internazionale SRL (MHRA Approved)
	Me-too Status	Could not be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of applied formulation/drug already approved by DRAP (generic/me-too status) along with registration number, brand name and name of firm could not be confirmed.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
341.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Madol P Tablet 375/37.5mg
	Diary No. Date of R& I & fee	Dy.No 42052 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Paracetamol……375mg Tramadol HCL……37.5mg
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved
	Me-too Status	Tramal Plus tablet by M/s Searle Company limited, Reg No.77129
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
342.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Rempro 5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42049 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each Tablet Contains: Procyclidine HCL…5mg
	Pharmacological Group	Anticholinergic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×100's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Kemadrin (uncoated) Tablets 5mg by M/s Aspen Pharma (MHRA Approved)
	Me-too Status	Proclidine 5mg Tablets by M/s Shaheen Pharmaceuticals, (Reg.# 041018)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	

343.	Name and address of manufacturer / Applicant	M/s Olive Laboratories 52-S6 National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Omnidol-CF Tablet 500mg/65mg
	Diary No. Date of R& I & fee	Dy.No 42056 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Composition	Each uncoated Tablet Contains: Paracetamol…..500mg Caffeine…….65mg
	Pharmacological Group	Analgesic /Xanthine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Panadol Extra Advance 500 mg/65 mg Film Coated Tablets by M/s GSK, MHRA Approved. Uncoated tablet also approved in MHRA
	Me-too Status	Paratol Extra tablet by M/s Highnoon (Reg.# 13346)
	GMP Status	Last inspection report dated 01-08-2017 shows that firm is operating at good level of GMP as of today.
	Remarks of the Evaluator.	The firm has changed the formulation from Uncoated to Film coated as per the reference product and submitted frr Rs. 5,000/- vide challan number 1921458 dated 25/02/2020. However, firm has claimed uncoated tablet as approved in MHRA.
	Decision: Approved.	
344.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	Vilmet 50/850mg Tablets
	Diary No. Date of R& I & fee	Dy.No 42460 dated 12-12-2018 Rs.20,000/- Dated 12-12-2018
	Composition	Each Film Coated Tablet Contains: Vildagliptin…..…50mg Metformin HCL…850mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	14's, 28's, 56's Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	GALVUMET 50/850 film coated tablet. TGA Australia approved approved
	Me-too Status	Galvus met 50mg/850mg tablets by M/s Novartis,. Reg. No. 66106
	GMP Status	Last inspection report dated 26/07/2018 confirms the good level of GMP compliance.
	Remarks of the Evaluator.	Approved in TGA with shelf life of 18 months
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
345.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	B-Fen Cold & Sinus Suspension
	Diary No. Date of R& I & fee	Dy.No 42458 dated 12-12-2018 Rs.20,000/- Dated 12-12-2018
	Composition	Each 5ml contains: Ibuprofen……100mg Pseudoephedrine HCl…..15mg
	Pharmacological Group	Analgesic and nasal decongestant
	Type of Form	Form 5
	Finished Product Specification	MFG sepcs
	Pack Size & Demanded Price	1×90ml, 1×120ml, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Children's Advil Cold suspension by M/s Pfizer (Approved by USFDA)
	Me-too Status	Arinac Suspension 100mg/15mg/5ml by M/s Abbott Pharma, Reg. No. 22353

	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
346.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	B-Fen Advance Max Tablets 400/60mg
	Diary No. Date of R& I & fee	Dy.No 42459 dated 12-12-2018 Rs.20,000/- Dated 12-12-2018
	Composition	Each Film Coated Tablet Contains: Ibuprofen…400mg Pseudoephedrine HCl…60mg
	Pharmacological Group	Analgesic and nasal decongestant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	50's, 100's, 250's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Lasynac Max Strength 400mg/60mg film coated tablets (MHRA)
	Me-too Status	Irofen Forte Tablets of M/Searle Pakistan Karachi (Reg.#042233)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
347.	Name and address of manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Delcort 6mg Tablet
	Diary No. Date of R& I & fee	Dy.No 44232 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Composition	Each Tablet Contains: Deflazacort…….6mg
	Pharmacological Group	glucocosteroid
	Type of Form	Form 5
	Finished Product Specification	Mfg sepcs
	Pack Size & Demanded Price	1×20's, MRP 200/-
	Approval Status of Product in Reference Regulatory Authorities	EMFLAZA Tablet 6mg in US-FDA Approved
	Me-too Status	Calcort Tablets 6mg Of M/S Hoechst Karachi (Reg No# 025224)
	GMP Status	GMP inspection dated 07-02-2018 concluding as under: "On the basis of current inspection it was observed that the firm rectified all observations noted during last GMPInspection."
	Remarks of the Evaluator.	Approval of Steroidal section is not confirmed. Stability study data is required as per the directions of Registration Board provided in 251st meeting and later amended in 278th meeting.
	Decision: Deferred for the following: • **Evidence or approval of relevant/required manufacturing facility.** • **Submission of stability studies of 3 batches accoriding to the conditions of zone IV-A as per the directions given in 278th meeting of Registration Board.**	
348.	Name and address of manufacturer / Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Xtin CR 37.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42055 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Tablet Contains: Paroxetine as HCL …37.5mg
	Pharmacological Group	SSRIs/ Anti- depressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	3×10's, as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil CR Tablet (enteric, film coated controlled relesased) of M/s Apotex Technologies (USFDA Approved)

	Me-too Status	Peroxa CR 37.5 mg Tablet by M/s Lisko, Reg No. 82148
	GMP Status	16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section, to M/s Siam Pharmaceuticals Islamabad
	Remarks of the Evaluator.	The composition of the applied product is different from the reference product. The product approved in reference country is Enetric Film coated Controll Release while applied product is uncoated tablet, clarify or otherwise submit revised formulation along witht the submission of requisite fee.
	Decision: Deferred for submission of evidence of approval of applied formulation as "Uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
349.	Name and address of manufacturer / Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Neoquel 200mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42054 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…200mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist/antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	3×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg,50mg 100mg, 200mg, 300mg, 400mg) by M/s Astrazeneca Pharms, USFDA Approved.
	Me-too Status	Qusel Tablet 200mg (25mg, 100mg, 200mg) by M/s Hilton pharma, Reg No. 37690
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
350.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name +Dosage Form + Strength	Alofex 180mg Tablet
	Diary No. Date of R& I & fee	Dy.No 42059 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…180mg
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Fexofenadine hydrochloride film coated tablet 180mg by M/s Cipla (MHRA Approved)
	Me-too Status	Epodin 180mg Tablet by M/s Epoch Pharma, Reg. No. 58058
	GMP Status	The firm had maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection as per the last inspection report dated 21/05/2018 & 05/07/2018.
	Remarks of the Evaluator.	
	Decision: Approved.	
351.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Novokast Sachet 4mg
	Diary No. Date of R& I & fee	Dy.No 40273 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018

	Composition	Each sachet contains: Montelukast as Sodium …4mg
	Pharmacological Group	Leukotriene antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	14's, as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Montelukast Sodium 4 mg Oral Granules by M/s Highnoon Laboratories, MHRA Approved.
	Me-too Status	Aerotel Sachet of M/s Highnoon Laboratories. (Reg.#044768)
	GMP Status	22-01-2019 Conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Nova-Med Lahore. is considered to be operating at Good level of compliance of GMP requirements.
	Remarks of the Evaluator.	
	Decision: Approved.	
352.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vicomid Syrup 10mg/ml
	Diary No. Date of R& I & fee	Dy.No 40252 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Composition	Each ml contains: Lacosamide…10mg
	Pharmacological Group	Anticonvulsive
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	100ml, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	VImpat syrup 10mg/ml by M/s UCB INC, USFDA Approved.
	Me-too Status	Could not be verified
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
353.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Artinew 120mg/vial for Injection IM/IV
	Diary No. Date of R& I & fee	Dy.No 41949 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial contains: Artesunate…120mg
	Pharmacological Group	Anti malarial
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too Status	Gen-M 120mg Injection of M/s Genix Pharma. Reg. No. 076073
	GMP Status	**Safe Pharma: Inspection date 04/03/2019** All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good. **Adamjee: Inspection date 20/082019** Based on the above stated observations their current compliance level is rated as GOOD.

	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
354.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Artinew 30mg/vial Injection IM/IV
	Diary No. Date of R& I & fee	Dy.No 41948 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Artesunate…30mg
	Pharmacological Group	Anti malarial
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too Status	Gen-M 120mg Injection of M/s Genix Pharma. Reg. No. 076072
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
355.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Altra 100mg/2ml Injection
	Diary No. Date of R& I & fee	Dy.No 41947 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Ampoule of 2ml contains: Tramadol HCL…100mg
	Pharmacological Group	Analgesics
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Tramadol 50mg/ml (2ml ampoule) Solution for Injection or Infusion by M/s Beacon Pharmaceuticals, MHRA Approved
	Me-too Status	Tonoflex Injection 100mg/2ml ampoule by M/s Sami Pharmaceuticals, Karachi, Reg. No. 053224
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
356.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Adopera Injection 1g Im/IV
	Diary No. Date of R& I & fee	Dy.No 41937 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Cefoperazone Sodium…….0.5g Sulbactam Sodium……..…0.5g
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form 5

	Finished Product Specification	JP
	Pack Size & Demanded Price	As pe rSRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, (Reg.# 047002)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The reference product contains Cefoperazone As Sodium and Sulbactam As Sodium (0.5g each) while the applied product contains Cefoperazone Sodium and Salbactum Sodium (0.5g each), clarify or otherwise submit revised formulation with correct equivalency factor along with the submission of requisite fee.
	Decision: Deferred for following: • **Submission of details of products which are already being manufactured on contract.** • **Submission of evidence of approval of applied formulation containing "Cefoperazone Sodium and Sulbactum Sodium" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.** • **Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
357.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Adopera Injection 2g IM/IV
	Diary No. Date of R& I & fee	Dy.No 41938 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Cefoperazone Sodium…1g Sulbactam Sodium…1g
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Approved by 3 European countries: **Czech:** http://www.sukl.eu/modules/medication/detail.php?code=0015273&tab=info **Slovakia:** https://www.sukl.sk/hlavna-stranka/english-version/specialpages/medical-product-detail?page_id=842&lie_id=6343A **Poland:** http://pub.rejestrymedyczne.csioz.gov.pl/?AspxAutoDetectCookieSupport=1#results
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The reference product contains Cefoperazone As Sodium and Sulbactam As Sodium (1g each) while the applied product contains Cefoperazone Sodium and Salbactum Sodium (1g each), clarify or otherwise submit revised formulation with correct equivalency factor along with the submission of requisite fee.
	Decision: Deferred for following: • **Submission of details of products which are already being manufactured on contract.** • **Submission of evidence of approval of applied formulation containing "Cefoperazone Sodium and Sulbactum Sodium" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.** • **Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	

358.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Azidime Injection 250mg IM/IV
	Diary No. Date of R& I & fee	Dy.No 41939 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Ceftazidime as pentahydrate …250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	CEFTAZIDIME PANPHARMA CHILDREN AND INFANTS 250 mg powder for solution for injection by M/s PANPHARMA Approved.
	Me-too Status	Fortez Injection 250mg IM/IV by M/s Biocef.,Reg. no. 082751
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
359.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Azidime Injection 500mg IM/IV
	Diary No. Date of R& I & fee	Dy.No 41940 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Ceftazidime as pentahydrate...500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Injection by M/s Villerton Invest SA, MHRA Approved
	Me-too Status	Fortez Injection 500mg IM/IV by M/s Biocef Reg. no. 082750
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
360.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Azidime Injection 1000mg IM/IV
	Diary No. Date of R& I & fee	Dy.No 41941 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Ceftazidime as penyahydrate…1000mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftazidime as pentahydrate (500mg&1000mg) Powder for Solution for Inj. by M/s Villerton Invest SA, MHRA Approved

	Me-too Status	Fortez Injection 1000mg IM/IV by M/s Biocef Reg. no. 82749
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
361.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Halonate 50mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 41951 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each ml contains: Haloperidol Decanoate…50mg
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	HALDOL Decanoate (50mg/ml, 100mg/ml) solution for injection by M/s Janssen-Cilag Limited, MHRA Approved.
	Me-too Status	SERENACE Injection 5mg/ml of Searle Pharma (Reg#000005)
	GMP Status	Same as stated above
	Remarks of the Evaluator.	Section confirmation The produict approved in reference country contains Haloperidol as Deconoate 50mg/ml while the composition of applied product is Haloperdol Decanoate 50mg/ml, clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for following: • **Submission of details of products which are already being manufactured on contract.** • **Evidence of approval of relevant/required manufacturing facility.** • **Submission of evidence of approval of applied formulation containing "Haloperidol Decanoate" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.** • **Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
362.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Lecetam Injection 500mg/5ml
	Diary No. Date of R& I & fee	Dy.No 41950 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each 5ml Ampoule contains: Piracetam……500mg
	Pharmacological Group	antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Keppra 500mg/5ml concentrate for solution for infusion by M/s UCB Pharma S.A
	Me-too Status	Eplipsa 500mg/5ml Injection by M/s Helix, Reg. No. 75918
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel.**	

363.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Jenirox Injection 2000mg IM Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41934 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of contains: Ceftriaxone Sodium eq to Ceftriaxone…2000mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Amacef Injection 2g IM by M/s Linear Pharma Reg. No. 75344
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
364.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Jenirox Injection 1000mg IM Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41933 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Ceftriaxone Sodium eq to Ceftriaxone…1000mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 1000mg Injection IM by M/s WelMark Reg. No. 69752
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
365.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Adpime Injection 500mg IM Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41931 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Ceftriaxone Sodium eq to Ceftriaxone…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in	Ceftriaxone powder for injection (250mg, 500mg, 1000mg,

	Reference Regulatory Authorities	2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 250mg Injection IM by M/s WelMark Reg. No. 69750
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
366.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Jenirox Injection 500mg IM Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41932 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Ceftriaxone Sodium eq to Ceftriaxone…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection IM by M/s WelMark Pharmaceutical, Reg. No. 69751
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
367.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Adpime Injection 500mg (IV/IM)
	Diary No. Date of R& I & fee	Dy.No 41935 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of dry substance contains: Cefepime as HCL (with L-Arginine)…1000mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride 1gm Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 1gm Injection by M/s Bosch, Reg. No. 44357
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
368.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Adpime Injection 1000mg IM/IV Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41936 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018

	Composition	Each vial of dry substance contains: Cefepime as HCL (with L-Arginine) …1000mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 500mg Injection by M/s Bosch, Reg. No. 44356
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
369.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Flunoate 25mg/ml Injection
	Diary No. Date of R& I & fee	Dy.No 41952 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each ampoule of 1ml contains: Fluphenazine Deconate…25mg
	Pharmacological Group	antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Modecate Concentrate Injection 100mg/ml (0.5ml, 1ml) by M/s Aventis Pharma Limited, MHRA Approved.
	Me-too Status	FLUPHENAZINE DECANOATE 250mg/ml injection By M/s S.M.YAHYA & CO, Reg. No. 14697
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
370.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Nalbu 10mg/ml Injection IM/IV
	Diary No. Date of R& I & fee	Dy.No 41946 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Ampoule (1ml) Contains: Nalbuphine HCl……10mg
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	NUBAIN (Nalbuphine Hydrochloride) Injection, 10 mg/mL (1ml ampule). Health Canada approved.
	Me-too Status	Nalburax Injection by M/s Mediceena Pharma, Reg. No. 28830
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for following: **a. Submission of details of products which are already being manufactured on contract.** **b. Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	

371.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Todol 30mg/ml Injection IV/IM
	Diary No. Date of R& I & fee	Dy.No 41942 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each Ampoule of 2ml contains: Ketorolac Tromethamine…30mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Couldnot be confirmed
	GMP Status	Same as stated above
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm (in same strength and filled volume)
	Decision: Deferred for follwong: • **Submission of details of products which are already being manufactured on contract.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting(in same strength and filled volume).** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm (in same strength and filled volume)** • **Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
372.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Nekcin 500mg/2ml Injection IM/IV
	Diary No. Date of R& I & fee	Dy.No 41945 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial of 2ml contains: Amikacin Suplhate…500mg
	Pharmacological Group	aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Amikacin Sulfate Injection USP, 250 mg/mL (500 mg/2 mL and 1000 mg/4 mL vials) by M/s Fresenius, USFDA Approved.
	Me-too Status	Amikacin injection 500mg/vial by M/s care & cure marketing, reg. No. 15782
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The product approved in reference country contains Amikacin as Sulfate 500mg/2ml while the applied product contains Amikacin Sulfate 500mg/2ml, Clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for follwong: • **Submission of details of products which are already being manufactured on contract.** • **Submission of evidence of approval of applied formulation containing "Amikacin sulfate" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.**	

	• **Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel**	
373.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Nikcin 250mg/ml Injection IM/IV
	Diary No. Date of R& I & fee	Dy.No 41944 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each 2ml vial contains: Amikacin Suplhate…250mg
	Pharmacological Group	aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Amikacin injection 250mg/vial by M/s care & cure marketing, reg. No. 15781
	GMP Status	Same as stated above
	Remarks of the Evaluator.	
	Decision: Deferred for follwong: • **Submission of details of products which are already being manufactured on contract.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel.**	
374.	Name and address of manufacturer / Applicant	**Applicant:** M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi **Manufactured By:** M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Nekcin 100mg/2ml Injection IM/IV
	Diary No. Date of R& I & fee	Dy.No 41943 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each ml contains: Amikacin Suplhate…100mg
	Pharmacological Group	aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Amikacin Sulfate Injection USP, 50 mg/mL (100mg/2mL vial) by M/s Fresenius, USFDA Approved.
	Me-too Status	Amikacin Injection 100mg/Vial By M/S Care & Cure Marketing, Reg. No. 15780
	GMP Status	Same as stated above
	Remarks of the Evaluator.	The product approved in reference country contains Amikacin as Sulfate 100mg/2ml while the applied product contains Amikacin Sulfate 100mg/2ml, Clarify or otherwise submit revised formulation along with the submission of requisite fee.
	Decision: Deferred for follwong: • **Submission of details of products which are already being manufactured on contract.** • **Submission of evidence of approval of applied formulation containing "Amikacin sulfate" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product.** • **Capacity assessment report of M/s safe Pharma, Karachi by already constituted panel.**	
375.	Name and address of manufacturer / Applicant	**Applicant:** M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad **Manufactured BY:** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore

	Brand Name +Dosage Form + Strength	Cxime Suspension 100mg/5ml Powder for oral suspension
	Diary No. Date of R& I & fee	Dy.No 41500 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	EACH 5ML (Reconstitued) CONTAINS: Cefixime as trihydrate ……100mg
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Cefixima Dry Suspension 100mg of M/s Advanced Pharmaceuticals, RCCI (Reg. # 065393)
	GMP Status	**M/s English Pharmaceutical Industries:** The firm was operating a Fair level of compliance with GMP guidelines, inspection date 17th to 18th January 2019. Oral Dry powder suspension (Ceph)-approved **M/s Magns Pharmaceuicals:** GMP certificate issued on the basis of inspection conduicted on 01/03/2019.
	Remarks of the Evaluator.	**M/s Magns Pharacetucals:** Number of approved sections: 03 Number of products all ready being manufactured on contract: 00
	Decision: Approved.	
376.	Name and address of manufacturer / Applicant	**Applicant:** M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad **Manufactured BY:** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Cxime DS Suspension 200mg/5ml Powder for oral suspension
	Diary No. Date of R& I & fee	Dy.No 41501 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	EACH 5ML (Reconstitued) CONTAINS: Cefixime as trihydrate…200mg(trihydrate to be confirmed)
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefixime as trihydrate (100mg/5ml, 200mg/5ml, 500mg/5ml) by M/s Aurobindo, USFDA Approved.
	Me-too Status	Xerak Oral Dry Powder Suspension (200mg/5ml) by M/s CKD, Reg. No. 81788
	GMP Status	Oral Dry powder suspension (Ceph)-approved Same as stated above
	Remarks of the Evaluator.	
	Decision: Approved.	
377.	Name and address of manufacturer / Applicant	**Applicant:** M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad **Manufactured BY:** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Cxime Capsule 400mg
	Diary No. Date of R& I & fee	Dy.No 41503 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Eachc capsule contains: Cefixime as trihydrate …400mg
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	JP

	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Suprax (cefixime as trihydrate) 400mg capsule by M/s Lupin ltd, USFDA approved.
	Me-too Status	Xalfocin 400mg Capsule by M/s Martin Dow (Reg. # 080646)
	GMP Status	Same as stated above Capsule 9ceph) section approved.
	Remarks of the Evaluator.	
	Decision: Approved.	
378.	Name and address of manufacturer / Applicant	**Applicant:** M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad **Manufactured BY:** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	D-Vit Injection 200000 IU/ml IM/Oral
	Diary No. Date of R& I & fee	Dy.No 41504 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each 1ml ampoule contains: Cholecalciferol (Vitamin D3)……200000IU
	Pharmacological Group	Vitamin D3 analogue
	Type of Form	Form-5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml, oral solution in ampoule and Vitamin D3 Good 200,000 IU / 1 ml, solution for injection IM in ampoule by Bouchara-Recordati. ANSM Approved.
	Me-too Status	ORA-D3 Injection by Ameer & Adnan Pharmaceuticals (Pvt) Ltd. Reg. No. 78639.
	GMP Status	Same as stated above Liquid injection ampoule (general) section approved.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
379.	Name and address of manufacturer / Applicant	**Applicant:** M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad **Manufactured BY:** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Orixone Injection 250mg/Vial IM Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41497 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial contains: Ceftriaxone as sodium…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 250mg Injection IM by M/s WelMark Pharmaceutical, Reg. No. 69750
	GMP Status	Same as stated above Dry powder injection vial (Ceph) section approved
	Remarks of the Evaluator.	
	Decision: Approved.	
380.	Name and address of manufacturer / Applicant	**Applicant:** M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad **Manufactured BY:** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Orixone Injection 500mg/Vial IM Powder for injection

	Diary No. Date of R& I & fee	Dy.No 41498 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial contains: Ceftriaxone as sodium…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 500mg Injection IM by M/s WelMark Pharmaceutical, Reg. No. 69751
	GMP Status	Same as stated above Dry powder injection vial (Ceph) section approved
	Remarks of the Evaluator.	
	Decision: Approved.	
381.	Name and address of manufacturer / Applicant	**Applicant:** M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad **Manufactured BY:** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Orixone Injection 1g/Vial IV Powder for injection
	Diary No. Date of R& I & fee	Dy.No 41499 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial vontains: Cefriaxone as sodium…1g
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ceftriaxone powder for injection (250mg, 500mg, 1000mg, 2000mg) by M/s Bowmed limited, MHRA Approved.
	Me-too Status	Trimark 1000mg Injection IM by M/s WelMark Pharmaceutical, Reg. No. 69752
	GMP Status	Same as stated above Dry powder injection vial (Ceph) section approved
	Remarks of the Evaluator.	
	Decision: Approved.	
382.	Name and address of manufacturer / Applicant	**Applicant:** M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad **Manufactured BY:** M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Magns 40mg Injection IV
	Diary No. Date of R& I & fee	Dy.No 41502 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Composition	Each vial vontains: Omeprazole as Sodium…40mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion by M/s Sandoz Limited, MHRA Approved.
	Me-too Status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP Status	Same as stated above Dry powder injectable vial (general) section approved.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

383.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Nomigrain 50mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41609 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Sumatriptan as succinate…50mg
	Pharmacological Group	Analgesics: Selective 5-HT1 receptor agonists. ATC code: N02CC01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	2's, 6's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sumatriptan 50mg film-coated Tablets BY M/s Dr. Reddy's Laboratories (UK) Ltd, MHRA Approved.
	Me-too Status	Imigran *50mg* TABLETS M/s GlaxoSmithKline, Reg. No. 41158
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved.	
384.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Nomigrain 100mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41608 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Sumatriptan as succinate…100mg
	Pharmacological Group	Analgesics: Selective 5-HT1 receptor agonists. ATC code: N02CC01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	2's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sumatriptan (50mg, 100mg) film-coated Tablets BY M/s Dr. Reddy's Laboratories (UK) Ltd, MHRA Approved.
	Me-too Status	Sumapan 100mg Tablets M/s Wilshire Laboratories (Pvt) Ltd, Reg. No. 52809
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved.	
385.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Nomigrain 60mg Injection Sc
	Diary No. Date of R& I & fee	Dy. No. 41610 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Contains: Sumatriptan as succinate…60mg
	Pharmacological Group	Analgesics: Selective 5-HT1 receptor agonists. ATC code: N02CC01
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.

	Remarks of the Evaluator.	Me-too status and availability in RRAs could not be confirmed.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
386.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Solifenac 5mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41631 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…5mg
	Pharmacological Group	Muscarinic antagonist
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vesicare® (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too Status	Solifen Tablet 5mg by M/s GetzPharma, Reg. No. 61202
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
387.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Solifenac 10mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41632 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…10mg
	Pharmacological Group	Muscarinic antagonist
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Vesicare® (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too Status	Solifen Tablet 10mg by M/s GetzPharma, Reg. No. 61203
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
388.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Zolid 2.5mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41611 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Zolmitriptan…2.5mg
	Pharmacological Group	selective serotonin receptor agonists/Anti-migrain preparation
	Type of Form	Form 5
	Finished Product Specification	USP SPECS.
	Pack Size & Demanded Price	1×3's, price As Per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Zomig tablets (2.5mg, 5mg) by M/s AstraZeneca Canada Inc. 1004 Middle gate Road Mississauga, Ontario, (USFDA Approved)
	Me-too Status	Engzol Tablet 2.5mg by M/s English pharma. Reg. No. 40153
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel

		recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved.	
389.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Zolid 5mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41612 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Zolmitriptan…5mg
	Pharmacological Group	selective serotonin receptor agonists/Anti-migrain preparation
	Type of Form	Form 5
	Finished Product Specification	USP SPECS.
	Pack Size & Demanded Price	1×3's, price As Per SRO.
	Approval Status of Product in Reference Regulatory Authorities	Zomig tablets (2.5mg, 5mg) by M/s AstraZeneca Canada Inc. 1004 Middle gate Road Mississauga, Ontario, (USFDA Approved)
	Me-too Status	Engzol Tablet 5mg by M/s ENGLISH PHARMA. Reg. No. 41416
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved,	
390.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Diazox for oral suspension (100mg/5ml)
	Diary No. Date of R& I & fee	Dy. No. 41624 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each 5ml reconstituted Suspension Contains: Nitazoxanide…100mg
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alini for Oral Suspension (100mg/5ml reconstituted) by M/s Romark, USFDA Approved.
	Me-too Status	Nitranex 100mg/5ml Suspension by M/s Nexus Pharma Karachi, Reg. No. 81596
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
391.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Diazox 500mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41623 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Nitazoxanide……500mg
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Mfg
	Pack Size & Demanded Price	1×20'sAs per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alinia 500mg film coated tablet by M/s Romark, USFDA Approved.
	Me-too Status	Nizonide 500mg Tablet by M/s AGP PvtLtd.Reg. No. 81101
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel

		recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
392.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Febzo 40mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41638 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Febuxostat…40mg
	Pharmacological Group	Antigout Agent
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	20's, 30's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Urolic (40mg, 80mg) film coated tablet by M/s TAKEDA PHARMS USA, USFDA Approved.
	Me-too Status	Febuxin 40mg tablet by M/s AGP, Karachi (Reg. No. 081104)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
393.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Febzo 80mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41639 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Febuxostat…80mg
	Pharmacological Group	Antigout Agent
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	20's, 30's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Urolic (40mg, 80mg) film coated tablet by M/s TAKEDA PHARMS USA, USFDA Approved.
	Me-too Status	Febuxin 80mg tablet by M/s AGP, Karachi (Reg. No. 081105)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
394.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Camron 4mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41626 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Lornoxicam…….4mg
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved)
	Me-too Status	Acabel 4mg Tablet by M/s Continental Pharma (Reg No:061603)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Complete composition was submitted on 08/04/2020 Dy.No. 6317.
	Decision: Approved with innovator's specifications.	

395.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Camron 8mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41627 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Lornoxicam……..8mg
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too Status	Recam Tablet 8 mg by M/s Regal Pharmaceuticals (Reg.#081952)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
396.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Alfa 0.5mcg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41619 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Tablet Contains: Alfacalcidol……0.5mcg
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	10's, 2×10's, 3×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	one alpha tablet 0.5µg by Teijin Pharma Corporation PMDA Japan approved
	Me-too Status	Alfasta Tablet 0.5mcg by M/s Star Labs, Reg. No. 81397
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The firm has revised the formulation FROM Film Coated to Uncoated tablet as per the reference product without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation as per the reference product.	
397.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Alfa 0.25mcg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41618 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Tablet Contains: Alfacalcidol……0.25mcg
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	1×10's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alfacalcidol tablet 0.25mcg PMDA Japan approved
	Me-too Status	Alfasta Tablet 0.25mcg by M/s Star Labs, Reg. No. 81398
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Firm has revised the formulation FROM Film Coated to Uncoated tablet as per the reference product without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation as per the reference product.	

398.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Alfa 1mcg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41620 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Tablet Contains: Alfacalcidol……1mcg
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished Product Specification	Mfg Specs
	Pack Size & Demanded Price	1×10's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Alfacalcidol tablet 1mcg PMDA Japan approved
	Me-too Status	Alfasta Tablet 1mcg by M/s Star Labs, Reg. No. 81399
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The firm has revised the formulation FROM Film Coated to Uncoated tablet as per the reference product without submission of fee.
	Decision: Deferred for submission of applicable fee for revision of formulation as per the reference product.	
399.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Ziprox 60mg Capsule
	Diary No. Date of R& I & fee	Dy. No. 41615 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Ziprasidone as HCl monohydrate…….60mg
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Geodon capsule (20mg, 40mg, 60mg, 80mg) by M/s Pfizer, USFDA Approved.
	Me-too Status	Ziprox 60mg capsule of M/s Nabiqasim Industries (Reg.#055652)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Following alternate brand names wee provided by the firm on 08/04/2020 dy.no.6317; Zipid Zipin Zirox
	Decision: Approved.	
400.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Ziprox 40mg Capsule
	Diary No. Date of R& I & fee	Dy. No. 41616 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Ziprasidone as HCl monohydrate…….40mg
	Pharmacological Group	Anti-psychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Geodon capsule (20mg, 40mg, 60mg, 80mg) by M/s Pfizer, USFDA Approved.
	Me-too Status	Ziprox 40mg capsule of M/s Nabiqasim Industries (Reg.#055651)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.

	Remarks of the Evaluator.	Following alternate brand names wee provided by the firm on 08/04/2020 dy.no.6317; Zipid Zipin Zirox
	Decision: Approved.	
401.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Neogaba 300mg capsule
	Diary No. Date of R& I & fee	Dy. No. 41646 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Pregabalin…300mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×14's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LYRICA (pregabalin) Capsules 300mg by M/s PF Prism (USFDA Approved)
	Me-too Status	Zeegap 300mg Capsules by M/s Hilton (Reg#047364)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Correct composition submitted on 08/04/2020 dy.no. 6317.
	Decision: Approved with innovator's specifications.	
402.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Neogaba 150mg capsule
	Diary No. Date of R& I & fee	Dy. No. 41645 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Pregabalin…150mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×14's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LYRICA (pregabalin) Capsules 150mg by M/s PF Prism (USFDA Approved)
	Me-too Status	Zeegap 150mg Capsules by M/s Hilton (Reg#047361)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Correct composition submitted on 08/04/2020 dy.no. 6317.
	Decision: Approved with innovator's specifications.	
403.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Neogaba 100mg capsule
	Diary No. Date of R& I & fee	Dy. No. 41644 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Pregabalin…100mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×14's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LYRICA (pregabalin) Capsules 100mg by M/s PF Prism (USFDA Approved)
	Me-too Status	Zeegap 100mg Capsules by M/s Hilton (Reg#047360)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Correct composition submitted on 08/04/2020 dy.no. 6317.

	Decision: Approved with innovator's specifications.	
404.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Neogaba 75mg capsule
	Diary No. Date of R& I & fee	Dy. No. 41643 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Pregabalin…75mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×14's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LYRICA (pregabalin) Capsules 75mg by M/s PF Prism CV (USFDA Approved)
	Me-too Status	Zeegap 75mg Capsules by M/s Hilton Pharma (Reg#047359)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Correct composition submitted on 08/04/2020 dy.no. 6317.
	Decision: Approved with innovator's specifications.	
405.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Neogaba 50mg capsule
	Diary No. Date of R& I & fee	Dy. No. 41642 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Pregabalin…50mg
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×14's, price As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LYRICA (pregabalin) Capsules 50mg by M/s PF Prism CV (USFDA Approved)
	Me-too Status	Zeegap 50mg Capsules by M/s Hilton Pharma (Reg#047358)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Correct composition submitted on 08/04/2020 dy.no. 6317.
	Decision: Approved with innovator's specifications.	
406.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Lopera 2mg Capsule
	Diary No. Date of R& I & fee	Dy. No. 41622 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Capsule Contains: Loperamide Hydrochloride…2mg
	Pharmacological Group	*Antidiarrheals*
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	6×10, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Loperamide Capsules 2 mg by M/s Galpharm Healthcare Limited, MHRA Approved.
	Me-too Status	LOPAMIDE 2mg CA by M/s Medicaids, Reg. No. 11240
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved.	
407.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Akzocin 400mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41630 dated 07/12/2018 Fee Rs. 20,000/-

	Composition	Each film Coated Tablet contains: Telithromycin……400mg
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	1×10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ketek 400mg film coated tablet by M/s Avents Pharma, ANSM France approved.
	Me-too Status	Telrom 400mg Tablets of M/s Genome pharma. (Reg.# 056089)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
408.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Dulosin 0.5 Capsules 0.4mg/0.5mg
	Diary No. Date of R& I & fee	Dy. No. 41633 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Hard capsule contains: Tamsulosin HCl SR pellets……...0.4mg Dustasteride (soft gel capsule)…….0.5mg
	Pharmacological Group	Drugs Used In Benign Prostatic Hyperplasia
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	30's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Combodart 0.5 mg / 0.4 mg hard capsules of M/s GSK, (approved by MHRA of UK)
	Me-too Status	DUODART of M/s GSK, Karachi
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The product approved in reference country contains Tamsulosin HCl SR pellets and Soft gel capsule of Dutasteride filled in hard gelatin capsule shell. Provide the following information regarding manufacturing of the product. **1.** Provide source of Tamsulosin Pellets, GMP certificate of pellet manufacturer, Certificate of analysis, stability study data of 3 batches accoroding to the climatic conditions of zone IV-A and in case of imported pellets submit differential fee as well. **2.** Provide source of Dutasteride soft gel capsule. In case of In-house manufacturing of Dutasteride soft gel capsule, provide approval of relevant section/manufacturing facility that is soft gel capsule.section. In case of imported dutasteride soft gel capsule provide the following along with the submission of differential fee; • GMP certificate of manufacturer of Dutasteride soft gel capsule. • Certificate of analysis. • Attested copy of valid Drug Sale License. • Attested copy of Valid Sole agency agreement /Authority letter • Original Embassy attested COPP • Original Embassy attested GMP certificate of manufacturer • Accelerated stability study data & Long term Stability studies according to Zone IV-A **3.** Complete method of manufactur of tamsulosin and

		dutasteride soft gel capsule into final dosage form. **4.** Manufacturing facility and equipment for manufacturing. **5.** Evidence of capsule in capsule filling machine.
	Decision: Deferred for confirmation of manufacturing facility	
409.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Zofen 0.5mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 41621 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Pizotifen as hydrogen maleate……. 0.5mg
	Pharmacological Group	Serotonergic antagonist/Antihistamine
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Pizotifen 0.5 mg Film Coated Tablets by M/s Edmond Pharma Srl, MHRA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved.	
410.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Sulosin 0.2mg capsule
	Diary No. Date of R& I & fee	Dy. No. 41634 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each capsule contains: Tamsulosin HCl (pellets SR 0.2%)……..0.2mg Pellets **Soruce:** M/s Vision Pharma.
	Pharmacological Group	Alph adrenergic antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 30's, 50's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Harnal 0.2mg Capsules by M/s Hilton Pharma, Reg No. 45084
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The firm has revised the formulation from Enteric Coated pellets to Sustained Released pellets as per the reference product with submission of fee Rs. 5000/- vide challan number 1983152 dated 30/03/2020.
	Decision: Deferred for submission of remaing fee	
411.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Diflocaine 75mg/20mg Injection
	Diary No. Date of R& I & fee	Dy. No. 41625 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each ampule of 2ml contains: Diclofenac Sodium……...75mg Lignocaine hydrochloride.....20mg
	Pharmacological Group	NSAID/Local anaesthetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	5×2ml, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diclofenac-Mepha Ampullen by M/s Mepha Pharma AG, Basel, (Swissmedic approved)

	Me-too Status	Dyclo Plus 2ml Injection by M/s Indus Pharma (Reg#076107)
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The firm has submitted revised composition containing Lignocaine HCl….20mg instead of Lignocaine….20mg as per the reference product and submitted Rs, 5000/- vide challan number 1983153 dated 30/03/2020.
	Decision: Approved as IM formulation.	
412.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Akocit Tablets 5mEq
	Diary No. Date of R& I & fee	Dy. No. 41635 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Potassium Citrate…….5mEq
	Pharmacological Group	Potassium salt
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×30's, 100's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Urocit-K (5mEq, 10mEq, 15mEq) Extended release tablet (wax matric tablet) by M/s Mission Pharma, USFDA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The product approved in reference country is extended release while the applied product is film coated, clarification or otherwise revised submission of formulation along with the submission of requisite fee is required. Me too status could not be confirmed.
	Decision: Deferred for following: • **Submission of evidence of approval of applied formulation as "film coated tablet" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** • **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
413.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Akocit Tablets 10mEq
	Diary No. Date of R& I & fee	Dy. No. 41636 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Potassium Citrate…….10mEq
	Pharmacological Group	Potassium salt
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×30's, 100's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Urocit-K (5mEq, 10mEq, 15mEq) Extended release tablet (wax matric tablet) by M/s Mission Pharma, USFDA Approved.
	Me-too Status	Uro-K 10mEq extended release Tablets by M/s Genome Pharma, Reg. No. 80530
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The product approved in reference country is extended release while the applied product is film coated, clarification or otherwise revised submission of formulation along with the submission of requisite fee is required.
	Decision: Deferred for submission of evidence of approval of applied formulation as "film coated	

	tablet" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.	
414.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Akocit Tablets 15mEq
	Diary No. Date of R& I & fee	Dy. No. 41637 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Potassium Citrate…….15mEq
	Pharmacological Group	Potassium salt
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×30's, 100's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Urocit-K (5mEq, 10mEq, 15mEq) Extended release tablet (wax matric tablet) by M/s Mission Pharma, USFDA Approved.
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The product approved in reference country is extended release while the applied product is film coated, clarification or otherwise revised submission of formulation along with the submission of requisite fee is required. Me too status could not be verified.
	Decision: Deferred for following: • **Submission of evidence of approval of applied formulation as "film coated tablet" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** • **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
415.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Arthobid 250mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41613 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet contains: Diflunisal……250mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diflunisal (250mg, 500mg) Film-coated Tablets by M/s Chemidex Pharma Limited, MHRA Approved.
	Me-too Status	Dolobis-250 Tablets by M/s Genome Pharma, Reg. No. 64015
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved.	
416.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Arthobid 500mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41614 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet contains: Diflunisal……500mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack Size & Demanded Price	2×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diflunisal (250mg, 500mg) Film-coated Tablets by M/s Chemidex Pharma Limited, MHRA Approved.
	Me-too Status	Dolobis-500 Tablets by M/s Genome Pharma, Reg. No. 64016
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	
	Decision: Approved.	
417.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Rabazole-10 tablets
	Diary No. Date of R& I & fee	Dy. No. 41628 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coatedS Tablet contains: Rabeprazole Sodium…….10mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Nfg specs
	Pack Size & Demanded Price	1×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Rabeprazole (10mg, 20mg) Gastro-resistant Tablets by M/s Accord Uk, MHRA Approved.
	Me-too Status	Raprazole Tablet, 10mg enteric coated by M/s Genix, Reg. No. 83279
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The firm has revised the formulation from film coated to Enteric Coated/Gastro resistant tablet as per the reference product without submission of fee.
	Decision: Deferred fro submission of applicable fee for revision of formulation as per the reference product.	
418.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Rabazole-20 tablets
	Diary No. Date of R& I & fee	Dy. No. 41629 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coated Tablet contains: Rabeprazole Sodium…….20mg
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Nfg specs
	Pack Size & Demanded Price	1×10's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Rabeprazole (10mg, 20mg) Gastro-resistant Tablets by M/s Accord Uk, MHRA Approved.
	Me-too Status	Ranzot 20mg gastro resistant Tablet by M/s Hygeia Pharmaceuticals, Reg. No. 81197
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	The firm has revised the formulation from film coated to Enteric Coated/Gastro resistant tablet as per the reference product without submission of fee.
	Decision: Deferred fro submission of applicable fee for revision of formulation as per the reference product.	
419.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Dapaglin-5 Tablet
	Diary No. Date of R& I & fee	Dy. No. 41641 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Dapagliflocin as propanediol monhydrate…….5mg

	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Farxiga Tablets by M/s Astrazaneca USFDA Approved.
	Me-too Status	Xiga 5mg tablet by CCL
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	Stability required
	Decision: Deferred for submission of application on Form 5D along with the submission of stability studies of 3 batches according to the conditions of zone IV-A as per directions given in 278th meeting of Registration Board	
420.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Private limited, Plot # 9-B/1&2, old Industrial Estate, Sector D1,Mirpur, Azad Kashmir.
	Brand Name +Dosage Form + Strength	Canaglin-100 tablet
	Diary No. Date of R& I & fee	Dy. No. 41640 dated 07/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet contains: Canagliflozin as Hemihydarte…..100mg
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	7's, 14's, 28's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Invokana tablet-USFDA approved
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 16/06/2017 and 25/07/2017, the panel recommended the renewal of license by the way of formulation.
	Remarks of the Evaluator.	As the product is not registered yet in Pakistan, therefore the application for the applied product shouldhave been submitted on form 5D. Submit the application on form 5D with the submission of differential fee of Rs. 30,000/- along with the stability studay data.
	Decision: Deferred for submission of application on Form 5D along with the submission of stability studies of 3 batches according to the conditions of zone IV-A as per directions given in 278th meeting of Registration Board and submission differential fee.	
421.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Semstar-N Tablet 20mg
	Diary No. Date of R& I & fee	Dy. No. 40999 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Simvastatin……20mg
	Pharmacological Group	HMG-CoA reductase inhibitor ATC-Code: C10A A01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Zocor® (10mg, 20mg, 40mg, 80mg) film-coated tablets BY Merck Sharp & Dohme Limited, MHRA Approved.
	Me-too Status	SIMPLACOR *20mg* TABLETS by M/s NOVARTIS PHARMA (PAK) LTD, reg. No. 26871
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	

422.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Quity 25mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41009 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated Tablet contains: Quetiapine as fumarate……. 25mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 150mg, 200mg) by M/s Aurobindo pharma, MHRA Approved.
	Me-too Status	Qusel Tablet (25mg, 100mg, 200mg) by M/s Hilton pharma, Reg No. 37684
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
423.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Quity 100mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41010 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated Tablet contains: Quetiapine as fumarate……. 100mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 150mg, 200mg) by M/s Aurobindo pharma, MHRA Approved.
	Me-too Status	Qusel Tablet (25mg, 100mg, 200mg) by M/s Hilton pharma, Reg No. 37685
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
424.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Quity 200mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41011 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated Tablet contains: Quetiapine as fumarate……. 200mg
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP Specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 150mg, 200mg) by M/s Aurobindo pharma, MHRA Approved.
	Me-too Status	Qusel Tablet (25mg, 100mg, 200mg) by M/s Hilton pharma, Reg No. 37690
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	

425.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dexin-B tablet 200mg
	Diary No. Date of R& I & fee	Dy. No. 41015 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Dexibuprofen…… 200mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Dexibuprofen (200mg, 300mg, 400mg) film coated tablet by M/s Strides Pharma UK ltd, MHRA Approved.
	Me-too Status	Tercica-200mg Tablet of M/s Sami Pharma Reg. No. 73697
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
426.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dexin-B tablet 300mg
	Diary No. Date of R& I & fee	Dy. No. 41014 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Dexibuprofen…… 300mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Dexibuprofen (200mg, 300mg, 400mg) film coated tablet by M/s Strides Pharma UK ltd, MHRA Approved.
	Me-too Status	Tercica-300mg Tablet of M/s Sami Pharma Reg. No. 58445
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
427.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Dexin-B tablet 400mg
	Diary No. Date of R& I & fee	Dy. No. 41013 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Dexibuprofen…… 400mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Dexibuprofen (200mg, 300mg, 400mg) film coated tablet by M/s Strides Pharma UK ltd, MHRA Approved.
	Me-too Status	Tercica-400mg Tablet of M/s Sami Pharma Reg. No. 58446
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
428.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Binaf 125mg tablet
	Diary No. Date of R& I & fee	Dy. No. 40988 dated 06/12/2018 Fee Rs. 20,000/-

	Composition	Each Tablet Contains: Terbinafine as HCL…125mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Terbinafine 125mg Tablets by M/s Dr. Reddy's Laboratories, MHRA Approved.
	Me-too Status	Logirid Tablet 125mg by M/s Lowitt Pharmaceutical, Reg No.80846
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
429.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Lumet 40mg/240mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41028 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Tablet Contains: Artemether……40mg Lumefantrine…240mg
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too Status	Gen-M Tablets (40/240) by M/s Genix, Reg. No. 42423
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGM P as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
430.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Lumet 80mg/480mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41026 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Tablet Contains: Artemether……80mg Lumefantrine…480mg
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too Status	R-Terine Forte (80/480/) Tab. of M/s Ardin Pharma, R.No.066814
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
431.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tino 20mg tablet
	Diary No. Date of R& I & fee	Dy. No. 40990 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated Tablet Contains: Paroxetine as HCl……..20mg

	Pharmacological Group	Anti-depressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Paxil (10mg, 0mg, 30mg, 40mg, 50mg=Eq base) film coated tablet by Apotex tech, USFDA Approved.
	Me-too Status	Neoxetine Tablets 20mg of M/s Neomedix (Reg. # 081407)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
432.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sofet 500mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41001 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Uncoated Tablet Contains: Sucralfate……500mg
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Sucralif Tablets by M/s Alliance Pharmaceuticals (Pvt) Ltd, (Reg#054695)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
433.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sofet 1g tablet
	Diary No. Date of R& I & fee	Dy. No. 41002 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Uncoated Tablet Contains: Sucralfate……1g
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Antepsin 1g uncoated Tablets by M/s Chugai Pharma UK Limited, MHRA Approved.
	Me-too Status	Sucralif Tablets by M/s Alliance Pharmaceuticals (Pvt) Ltd, (Reg#054696)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
434.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals,Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Melopem 10mg Tablet

	Diary No. Date of R& I & fee	Dy. No. 40192 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Tablet Contains: Amlodipine as Besylate …5mg
	Pharmacological Group	Selective calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	NORVASC® (amlodipine as besylate) (2.5mg, 5mg, 10mg) Tablets for oral administration. USFDA approved
	Me-too Status	NORVASC 5MG TAB by M/s Pfizer, Reg. No. 11825
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
435.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	M-Relief Tablet 100mg
	Diary No. Date of R& I & fee	Dy. No. 40993 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Aceclofenac……100mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Aceclofenac 100 mg film-coated Tablets by M/s Accord Healthcare, MHRA Approved.
	Me-too Status	Gratis Tablets 100mg BP by M/s Navegal, Reg. No. 43900
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
436.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Trisodil 37.5mg/325mg tablet
	Diary No. Date of R& I & fee	Dy. No. 40991 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Tramadol HCL……37.5mg Paracetamol……375mg
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Ultracet film coated tablet by M/s Janssen Pharms, USFDA Approved
	Me-too Status	Tramal Plus tablet by M/s Searle Company limited, Reg No.77129
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
437.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metfo 500mg/2.5mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 40985 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Metformin Hydrochloride…500mg Glibenclamide……...2.5mg

	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GLUCOVANCE 500 mg / 2.5 mg film-coated tablets by M/s MERCK SANTE S.A.S (ANSM Approved)
	Me-too Status	Glucovance 500 mg / 2.5 mg Tablets by M/s Merck (Reg#030009)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
438.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metfo 500mg/5mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 40995 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Metformin Hydrochloride…500mg Glibenclamide……...5mg
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GLUCOVANCE 500mg/5mg film-coated tablets by M/s MERCK SANTE S.A.S (ANSM Approved)
	Me-too Status	Glucovance 500mg/5mg Tablets by M/s Merck (Reg#030008)
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
439.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals,Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metfo 1000mg/5mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 40996 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Metformin Hydrochloride…1000mg Glibenclamide……...5mg
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	GLUCOVANCE 1000mg/5mg film-coated tablets by M/s MERCK SANTE S.A.S (ANSM Approved)
	Me-too Status	Could not be confirmed
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
440.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals,Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Daiko-P 75mg Tablet
	Diary No. Date of R& I & fee	Dy. No. 40994 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each enteric coated tablet contains: Diclofenac Postassium…..75 mg
	Pharmacological Group	NSAID

	Type of Form	Form 5
	Finished Product Specification	MFg spcs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Dicomak 75mg Tablets by M/s Makson Pharma, Reg. No. 37975
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
441.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals,Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Metlipsy 800mg tablet
	Diary No. Date of R& I & fee	Dy. No. 41000 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Piracetam…800mg
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Piracetam 800mg film-coated tablet by M/s USB Pharma, MHRA approved
	Me-too Status	Nootropil Tablet 800mg by M/s GSK Reg. No. 82277
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
442.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mebgel tablet 135mg
	Diary No. Date of R& I & fee	Dy. No. 41011 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Mebeverine hydrochloride……135mg
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Mebeverine 135 mg film-coated tablets by M/s Generics, MHRA Approved (tablets are approved as sugar coated as well as film coated)
	Me-too Status	Spasmorin 135mg Tablets by M/s Legacy Pharmaceuticals (Pvt) Ltd, Reg. No. 53622
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
443.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Lostin tablet 50mg
	Diary No. Date of R& I & fee	Dy. No. 41028 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…50mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar (12.5mg, 25mg, 50mg, 100mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Acozar 50mg Tablet by M/s AGP, Reg. No. 82245
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
444.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Lostin tablet 100mg
	Diary No. Date of R& I & fee	Dy. No. 41027 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…100mg
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cozaar (12.5mg, 25mg, 50mg, 100mg) film coated tablet by M/s MSD, MHRA Approved.
	Me-too Status	Acozar 100mg Tablet by M/s AGP, Reg. No. 82246
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
445.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Keto tablet 10mg
	Diary No. Date of R& I & fee	Dy. No. 41029 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each film coated tablet contains: Ketorolac Tromethamine…….10mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	KETOROLAC TROMETHAMINE 10mg film coated tablet by M/s Teva, USFDA Approved.
	Me-too Status	Could no tbe confirmed
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of generic status.	
446.	Name and address of manufacturer / Applicant	M/s Metro Pharmaceuticals, Plot # 14, street No. SS-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Melgesic Tablet 35mg/450mg
	Diary No. Date of R& I & fee	Dy. No. 41031 dated 06/12/2018 Fee Rs. 20,000/-
	Composition	Each tablet contains: Orphenadrine citrate……. 35mg Paracetamol…….. 450mg
	Pharmacological Group	Skeletal muscle relaxant/Antipyretic&Analgesic
	Type of Form	Form 5
	Finished Product Specification	Mfg specs
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in	Norgesic tablets (uncoated) M/s iNova Pharmaceuticals Australia

	Reference Regulatory Authorities	Pvt. Ltd. approved by TGA of Australia
	Me-too Status	Nuberol Tablet by M/s Searle Pakistan Ltd,, Reg. No. 20373
	GMP Status	Last inspection report dated 22/05/2018, the firm is operating with cGMP as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

Case No 02: Import cases Human (Deferred)

447.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3555 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 50mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 50mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	USFDA Approved
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150006) issued by Shanxi Food and Drug Administration valid till 31/08/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same	

	strength/volume/dosage form. d. Original, legalized and valid CoPP Evaluation by PEC: a. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (1845027 Mfg date:June5, 1845028 Mfg date: June 6, 2017, 1845029 Mfg date:June 07 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. b. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. c. The product approved in USFDA with same strength and dosage form that is 50mg Powder For injection is discontinued and reason for discontinuation is mentioned on the official website of the authority while 50mg/2ml solution for injection is approved in USFDA. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. d. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.	
448.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3556 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 100mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 100mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	USFDA Approved
	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150006) issued by Shanxi Food and Drug Administration valid till 03/11/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the

		letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Evaluation by PEC: a. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (19456620 Mfg date:July 09, 19456621 Mfg date: July 10, 2017, 19456622 Mfg date: July 11, 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. b. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. c. The product approved in USFDA with same strength and dosage form that is 100mg For injection is discontinued and reason for discontinuation is mentioned on the official website of the authority while 100mg/4l solution for injection is available in USFDA. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. d. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.	
449.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Econmic & Development Zone of Datong, Shanxi, China (as per CoPP and sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (As per sole agency agreement)
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3558 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	METHOTREXATE for IV injection 500mg/vial Freeze dried cake for solution for injection (Lyophilized Powder)
	Composition	Each vial contains: Methotrexate…. 500mg
	Finished Product Specification	USP
	Pharmacological Group	L04AX Other immunosuppressants
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	

	Me-too status	Methogen by Gene Tech Laboratories
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. (20150011) issued by Shanxi Food and Drug Administration valid till 03/11/***2017*** *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	Reason for Discontinuation cannot be confirmed. The formulation in other reference countries is registered as solution for injection. Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Evaluation by PEC: a. The firm has submitted Real Time Stability data (24 months) and Accelarated stability data (6months) of 3 batches (2010100 Mfg date: Aug 15, 2010101 Mfg date: Aug16, 2017, 2010102 Mfg date: Aug 18, 2017). However, the firm has not submitted any reply/clarification regarding previously submitted stability data of the same product. b. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. c. The product (500mg for injection) with same strength and dosage form is not available in reference authorities while 500mg/20ml solution for injection is discontinued for reasons other than safet and efficacy. However, another higher strength is approved in USFDA, Methotrexate For Injection by M/s Fresenius Kabi USA (Each vial contains Methotrexate as sodium.....1000mg with no preservative). Moreover, USP monograph for Methotrexate For Injection is also available. d. Original legalized CoPP (certificate No. (2018002) issued by Shanxi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer.	
	Decision: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.	
450.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 356 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	IRINOTECAN injection 40mg

	Composition	Each ampoule (2ml) contains: Irinotecan…… 40mg
	Finished Product Specification	In-house (USP)
	Pharmacological Group	Antineoplastic
	Shelf life	3 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	Each vial with 2 ml contains 40 mg Irinotecan hydrochloride trihydrate (UK)
	Me-too status	Irinotecan Ebewe by Novartis Pharma Pakistan (Reg #066186)
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 151100B0/62246) issued by Jining Food and Drug Administration valid till 14/12/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	• The firm has claimed In House manufacturing specifications and the product is present in USP. • The product is not available in reference countries as Powder for Solution but it is available as Solution for injection. • Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Now the firm has submitted: a. In response to decision of Registration Board the firm has submitted (dated 15th August 2017, and after that on dated 13th December 2019 of three batches is submitted. Different years but same batch no., assay and other parameters as well. b. Reference formulation is Each vial with 2 ml contains 40 mg Irinotecan hydrochloride trihydrate (UK) while applied is Each ampoule (2ml) contains: Irinotecan…… 40mg CoPP valid till 14-12-2017 Copy of valid DSL Composition different from reference?	
	Evaluation by PEC: a) The composition of the product as presented in 274th meeting is not correct, the correct composition of the product is given in the following confirmed from the original dossier. Each 2ml Ampoule contains: Irinotecan hydrochloride trihydrate……20mg (equivalent to Irinotecan……17.33mg) b) Approval status of the product in reference regulatory authorities is confirmed. CAMPTO 20 mg/ml concentrate for solution for infusion (2ml Vial, 5ml Vial, 15ml Vila) by M/s Pfizer limited, MHRA Approved. c) The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (19277800 Mfg date: Oct 20, 2017, 19277801 Mfg date: Oct 21, 2017, 19277802 Mfg Date: Oct 22, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. d) COPP is not valid and was expired on 14/12/2017.	
	Decision: Registration Board deferred the case and decided that Secretary Registration Board will	

	confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.	
451.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R.China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 356 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	IRINOTECAN injection 100mg
	Composition	Each ampoule (5ml) contains: Irinotecan…… 100mg
	Finished Product Specification	In-house (USP)
	Pharmacological Group	Antineoplastic
	Shelf life	3 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	Each vial with 5 ml contains 100 mg Irinotecan hydrochloride trihydrate (UK)
	Me-too status	Irinotecan Ebewe by Novartis Pharma Pakistan (Reg #066187)
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 151100B0/47074) issued by Jining Food and Drug Administration valid till 16/09/2017 **declaring the free sale of applied product and GMP compliant status of the manufacturer.**
	Remarks of the Evaluator.	• The firm has claimed In House manufacturing specifications and the product is present in USP. • The product is not available in reference countries as Powder for Solution but it is available as Solution for injection. • Firm has initially submitted real-time stability data conducted at 25 ± 2oc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2oc and 65 ± 5%RH with same results at each time point
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: d. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true e. Detail of diluent to be used for reconstitution. f. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. Now the firm has submitted: c. In response to decision of Registration Board the firm has submitted data dated 13th December 2019 of three batches is submitted. Different years but same batch no., assay and other parameters as well.	

	d. Reference formulation is Each vial with 5 ml contains 100 mg Irinotecan hydrochloride trihydrate (UK) while applied is Each ampoule (5ml) contains: Irinotecan…… 100mg CoPP valid till 16-09-2017	
	Evaluation by PEC: e) The composition of the product as presented in 274th meeting is not correct, the correct composition of the product is given in the following confirmed from the original dossier. Each 2ml Ampoule contains: Irinotecan hydrochloride trihydrate……20mg (equivalent to Irinotecan……17.33mg) f) Approval status of the product in reference regulatory authorities is confirmed. CAMPTO 20 mg/ml concentrate for solution for infusion (2ml Vial, 5ml Vial, 15ml Vila) by M/s Pfizer limited, MHRA Approved. g) The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (1977803 Mfg date: Oct 23, 2017, 19277804 Mfg date: Oct 24, 2017, 19277805 Mfg Date: Oct 25, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. h) COPP is not valid and was expired on 16/09/2017.	
	Decision: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.	
452.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical zone , Economic & Technological and Developlment Zone, Datong, Shanxi
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 395 Dated 16-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 15-03-2017
	Brand Name +Dosage Form + Strength	VINORELBINE Injection 10mg **Lyophilized powder for injection**
	Composition	Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 10mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 20150010) issued by Shan Xi Food and Drug Administration valid till 31/08/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*
	Remarks of the Evaluator.	• The firm has applied the registration application with generic name. • The firm has claimed USP specifications and the product is not present in USP/BP. • The product in reference countries is registered as solution for injection while the applied formulation is in the form of lyophilized powder for injection. Moreover, the Vinorelbine tartrate Equivalent to 10mg/ml base is registered in reference countries while the applied product is Vinorelbine bitartrate 10mg/vial.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for:	

	a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. d. The salt form of the drug as it is different from the approved product in reference countries. e. Finished product specifications. Evaluation by PEC: a. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. b. Reference formulation is NAVELBINE® 10 mg/ml concentrate for solution for infusion (UK) while applied is VINORELBINE Injection 10mg Lyophilized powder for injection. c. Legalized CoPP (certificate No. 2018006) issued by Shan Xi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer and showing Correct salt form is submitted. d. Firm submitted CFDA standard specification. e. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (21000401 Mfg date: Sep 15, 2017, 21000402 Mfg date: Sep 16, 2017, 21000403 Mfg Date: Sep 17, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. f. Salt form	
	Decision: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.	
453.	Name and address of Applicant	M/s Mehran International, Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of Drug Sale License	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 01/08/2021
	Manufacturer & Product License Holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical zone , Economic & Technological and Developlment Zone, Datong, Shanxi
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3560 Dated 06-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 03-03-2017
	Brand Name +Dosage Form + Strength	VINORELBINE Injection 50mg **Lyophilized powder for injection**
	Composition	Each vial contains: Vinorelbine Tartrate Eq. to Vinorelbine….. 50mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 Years
	Demanded Price	As per SRO
	Pack size	1's
	International Availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Original legalized CoPP (certificate No. 20150010) issued by Shan Xi Food and Drug Administration valid till 03/11/2017 *declaring the free sale of applied product and GMP compliant status of the manufacturer.*

	Remarks of the Evaluator.	• The firm has applied the registration application with generic name. • The firm has claimed USP specifications and the product is not present in USP/BP. • The product in reference countries is registered as solution for injection while the applied formulation is in the form of lyophilized powder for injection. Moreover, the Vinorelbine tartrate Equivalent to 50mg/5ml base is registered in reference countries while the applied product is Vinorelbine bitartrate 50mg/vial.
	Decision of 274th meeting of Registration Board: Registration Board deferred the cases for: a. Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2oc and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2oc and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2oc and 65 ± 5%RH) is not true b. Detail of diluent to be used for reconstitution. c. Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form. d. The salt form of the drug as it is different from the approved product in reference countries. e. Finished product specifications. f. Sole agency agreement Evaluation by PEC: a. Detail of diluent used for reconstitutions are 5% dextrose or 0.9% NaCL. b. Reference formulation is NAVELBINE® 10 mg/ml concentrate for solution for infusion (UK) while applied is VINORELBINE Injection 10mg Lyophilized powder for injection. c. Legalized CoPP (certificate No. 2018006) issued by Shan Xi Food and Drug Administration valid till 26/02/2020 declaring the free sale of applied product and GMP compliant status of the manufacturer and showing Correct salt form is submitted. d. Firm submitted CFDA standard specification. e. The firm has submitted 24 months Real time stability and 06 months Accelerated stability data of 3 batches (21000404 Mfg date: Sep 18, 2017, 21000405 Mfg date: Sep 19, 2017, 21000406 Mfg Date: Sep 19, 2017). However the firm has not submitted the reply/clarification regarding previously submitted stability data. f. Salt form	
	Decision: Registration Board deferred the case and decided that Secretary Registration Board will confirm from manufacturer M/s Shanxi PUDE Pharmaceutical Co., Ltd (Marketing Authorization Holder) via e-mail regarding authenticity of the latest submitted stability data.	

Case No. 03 : Human Import on Form 5F

454. **FORM 5-F ASSESMENT REPORT**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 23130 Dated 08-11-2019 PKR: 100,000/- dated 07-11-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Getz Pharma (Pvt.) Limited Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi
	1.3.2	Name, address and contact details of Manufacturing site. Manufacturing & Product License Holder: M/s Shanghai Hengrui Pharmaceutical Co., Ltd. No. 279, Wenjing Road, Minhang Development Zone, Shanghai, P.R China
	1.3.3	Specify whether the Applicant is: Importer
	1.3.4	Drug Sale License Drug License by way of Wholesale No. 00774 valid upto 16-Aug-2020
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: Domestic sale
	1.4.2	For imported products, please specify one of following: Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Sevoflurane for Inhalation
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit **Sevoflurane 250ml**
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. **SEVOF (Sevoflurane) Liquid for Inhalation 250ml**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's (250ml) & MRP: Rs. 17,000/-
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) General anesthetic
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Inhalation
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price Sevorance Volatile Liquid For Inhalation of M/s ABBOTT LABS
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Sevoflurane 100% Inhalation Vapour, liquid (UK)
	1.5.10	Dosage form of applied drug Inhalation anesthetic 250ml
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens

		Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. M/s Jiangsu Hengrui Medicine Co., Ltd. No. 22, Jinqiao Road, Dapu Industrial Zone Lianyungang, Jiangsu Province, P.R. China
	• Original Legalized CoPP (Certificate#. 20190197) dated 27-08-2019 issued by Shanghai Municipal Medical Products Administration 728 Yishan Road, Shanghai, China declaring the free sale of applied product and GMP compliant status of the manufacturer. This certificate valid until: 26-08-2021. • Copy of Product specific Authorization letter from product License holder is submitted.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.5	Process Validation and/or Evaluation Not submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted

	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable

	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 36 months at 30 ± 2^0C, 75±5%RH and 6 months at 40^0C±75%RH for three batches.

i. Original Product Specific Sole Agency agreement submitted.
ii. Firm claim that Drug product contains only sevoflurane therefore USP specification monograph of drug substance is applicable.
iii. The firm has requested for exemption from inspection and stated that the product is manufactured by M/s Shanghai Hengrui Pharmaceutical Co. Ltd. 279 wenjing road minhang district Shaghai 200245 has also been approved by USFDA and the product is also approved by USFDA. The firm has provided original CoPP indicating that the manufacturer of the product was complying to FDA cGMP at the time of inspection.

Decision: Approved as per Policy for inspection of Manufacturer abroad.

455. **M/s Atco Pharma International Pvt. Ltd. B-18, S.I.T.E, Karachi (FORM 5-F)**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 13556 Dated 30-07-2019 (Rs. 100,000/- Dated 24-07-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Atco Pharma International Pvt. Ltd. B-18, S.I.T.E, Karachi
	1.3.2	Name, address and contact details of Manufacturing site. Manufacturer & Product License Holder: M/s Fresenius Kabi Oncology Limited, Village Kishanpura, P.O Guru Majra, Tehsil: Nalagarh. Solan Himachal Pradesh, In-174 101, India
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	**Drug Sale License** Drug License by way of WholeSale no. 10573 valid till 23-Jan-2020 apply for renewal receipt dated 16-01-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product Oxitan 50mg/10ml Injection
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Oxaliplatin Injection USP
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit **5mg/ml (50mg/10ml)**
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. **Oxitan Injection (50mg/10ml)**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anticancer

	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Injection
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Oxaltie 50 Injection of M/s Ferozsons
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. **OXALIPLATIN 50MG/10ML (5MG/ML) (USFDA)**
	1.5.10	Dosage form of applied drug Injection
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. **Submitted**
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. **Submitted**
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. **Submitted**
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. **Submitted**
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. **Submitted**
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance

		department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Approval of manufacturing facility of API by regulatory body of country and validity. M/s Fresenius Kabi Oncology Limited, India
	• **Original Legalized CoPP (Certificate#. HFW-H (Drug) 488/06 Vol-V/19-345)** dated 05-08-2019 by **HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH** declaring the free sale of applied product and GMP compliant status of the manufacturer. Certificate valid upto 28-08-2021.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	**Drug substance (API)** General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Submitted
	3.2.S.2.4	Control of Critical steps and intermediates Submitted
	3.2.S.2.5	Process Validation and/or Evaluation Submitted
	3.2.S.2.6	Manufacturing process development Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable

3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		Container Closure System Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 24 months at 30 ± 2^0C,75%RH and 6 months at 40^0C±75%RH.
Remarks of Evaluator: i. CoPP is issued by HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH. ii. Product specific sole agency agreement is not submitted.		
Decision: Deferred for following: • **Submission of product specific sole agency agreement** • **Clarification regarding the CoPP issuing authority.**		

456. **M/s Atco Pharma International Pvt. Ltd. B-18, S.I.T.E, Karachi (FORM 5-F)**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 13555 Dated 30-07-2019 (Rs. 100,000/- Dated 24-07-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Atco Pharma International Pvt. Ltd. B-18, S.I.T.E, Karachi
	1.3.2	Name, address and contact details of Manufacturing site. Manufacturer & Product License Holder:

		M/s Fresenius Kabi Oncology Limited, Village Kishanpura, P.O Guru Majra, Tehsil: Nalagarh. Solan Himachal Pradesh, In-174 101, India
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	**Drug Sale License** Drug License by way of WholeSale no. 10573 valid till 23-Jan-2020 apply for renewal receipt dated 16-01-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product Oxitan 100mg/20ml Injection
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Oxaliplatin Injection USP
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit 5mg/ml (100mg/20ml)
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. **Oxitan Injection 100mg/20ml**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anticancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Injection
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Oxaltie 100 Injection of M/s Ferozsons
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. **OXALIPLATIN 100MG/20ML (5MG/ML) (USFDA)**
	1.5.10	Dosage form of applied drug Injection
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was

		not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. **Submitted**
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. **Submitted**
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. **Submitted**
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. **Submitted**
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. **Submitted**
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Approval of manufacturing facility of API by regulatory body of country and validity. M/s Fresenius Kabi Oncology Limited, India
	• **Original Legalized CoPP (Certificate#. HFW-H (Drug) 488/06 Vol-V/19-345)** dated 05-08-2019 by **HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH** declaring the free sale of applied product and GMP compliant status of the manufacturer. Certificate valid upto 28-08-2021.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted

2.2 CTD Introduction Submitted

2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	**Drug substance (API)** General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted

	Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Submitted
	3.2.S.2.4	Control of Critical steps and intermediates Submitted
	3.2.S.2.5	Process Validation and/or Evaluation Submitted
	3.2.S.2.6	Manufacturing process development Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers

	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		Container Closure System Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted

	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 24 months at 30±2^{0}C,75%RH and 6 months at 40^{0}C±75%RH.
Remarks of Evaluator: iii. CoPP is issued by HEALTH & FAMILY WELFARE DEPARTMENT BADDI, HIMACHAL PRADESH. iv. Product specific sole agency agreement is not submitted.		
Decision: Deferred for following: • **Submission of product specific sole agency agreement** • **Clarification regarding the CoPP issuing authority.**		

457. **M/s Greerays, suite. No. 1, Street No. 6, Anwar Plaza Islamabad Valley Rawalpindi (FORM 5-F)**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 15008 Dated 20-08-2019 (Rs. 100,000/- Dated 29-07-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Greerays, suite. No. 1, Street No. 6, Anwar Plaza Islamabad Valley Rawalpindi
	1.3.2	Name, address and contact details of Manufacturing site. Marketing Authorization Holder: M/s Pharmada Ilac San. Ve Tic. A.S. Inonu Mahallesi kayisdagi Caddesi No: 172 Dem Plaza 34755 Atasehir- Istanbul/Turkey Manufacturer: M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No:20 Kurtkoy-Pendik/Istanbul/Turkey
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	**Drug Sale License** License to sell drugs as a distributor no. 0011000 0002581 valid upto 10-Sep-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Tirofiban 12.5mg/50ml concentrate for solution for I.V. Infusion
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each 50ml contains: **Tirofiban HCl monohydrate (Equivalent to tirofiban)……14.05 (12.5mg)**
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. **Aggraban Injection**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's & Rs. 20500/vial

	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) antiplatelet drug
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration I.V. Infusion
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Aggrastat Injection of M/s MULLER & PHIPPS
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. AGGRASTAT®*(250 micrograms/ml) concentrate for solution for infusion UK
	1.5.10	Dosage form of applied drug Solution for I.V.Infusion
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. **Submitted**
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. **Submitted**
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. **Submitted**
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. **Submitted**
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals.

		Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. M/s Via Pavia, 1 27027 Gropello Cairoli, (PV) Italy Approval of manufacturing facility of API by regulatory body of country and validity.
	• **Original Legalized CoPP (Certificate#. 2019/1230)** issued on 03-04-2019 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Mefar Ilac Sanayii A.S. Ramazanoglu Mah. Ensar Cad. No:20 Kurtkoy-Pendik/Istanbul/Turkey valid until 03/04/2021. • **Letter of Authorization from Product License Holder (**M/s Pharmada Ilac San. Ve Tic. A.S. Inonu Mahallesi kayisdagi Caddesi No: 172 Dem Plaza 34755 Atasehir- Istanbul/Turkey**) to Importer (**M/s Greerays, suite. No. 1, Street No. 6, Anwar Plaza Islamabad Valley Rawalpindi**) for applied product (**Tirofiban 12.5mg/50ml concentrate for solution for I.V. Infusion**) is submitted.** • GMP inspection dated 21-09-2018 of Manufacturer online verified dated 20-09-2019, link given below http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do		

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	**Drug substance (API)** General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted

2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Not Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.4	Control of Critical steps and intermediates Not Submitted
	3.2.S.2.5	Process Validation and/or Evaluation Not submitted
	3.2.S.2.6	Manufacturing process development not Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY provided	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted

		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 75% RH and 6 months at 40^{0}C±75%RH.
Decision: Approved as per Policy for inspection of Manufacturer abroad.		

458. **FORM 5-F**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No. 530 Dated 13-03-2019 (Rs. 100,000/- Dated 13-03-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Karachi
	1.3.2	Name, address and contact details of Manufacturing site.

		Product License Holder: Sandoz GmbH BiochemiestraBe 10 6250 Kundle Austria Manufacturer: M/s Ebewe Pharma Ges.m.b.H. Nfg. KG Mondseestrasse 11, 4866 Unterach am Attersee, Austria
	1.3.3	Specify whether the Applicant is: Importer will import from Austria.
	1.3.4	Drug Sale License Drug License by way of Wholesale No. 0488 valid upto 26-Nov-2019 apply for renewed receipt dated 29-11-2019
	1.3.8	Manufacturer's Site Master File and Credential (for importer)
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: Domestic and Export sale
	1.4.2	For imported products, please specify one of following: Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Brand (Proprietary) name: Fulvestrant Sandoz Chemical name: Fulvestrant
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit **Each pre-filled syringe Contains: Fulvestrant 250mg/5mL**
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. **Fulvestrant Sandoz**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1 pack of 1PFS, 1 pack of 2PFS & As per DPC
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anti-cancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation Firm claim Innovator's specification
	1.5.7	Route of administration Parentral
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Not available
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. USFDA Approved
	1.5.10	Dosage form of applied drug Pre-filled syringe
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system Submitted
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects,

		Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. Submitted
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. Submitted
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
1.6		Miscellaneous Information Submitted
	1.5.5	Drug Substance related Document including following: Name and address of API manufacturer: M/s Sicor S.R.L. Via Terrazzano 77 Italy 20017 rho, Milano
	• Original Legalized CoPP (No. 11787402) dated 21st Feb. 2019 issued by federal office for security in health care Traisengasse 5 1200 vienna, Austria declaring the not-free sale of applied product in exporting country but confirm the GMP compliant status of the manufacturer. • Original Legalized CoPP (No. 19001494) dated 01-03-2019 issued by Swissmedic declaring the free sale of applied product in Switzerland and the GMP compliant status of the manufacturer. • Copy of Sole agency agreement with product license holder is submitted.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted

	Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.4	Control of Critical steps and intermediates Not Submitted
	3.2.S.2.5	Process Validation and/or Evaluation Not submitted
	3.2.S.2.6	Manufacturing process development not Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.3	Validation of analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data (24 months) at 5 ± 3^0C and 6 months at 25^0C±60%RH for three batches.

Remarks of Evaluators:

i. Copy of Letter of authorization from product license holder is submitted.
ii. QOS as per Form-5F format?
iii. Submitted application is not as per Form-5F format.

Decision: Deferred for following:

- **Submission of complete Form 5F as per the guidelines of 293rd meeting of Registration Board.**
- **QOS as per WHO QOS-PD Template.**

Case No. 3: Routine Applicatins of Import (Veterinary)

459.	Name and address of Applicant	M/s Mustafa Brothers 186-D, People colony No.i, Faisalabad 38090, Pakistan
	Detail of Drug Sale License	Address: M/s Mustafa Brothers 186-D, People colony No.i, Faisalabad 38090, Pakistan License to sell drug as distributor valid upto : 21-06-2020
	Marketing authorization holder & Manufacturer	M/s CENAVISA, S.L. Cami Pedra Estela, s/n 43205 REUS/SPAIN
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 24461 Dated 13-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 13-07-2018
	Brand Name +Dosage Form + Strength	COLICEN Solution for use in drinking water or milk
	Composition	Each ml contains: Colistin (Sulphate)……..4000,000IU
	Finished Product Specification	USP
	Pharmacological Group	Antibiotic
	Shelf life	12 months
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml, 500ml, 1000ml and 5000ml
	International availability	Spain
	Me-too status	
	Stability studies	Firm has submitted long term (12 months) at 30^{o}C 65±5%RH & accelerated (06 months) stability data at 40^{o}C, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP dated 08-05-2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s CENAVISA, S.L. Cami Pedra Estela, s/n 43205 REUS/SPAIN. **Product specific Distribution agreement between manufacturer** M/s CENAVISA, S.L. SPAIN and importer M/s Mustafa Brothers 186-D, People colony No.i, Faisalabad 38090, Pakistan is submitted.
	Remarks of the Evaluator.	Evidence of applied formulations of same strength of already approved (generic/me-too) by DRAP/DCO for product
	Decision: Approved with shelf life of 12 months and as per Policy for inspection of Manufacturer abroad.	
460.	Name and address of Applicant	M/s Mustafa Brothers 186-D, People colony No.i, Faisalabad 38090, Pakistan
	Detail of Drug Sale License	Address: M/s Mustafa Brothers 186-D, People colony No.i, Faisalabad 38090, Pakistan License to sell drug as distributor valid upto : 12-02-2019
	Marketing authorization holder & Manufacturer	M/s CENAVISA, S.L. Cami Pedra Estela, s/n 43205 REUS/SPAIN
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 24460 Dated 13-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 13-07-2018
	Brand Name +Dosage Form + Strength	MARBOCEN 100mg/ml Solution for Injection
	Composition	Each ml contains: Marbofloxacin…….100mg
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial

	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	50ml, 100ml & 250ml
	International availability	Spain
	Me-too status	MARBOSTAR 10% SOLUTION of Huzaifa International
	Stability studies	Firm has submitted long term (12 months) at 30°C 65±5%RH & for three batches. Firm has also submitted accelerated stability study data.
	Detail of certificates attached	**Original Legalized CoPP dated 08-05-2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s CENAVISA, S.L. Cami Pedra Estela, s/n 43205 REUS/SPAIN. **Product specific Distribution agreement between manufacturer** M/s CENAVISA, S.L. SPAIN and importer M/s Mustafa Brothers 186-D, People colony No.i, Faisalabad 38090, Pakistan is submitted.
	Remarks of the Evaluator.	
	Decision: Approved with shelf life of 12 months and as per Policy for inspection of Manufacturer abroad.	
461.	Name and address of Applicant	M/s Prix Pharmaceutica, Plot No. 5, Pharmacity, 30Km, Multan Road Lahore.
	Detail of Drug Sale License	Address: 26 abbot road Lahore (godown: Plot NO. 5, Pharmacity 30 KM, Multan Road Lahore. Validity: 12/06/2020
	Product License Holder & Manufacturer	M/s Fatro S.P.A Via Emilia, 285 Ozzano dell Emilia (Bologna) Italy
	Name of exporting country	Italy
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 43883 Dated 26-12-2018
	Fee including differential fee	Rs. 100,000/- Dated 26-12-2018
	Brand Name +Dosage Form + Strength	Prontocill Suspension for Injection
	Composition	Each ml contains: Benzylpenicillin procaine……300,000IU
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Pack size & Demanded Price	100ml Bottle
	International availability	Italy
	Me-too status	
	Stability studies	Firm has submitted long term (24 months) at 30±2°C, 65±5%RH & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 246/2018/C) issued on 24-09-2018 by Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products declaring the free sale of applied product in country of origin and GMP compliant status of the manufacturer.
	Remarks of the Evaluator.	The GMP certificate (No. NBF/20/2020/V) submitted by the firm and also available at EUDRA GMP database specifies beta lactam antibiotics facility under small volume liquids under the sterile products manufacturing operations facility.
	Decision: Approved with innovator's specifications and as per policy for inspection of manufacturer abroad.	
462.	Name and address of Applicant	M/s Prix Pharmaceutica, Plot No. 5, Pharmacity, 30Km, Multan Road Lahore.
	Detail of Drug Sale License	Address: 26 abbot road Lahore (godown: Plot NO. 5, Pharmacity 30 KM,

		Multan Road Lahore. Validity: 12/06/2020
	Product License Holder & Manufacturer	M/s Fatro S.P.A Via Emilia, 285 Ozzano dell Emilia (Bologna) Italy
	Name of exporting country	Italy
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 43884 Dated 26-12-2018
	Fee including differential fee	Rs. 100,000/- Dated 26-12-2018
	Brand Name +Dosage Form + Strength	Repen Suspension for Injection
	Composition	Each ml contains: Benzylpenicillin procaine eq. to Benzylpenicillin ……200,000IU Dihydrostreptomycin sulphate eq. to Dihydrostreptomycin ..250mg
	Finished Product Specification	inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Pack size & Demanded Price	100ml Bottle
	International availability	Italy
	Me-too status	Pro-step injection Reg. No. 43151
	Stability studies	Firm has submitted long term (24 months) at 30±2°C, 65±5%RH & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• Original Legalized CoPP (Certificate#. 247/2018/C) issued on 24-09-2018 by Ministry of Health Directorate General for Animal Health and Veterinary Medicinal Products declaring the free sale of applied product in country of origin and GMP compliant status of the manufacturer.
	Remarks of the Evaluator.	The GMP certificate (No. NBF/20/2020/V) submitted by the firm and also available at EUDRA GMP database specifies beta lactam antibiotics facility under small volume liquids under the sterile products manufacturing operations facility.
	Decision: Approved with innovator's specifications and as per policy for inspection of manufacturer abroad.	

Case no. 4: Import cases (human) Deferred

463.	Name and address of Applicant	M/s Genome Pharmaceuticals Pvt. Ltd. House # 166-A, Street#9, Chaklala Scheme III, Rawalpindi
	Name and address of manufacturer	M/s Halocarbon Products Corporation, 1100 Dittman court, North Augusta, SC 29841 USA
	Name and address of marketing authorization holder	M/s Halocarbon Products Corporation, 1100 Dittman court, North Augusta, SC 29841 USA
	Name of exporting country	USA
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 32574 Dated 01-10-2018
	Fee including differential fee	Rs. 100,000/- Dated 28-09-2018
	Brand Name +Dosage Form + Strength	SEVOFLURANE, Inhalant
	Composition	250ml Sevoflurane 100%
	Finished Product Specification	In-house
	Pharmacological Group	Halogenated general inhalation anesthetic drug
	Shelf life	36 Months
	Demanded Price	Rs. 7700/1's
	Pack size	1's 250ml vial
	International availability	USA

	Me-too status	Sevorane of M/s Getz Pharma
	Stability studies	Firm has submitted long term (36 months) at 30±2°C, 75±5%RH & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 3WSG-JU2C)** issued on 18-08-2017 by USFDA declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Halocarbon Products Corporation, 1100 Dittman court, North Augusta, SC 29841 USA. Expiration date of CoPP is 17th August, 2019 • Copy of Sole agency agreement dated 8th November 2017 of importer M/s Genome Pharmaceuticals with Product License Holder valid for 2 years.
	Remarks of the Evaluator.	Stability data is not as per Zone iva. CoPP invalid.
	Decision of 293rd meeting: Deferred for following: i. Stability data throughout shelf life as per Zone IVA. ii. Legalized CoPP/GMP along with FSC issued by concerned regulatory Authority. **Evaluation by PEC:** • Firm has submitted long term (36 months) at 30±2°C, 75±5%RH & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches. • The firm has submitted that New valid CoPP is in process of legalization and will be provided before issuance of registration certificate.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	

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

a. New cases

464.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By: M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 500mg IM Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone……500mg"
	Diary No. Date of R& I & fee	Dy.No 17665 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	El-cef Injection of M/s Linear Pharma Rawat (Reg.# 075342)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019. *Registration Board after thorough deliberation decided to allow contract manufacturing from M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore for following sections:* *i. Dry Powder Injection (Cephalosporin) Section* *ii. Dry Powder Suspension (Cephalosporin) Section* *iii. Capsule (Cephalosporin) Section* *iv. General Liquid Injection (Ampoule)* **v.** *General Liquid Injection Vials (SVP)*
	Decision: Approved.	
465.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals. 146 S.I.Z. Risalpur, KPK, Pakistan By M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awablock 40mg Injection
	Composition	"Each Vial Contains: Esomeprazole……40mg"
	Diary No. Date of R& I & fee	Dy. No 11728 dated 30-03-2018 Rs.50,000/- Dated 29-03-2018
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and	Nexum IV 40mg Injection by M/s Getz Pharma, Karachi,

	dosage form)	(Reg#050651)
	GMP status	Last inspection dated 18 & 23-04-2019 concluded acceptable level of GMP compliance
	Remarks of the Evaluator[II]	
	Decision: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.	

b. Deferred cases

466.	Name and address of manufacturer / Applicant	M/s K.M.Int Pvt Ltd, Plot No. 74-A Hayatabad Industrial Estate Peshawar.
	Brand Name +Dosage Form + Strength	Kmisulzon-2gm injection (IM/IV)
	Diary No. Date of R& I & fee	Dy. No. 27382 dated 17/12/2019 Rs. 20,000/-
	Composition	Each vial contains: Cefoperazone as sodium……1000mg Sulbactam as sodium……1000mg
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Approved by 3 European countries: **Czech:** http://www.sukl.eu/modules/medication/detail.php?code=0015 273&tab=info **Slovakia:** https://www.sukl.sk/hlavna-stranka/english-version/specialpages/medical-product-detail?page_id=842&lie_id=6343A **Poland:** http://pub.rejestrymedyczne.csioz.gov.pl/?AspxAutoDetectCookieSupport=1#results Links are assessed on 1st Oct 2018
	Me-too Status	2Sum Injection 1g by M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP Status	New DML
	Remarks of the Evaluator.	Master formulation is not submitted for the applied strength.
	Decision of 293rd meeting: Deferred for submission of master formulation of the applied product.	
	Firm's response: Firm has submitted master formulation for applied product	
	Decision: Approved.	
467.	Name and address of manufacturer / Applicant	M/s K.M.Int Pvt Ltd, Plot No. 74-A Hayatabad Industrial Estate Peshawar.
	Brand Name +Dosage Form + Strength	Kmisulzon-1gm injection (IM/IV)
	Diary No. Date of R& I & fee	Dy. No. 27382 dated 17/12/2019 Rs. 20,000/-
	Composition	Each vial contains: Cefoperazone as sodium……500mg Sulbactam as sodium……500mg
	Pharmacological Group	Cephalosporin/beta lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too Status	2Sum Injection 1g by M/s Sami Pharma, (Reg.# 047002)
	GMP Status	New DML
	Remarks of the Evaluator.	Submit method of manufacturing along with the matser

		formulation.
	Decision of 293rd meeting: Deferred for the submission of method of manufacturing along with the master formulation.	
	Firm's response: Firm has submitted master formulation & method of manufacturing for applied product.	
	Decision: Approved.	
468.	Name and address of manufacturer / Applicant	M/s K.M.Int Pvt Ltd, Plot No. 74-A Hayatabad Industrial Estate Peshawar.
	Brand Name +Dosage Form + Strength	Kypime-500mg Injection (IV/IM)
	Diary No. Date of R& I & fee	Dy. No. 27380 dated 17/12/2019 Rs. 20,000/-
	Composition	Each vial contains: Cefepime as HCl (with L-Arginine)……..500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 500mg Injection by M/s Bosch, Reg. No. 44356
	GMP Status	New DML
	Remarks of the Evaluator.	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision of 293rd meeting: Deferred for following clarification; The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.	
	Firm's response: Firm has submitted master formulation containing L-Arginine	
	Decision: Approved.	
469.	Name and address of manufacturer / Applicant	M/s K.M.Int Pvt Ltd, Plot No. 74-A Hayatabad Industrial Estate Peshawar.
	Brand Name +Dosage Form + Strength	Kypime-1gm Injection (IV/IM)
	Diary No. Date of R& I & fee	Dy. No. 27379 dated 17/12/2019 Rs. 20,000/-
	Composition	Each vial contains: Cefepime as HCl (with L-Arginine)……..1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cefipime hydrochloride 1gm Injection M/s Hospira, Inc. (USFDA approved)
	Me-too Status	Nuxipim 1gm Injection by M/s Bosch, Reg. No. 44357
	GMP Status	New DML
	Remarks of the Evaluator.	The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.
	Decision of 293rd meeting: Deferred for following clarification; The product approved in reference country contains L-Arginine in addition to the API while the applied product contains only API. Clarify or otherwise submit revised formulation containing L-Arginine.	
	Firm's response: Firm has submitted master formulation containing L-Arginine	
	Decision: Approved.	

470.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Resperon 3mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…….3mg"
	Diary No. Date of R& I & fee	Dy. No 12312 dated 04-04-2018 Rs.20,000/- Dated 04-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Becalm 3mg Tablet of M/s Maple Pharmaceuticals, Karachi (Reg.# 058206)
	GMP status	Last inspection dated 13-02-2018 concluding as under: "Overall the firm was in good working condition and following the cGMP guidelines as per Drugs Act, 1976 and rules framed there under, Based on the area inspected the people met and document reviewed and considering the findings of Inspection of M/s Say don Pharmaceuticals Pvt. Ltd Peshawar is considered at acceptable level of compliance with CGMPguidelines as per Drugs Act, 1976 and rules framed under." (No of Recommendations written by Area FID in the detail report after conclusion.) **Recommendations:** The management is advised to appoint fill time QA In charge with sufficient experience and testing of their products, according to Pharmacopeia methods. All the above points discuss with the management and they are agreed to rectify at their earliest. The HPLC operator and microbiologist need training. The firm is further advised to purchase latest official books. The firm is also directed to upgrade their SOPs for "Sterility Testing" and arrange official strains of microbes for media testing."
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
471.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Sebixa 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Memantine HCl……10mg"

	Diary No. Date of R& I & fee	Dy. No 12314 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Stir-UP 10mg Tablets of M/s Nabiqasim Pharmaceuticals (Reg.# 047453)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
472.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Sebixa 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Memantine HCl…….20mg"
	Diary No. Date of R& I & fee	Dy. No 12315 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Rement 20mg Table of M/s High-Q Pharmaceuticals, Karachi (Reg.# 073884)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	

473.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Topadon 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Topiramate…..25mg"
	Diary No. Date of R& I & fee	Dy. No 12316 dated 04-04-2018 Rs.20,000/- Dated 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Engrax Tablets 100mg of M/s English Pharmaceuticals Industries. (Reg.# 040144)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
474.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Resperon 2mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…….2mg"
	Diary No. Date of R& I & fee	Dy. No 12311 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tablet Resjun -2 of M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad. (Reg.# 081922)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the

		findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
475.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Damictal 50mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine…….50mg"
	Diary No. Date of R& I & fee	Dy. No 12320 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sportin 50mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 070345)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
476.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Damictal 25mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine……25mg"
	Diary No. Date of R& I & fee	Dy. No 12319 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sportin 25mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 070344)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**

	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
477.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Resperon 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…….1mg"
	Diary No. Date of R& I & fee	Dy. No 12310 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tablet Resjun -1 of M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad. (Reg.# 081921)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
478.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Damictal 100mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine……100mg"
	Diary No. Date of R& I & fee	Dy. No 12321 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Epicta 100mg Tablets of M/s Alina Combine Pakistan, Karachi (Reg.# 039081)
	GMP status	
	Previous remarks of the Evaluator.	

	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
479.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Topadon 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Topiramate……50mg"
	Diary No. Date of R& I & fee	Dy. No 12317 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Engrax Tablets 100mg of M/s English Pharmaceuticals Industries. (Reg.# 040144)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
480.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Zepidep 15mg Tablet
	Composition	"Each Film Coated Tablet Contains: Mirtazapine Hemihydrate……15mg"
	Diary No. Date of R& I & fee	Dy. No 12326 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Mirton-15 Tablets of M/s Genome Pharmaceuticals (Pvt.) Ltd (Reg.# 053546)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
481.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Topadon 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Topiramate……100mg"
	Diary No. Date of R& I & fee	Dy. No 12318 dated 04-04-2018 Rs.20,000/- Dated 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Topamid 100mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 062311)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	
482.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Perica 100mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…….100mg"
	Diary No. Date of R& I & fee	Dy. No 12324 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5

	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved with innovator's specification.	
483.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Perica 75mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…….75mg"
	Diary No. Date of R& I & fee	Dy. No 12323 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica Capsule by PF Prism (USFDA Approved)
	Me-too status (with strength and dosage form)	Gabica by Getz Pharma
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved with innovator's specification.	
484.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Perica 25mg Capsule
	Composition	"Each Capsule Contains: Pregabalin……25mg"

	Diary No. Date of R& I & fee	Dy. No 12322 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica Capsule by PF Prism (USFDA Approved)
	Me-too status (with strength and dosage form)	Neugast 25mg Capsule by M/s S.J & G, Karachi (Reg.#076771)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved with innovator's specification.	
485.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Resperon 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…..4mg"
	Diary No. Date of R& I & fee	Dy. No 12313 dated 04-04-2018 Rs.20,000/- Dated 04-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Riss 4mg Tablet of M/s M/s Shawan Pharmaceuticals, Islamabad (Reg.# 080376)
	GMP status	
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following reasons: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. **(M-289)**
	Evaluation by PEC	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Decision: Approved.	

486.	Name and address of manufacturer / Applicant	M/s Searle IV Solutions Pvt. Ltd. 1.5 km, Manga Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Phenoxpin Tablet
	Composition	Each Tablet Contains: Diphenoxylate…..2.5mg Atropine……0.025mg
	Diary No. Date of R& I & fee	Dy. No.17292 (10-05-2018) Rs.20,000/- 10-05-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Distop Tables of M/s We
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	PMDA approved (as sugar coated). While the firm has applied as film coated tablet.
	Previous decision of 290th meeting	Deferred for evidence of approval of required manufacturing facility i.e., "Tablet Psychotropic" section.
	Firm's response	Firm has submitted copy of section approval letter (No. F.1-34/2003-Lic (Vol-IV)) dated 11-04-2016 for the "Tablet (Psychotropic) section"
	Decision: Approved with innovator's specification.	
487.	Name and address of manufacturer / Applicant	M/s Bajwa Pahrmaceuticals (Pvt) Ltd, 36 K.M, G.T Road, Khori Muridke (Sheikhupura)
	Brand Name +Dosage Form + Strength	Pivacaine-SP 0.5% Heavy Injection
	Composition	Each 4ml contains: Bupivacine Hydrochloride.....20mg Glucose monohydrate 320mg
	Diary No. Date of R& I & fee	Dy. No. 339, 22-08-2016; Rs. 20,000/- (22-08-2016)
	Pharmacological Group	Local anaesthetic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	4ml x 05 ampoules 4ml x 10 ampoules; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Marcain Heavy, 0.5% solution for injection of M/s Aspen Pharma Trading Limited pproved by MHRA of UK
	Me-too status	Sensocain Spinal 0.5% Injection of Brookes Pharmaceuticals Laboratories (Reg.# 057745)
	GMP status	Last inspection report conducted on 21-02-2018 with following conclusion: "Overall hygienic condition of firm was satisfactory at time of inspection. They were advised to improve further their documentation as mentioned in above. They agreed."
	Remarks of the Evaluator.	● In reference product Glucose monohydrate is mentioned as excipient. ● Firm has proposed following alternate brand names: i. B-vacaine-SP 0.5% Heavy Injection ii. Verticaine-SP 0.5% Heavy Injection
	Previous Decision	Registration Board in its 281st meeting deferred for clarification of role of Glucose monohydrate in the applied formulation.
	Response by Firm	Firm has submitted that glucose monohydrate is used as an excipient for spinal injection to make the solution hyperbolic.
	Previous decision of 293rd meeting	Deferred for submission of revised Form 5 for new

		composition, excluding Glucose monohydrate from label claim.
	Evaluation by PEC	Firm has submitted revised form 5 with following composition: "Each 4ml contains: Bupivacine Hydrochloride.....20mg"
	Decision: Approved with following composition: **"Each 4ml contains:** **Bupivacine Hydrochloride.....20mg"**	
488.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceutical Industries (Pvt)Ltd. Plot No. 108- R-2,IndustrialEstate Gadoon, Dist. Swabi, KPK
	Brand Name +Dosage Form + Strength	Mecowel Tablet 500mcg
	Composition	Diary No:19684, 1/11/2017, Rs: 20,000/- 19-Oct-2017
	Diary No. Date of R& I & fee	Each film coated tablet contains: Mecobalamin…500mcg
	Pharmacological Group	WHO ATC index also classifies Mecobalamin as "Antianemic preparations"
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	7's, 14;s, 28's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA approved (as sugar coated)
	Me-too status	039173 Nervon 500ug Tablets Each film coated tablet contains: Mecobalamin….500ug Getz Pharma, Karachi
	GMP status	04-03-2017, Renewal of DML and grant of additional sections.
	Remarks of the Evaluator.	PMDA approved (as sugar coated). While the firm has applied as film coated tablet.
	Previous decision of 288th meeting	Deferred for submission of Form-5 and revised master formulation as per reference product along with requisite fee for change of formulation.
	Firm's response	Firm has submitted revised form 5 with following composition: "Each sugar coated tablet contains: Mecobalamin…500mcg" Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 2044402 dated 03-03-2020.
	Decision: Decision: Approved with following composition: **"Each sugar coated tablet contains:** **Mecobalamin…500mcg"**	
489.	**Name and address of manufacturer / Applicant**	M/s Welmed Pharmaceutical Industries (Pvt.) Ltd, Plot # 108, R:2 Industrial Estate Gadoon Swabi, KPK
	Brand Name +Dosage Form + Strength	MONTIMED TABLET 5mg
	Composition	Each film coated tablet contains: Montelukast sodium……5mg
	Diary No. Date of R& I & fee	4832, 05-06-2017, 20,000/-, 31-05-2017
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 × 10's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Montelukast Hexal 5mg Chewable Tablets (MHRA)
	Me-too status	Montekast 5mg tablet of M/s Global pharmaceutical
	GMP status	• Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under: "The firm has rectified majority of observations noted

		in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance."
	Remarks of the Evaluator.	Master formulation shows film coating while reference product is chewable tablet. Clarification is required.\ Label claim is not as per reference product.
	Previous decision of 288th meeting	Deferred for clarification of manufacturing outline as in reference regulatory authorities the approved drug is chewable tablet, while the applied drug is film coated tablet.
	Firm's response	Firm has submitted revised form 5 with following composition: "Each chewable tablet contains: Montelukast as sodium …… 5mg" Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 2044405 dated 03-03-2020.
	Decision: Decision: Approved with following composition: "Each chewable tablet contains: Montelukast as sodium …… 5mg"	
490.	**Name and address of manufacturer / Applicant**	M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd., Plot No. 108, R-02, Industrial Estate Gadoon, Dist. Swabi, KPK
	Brand Name +Dosage Form + Strength	Welfine tablet 125mg
	Composition	Each uncoated tablet contains: Terbinafine as HCl…...125mg
	Diary No. Date of R& I & fee	Dy.No.4831;05-06-2017; Rs.20,000/- (05-06-2017)
	Pharmacological Group	Anti-fungal
	Type of Form	Form- 5
	Finished product Specification	Not claimed.
	Pack size & Demanded Price	7's, 14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved as uncoated tablet
	Me-too status	Afert tablet 125mg of M/s Genix (Reg. # 055856)
	GMP status	Last GMP inspection was conducted on 04-03-2017 and the report concludes renewal of DML.
	Remarks of the Evaluator.	• Film-coating is applied in the master formulation while the applied formulation is uncoated and approved in reference regulatory authority as uncoated as well. • The official monograph for the applied formulation is available in USP.
	Previous decision of 288th meeting	Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film coated tablet.
	Firm's response	Firm has submitted revised form 5 with manufacturing outline for uncoated tablet.
	Decision: Approved with USP specifications.	

- Following applications were presented in 285th meeting of Registration board held on 3rd to 4th October, 2018 wherein Board deferred the c ases for confirmation from Licensing Division whether M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. has facility of dry powder filling in their approved section of "Lyophilization (sterile area) powder injection general section."
  With reference to above cited decision Incharge PEC sought confirmation form Licensing Division, to which Assistant Director (Lic) vide letter No. F. 2-44/84-Lic (Vol-IV) dated 09th January, 2020 has replied as under:

"As per record of Licensing Division, DRAP, Islamabad M/s S.J & G Fazul Ellahie (Pvt.) Ltd, Karachi under DML No. 000083 (Formulation) possess licensed section with the title of **"Lyophilization (sterile area) Powder injection (General)".** Copy of approved layout plan of said section along with approval letter of section issued by the Central licensing Board is enclosed."

With reference to above cited response from Licensing Division, following cases are again presented before Registration Board for consideration:

491.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt. Ltd., A-39, S.I.T.E. II, Super Highway, Karachi. Contract manufacturing by M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Keuz injection 20mg
	Composition	Each vial contains: Esomeprazole as sodium (lyophilized powder).....20mg
	Diary No. Date of R& I & fee	Dy. No.7062; 22-06-2017; Rs.50,000/- (22-06-2017)
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1's vial; As per PRC's price
	Approval status of product in Reference Regulatory Authorities.	Nexium IV(USFDA approved)
	Me-too status	Contour 20mg Injection of M/s S.J.&G. Fazul Ellahie
	GMP status	Last inspection report of M/s Zephyr Pharmatech conducted on 30-01-2018 concluding good level of GMP compliance. Last GMP Inspection of M/s S.J. & G. Fazul Ellahie conducted on 02-05-2018 with conclusive remarks as under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process"
	Remarks of the Evaluator.	M/s Zephyr Pharmatec has 9 approved sections, and the firm has no product already registered under the contract manufacturing as confirmed by relevant registration section. M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. has approved Lyophilization (sterile area) powder injection general section.
	Previous Decision:	Registration Board in its 283rd meeting deferred for deferred for clarification of applied dosage form whether lyophilized powder or lyophilized cake.
	Evaluation by PEC:	• Firm has submitted that bulk lyophilization will be done in our lyophilization facility and our product filling will be done at sterile powder filling injectable area. • Moreover firm has submitted GMP inspection report dated 29-08-2019, wherein following observation has been recorded under the section title of "Lyophilization (sterile area) powder injectable (general)": "Well equipped separate proper lyophilized powder/product filling. Packing activity is also carried out under the supervision of qualified person. Contour 40mg injection (Esomeprazole) was under production process with requisite documentation system in place."
	Decision: Deferred for following clarifications: **a. Confirmation for permission to M/s SJG&Fazul Ellahi for bulk lyophilization of**	

	Esomeprazole from Licensing Division. **b. Whether M/s SJG&Fazul Ellahi has manufacturing facility for dry powder injection.** **c. Confirmation whether Contour 40mg injection (Esomeprazole) is by powder filling or lyophilization.**	
492.	**Name and address of manufacturer / Applicant**	M/s Zephyr Pharmatec Pvt. Ltd., A-39, S.I.T.E. II, Super Highway, Karachi. **Contract manufacturing** by M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Keuz injection 40mg
	Composition	Each vial contains: Esomeprazole as sodium (lyophilized powder)…….40mg
	Diary No. Date of R& I & fee	Dy. No.7065; 22-06-2017; Rs.50,000/- (22-06-2017)
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1's vial; As per PRC's price
	Approval status of product in Reference Regulatory Authorities.	Nexium IV(USFDA approved)
	Me-too status	Nexum 40mg Injection of M/s Getz
	GMP status	Last inspection report of M/s Zephyr Pharmatech conducted on 30-01-2018 concluding good level of GMP compliance. Last GMP Inspection of M/s S.J. & G. Fazul Ellahie conducted on 02-05-2018 with conclusive remarks as under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process"
	Remarks of the Evaluator.	M/s Zephyr Pharmatec has 9 approved sections, and the firm has no product already registered under the contract manufacturing as confirmed by relevant registration section. M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. has approved Lyophilization (sterile area) powder injection general section.
	Previous Decision:	Registration Board in its 283rd meeting deferred for deferred for clarification of applied dosage form whether lyophilized powder or lyophilized cake.
	Evaluation by PEC:	• Firm has submitted that bulk lyophilization will be done in our lyophilization facility and our product filling will be done at sterile powder filling injectable area. • Moreover firm has submitted GMP inspection report dated 29-08-2019, wherein following observation has been recorded under the section title of "Lyophilization (sterile area) powder injectable (general)": "Well equipped separate proper lyophilized powder/product filling. Packing activity is also carried out under the supervision of qualified person. Contour 40mg injection (Esomeprazole) was under production process with requisite documentation system in place."
	Decision: Deferred for following clarifications: **a. Confirmation for permission to M/s SJG&Fazul Ellahi for bulk lyophilization of**	

	Esomeprazole from Licensing Division. **b. Whether M/s SJG&Fazul Ellahi has manufacturing facility for dry powder injection.** **c. Confirmation whether Contour 40mg injection (Esomeprazole) is by powder filling or lyophilization.**	
493.	**Name and address of manufacturer / Applicant**	M/s Zephyr Pharmatec Pvt. Ltd., A-39, S.I.T.E. II, Super Highway, Karachi. **Contract manufacturing** by M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Tikonin injection 200mg
	Composition	Each vial contains: Tiecoplanin (lyophilized powder)…….....200mg
	Diary No. Date of R& I & fee	Dy. No.7055; 22-06-2017; Rs.50,000/- (22-06-2017)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1's vial; As per PRC price
	Approval status of product in Reference Regulatory Authorities.	Targocid 200mg powder for solution for injection/infusion (MHRA approved)
	Me-too status	Targocid injection 200mg of M/s Hoechst Pakistan Ltd
	GMP status	Last inspection report of M/s Zephyr Pharmatech conducted on 30-01-2018 concluding good level of GMP compliance. Last GMP Inspection of M/s S.J. & G. Fazul Ellahie conducted on 02-05-2018 with conclusive remarks as under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process"
	Remarks of the Evaluator.	M/s Zephyr Pharmatec has 9 approved sections, and the firm has no product already registered under the contract manufacturing as confirmed by relevant registration section. M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. has approved Lyophilization (sterile area) powder injection general section.
	Previous Decision:	Registration Board in its 283rd meeting deferred for deferred for clarification of applied dosage form whether lyophilized powder or lyophilized cake.
	Evaluation by PEC:	• Firm has submitted that ready to fill powder will be procured and powder filling will be done at sterile powder injectable area. • Moreover firm has submitted GMP inspection report dated 29-08-2019, wherein following observation has been recorded under the section title of "Lyophilization (sterile area) powder injectable (general)": "Well equipped separate proper lyophilized powder/product filling. Packing activity is also carried out under the supervision of qualified person. Contour 40mg injection (Esomeprazole) was under production process with requisite documentation system in place."
	Decision: Deferred for clarification from Licensing Division whether firm either has lyophilization or dry powder injection or both facilities.	

494.	**Name and address of manufacturer / Applicant**	M/s Zephyr Pharmatec Pvt. Ltd., A-39, S.I.T.E. II, Super Highway, Karachi. **Contract manufacturing** by M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Tikonin injection 400mg
	Composition	Each vial contains: Tieccoplanin (lyophilized powder)…….....400mg
	Diary No. Date of R& I & fee	Dy. No.7054; 22-06-2017; Rs.50,000/- (22-06-2017)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1's vial; As per PRC price
	Approval status of product in Reference Regulatory Authorities.	Targocid 400mg powder for solution for injection/infusion (MHRA approved)
	Me-too status	Targocid injection 400mg of M/s Hoechst Pakistan Ltd
	GMP status	Last inspection report of M/s Zephyr Pharmatech conducted on 30-01-2018 concluding good level of GMP compliance. Last GMP Inspection of M/s S.J. & G. Fazul Ellahie conducted on 02-05-2018 with conclusive remarks as under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process"
	Remarks of the Evaluator.	M/s Zephyr Pharmatec has 9 approved sections, and the firm has no product already registered under the contract manufacturing as confirmed by relevant registration section. M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. has approved Lyophilization (sterile area) powder injection general section.
	Previous Decision:	Registration Board in its 283rd meeting deferred for deferred for clarification of applied dosage form whether lyophilized powder or lyophilized cake.
	Evaluation by PEC:	• Firm has submitted that ready to fill powder will be procured and powder filling will be done at sterile powder injectable area. • Moreover firm has submitted GMP inspection report dated 29-08-2019, wherein following observation has been recorded under the section title of "Lyophilization (sterile area) powder injectable (general)": "Well equipped separate proper lyophilized powder/product filling. Packing activity is also carried out under the supervision of qualified person. Contour 40mg injection (Esomeprazole) was under production process with requisite documentation system in place."
	Decision: Deferred for clarification from Licensing Division whether firm either has lyophilization or dry powder injection or both facilities.	
495.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt. Ltd., A-39, S.I.T.E. II, Super Highway, Karachi. Contract manufacturing by M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Venko injection 500mg
	Composition	Each vial contains: Vancomycin as hydrochloride…….....500mg

	Diary No. Date of R& I & fee	Dy. No.7059; 22-06-2017; Rs.50,000/- (22-06-2017)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As per PRC's price
	Approval status of product in Reference Regulatory Authorities.	(USFDA approved**)**
	Me-too status	Maparix 500mg Injection of M/s S.J.&G. Fazul Ellahie
	GMP status	Last inspection report of M/s Zephyr Pharmatech conducted on 30-01-2018 concluding good level of GMP compliance. Last GMP Inspection of M/s S.J. & G. Fazul Ellahie conducted on 02-05-2018 with conclusive remarks as under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process"
	Remarks of the Evaluator.	M/s Zephyr Pharmatec has 9 approved sections, and the firm has no product already registered under the contract manufacturing as confirmed by relevant registration section. M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. has approved Lyophilization (sterile area) powder injection general section.
	Previous Decision:	Registration Board in its 283rd meeting deferred for deferred for clarification of applied dosage form whether lyophilized powder or lyophilized cake.
	Evaluation by PEC:	• Firm has submitted that ready to fill powder will be procured and powder filling will be done at sterile powder injectable area. • Moreover firm has submitted GMP inspection report dated 29-08-2019, wherein following observation has been recorded under the section title of "Lyophilization (sterile area) powder injectable (general)": "Well equipped separate proper lyophilized powder/product filling. Packing activity is also carried out under the supervision of qualified person. Contour 40mg injection (Esomeprazole) was under production process with requisite documentation system in place."
	Decision: Deferred for clarification from Licensing Division whether firm either has lyophilization or dry powder injection or both facilities.	
496.	**Name and address of manufacturer / Applicant**	M/s Zephyr Pharmatec Pvt. Ltd., A-39, S.I.T.E. II, Super Highway, Karachi. **Contract manufacturing** by M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Venko injection 1Gm
	Composition	Each vial contains: Vancomycin as hydrochloride…….1gm
	Diary No. Date of R& I & fee	Dy. No.7064; 22-06-2017; Rs.50,000/- (22-06-2017)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As per PRC's price
	Approval status of product in Reference Regulatory Authorities.	(USFDA approved**)**

	Me-too status	Maparix 1gm Injection of M/s S.J.&G. Fazul Ellahie
	GMP status	Last inspection report of M/s Zephyr Pharmatech conducted on 30-01-2018 concluding good level of GMP compliance. Last GMP Inspection of M/s S.J. & G. Fazul Ellahie conducted on 02-05-2018 with conclusive remarks as under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process"
	Remarks of the Evaluator.	M/s Zephyr Pharmatec has 9 approved sections, and the firm has no product already registered under the contract manufacturing as confirmed by relevant registration section. M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. has approved Lyophilization (sterile area) powder injection general section.
	Previous Decision:	Registration Board in its 283rd meeting deferred for deferred for clarification of applied dosage form whether lyophilized powder or lyophilized cake.
	Evaluation by PEC:	• Firm has submitted that ready to fill powder will be procured and powder filling will be done at sterile powder injectable area. • Moreover firm has submitted GMP inspection report dated 29-08-2019, wherein following observation has been recorded under the section title of "Lyophilization (sterile area) powder injectable (general)": "Well equipped separate proper lyophilized powder/product filling. Packing activity is also carried out under the supervision of qualified person. Contour 40mg injection (Esomeprazole) was under production process with requisite documentation system in place."
	Decision: Deferred for clarification from Licensing Division whether firm either has lyophilization or dry powder injection or both facilities.	
497.	**Name and address of manufacturer / Applicant**	M/s Zephyr Pharmatec Pvt. Ltd., A-39, S.I.T.E. II, Super Highway, Karachi. **Contract manufacturing** by M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. E/46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Ozop injection 40mg
	Composition	Each vial contains: Omeprazole as sodium (lyophilized powder)…….40mg
	Diary No. Date of R& I & fee	Dy. No.7057; 22-06-2017; Rs.50,000/- (22-06-2017)
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1's vial; As per PRC's price
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for infusion (UK-MHRA approved**)**
	Me-too status	Fymezole dry powder injection IV 40mg of M/s Fynk Pharmaceuticals
	GMP status	Last inspection report of M/s Zephyr Pharmatech conducted on 30-01-2018 concluding good level of GMP compliance. Last GMP Inspection of M/s S.J. & G. Fazul Ellahie conducted on 02-05-2018 with conclusive remarks as

		under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process"
	Remarks of the Evaluator.	M/s Zephyr Pharmatec has 9 approved sections, and the firm has no product already registered under the contract manufacturing as confirmed by relevant registration section. M/s S.J.&G. Fazul Ellahie (Pvt.) Ltd. has approved Lyophilization (sterile area) powder injection general section.
	Previous Decision:	Registration Board in its 283rd meeting deferred for deferred for clarification of applied dosage form whether lyophilized powder or lyophilized cake.
	Evaluation by PEC:	• Firm has submitted that bulk lyophilization will be done in our lyophilization facility and our product filling will be done at sterile powder filling injectable area. • Moreover firm has submitted GMP inspection report dated 29-08-2019, wherein following observation has been recorded under the section title of "Lyophilization (sterile area) powder injectable (general)": "Well equipped separate proper lyophilized powder/product filling. Packing activity is also carried out under the supervision of qualified person. Contour 40mg injection (Esomeprazole) was under production process with requisite documentation system in place."
	Decision: Deferred for following clarifications: **a. Confirmation for permission to M/s SJG&Fazul Ellahi for bulk lyophilization of Esomeprazole from Licensing Division.** **b. Whether M/s SJG&Fazul Ellahi has manufacturing facility for dry powder injection.** **c. Confirmation whether Contour 40mg injection (Esomeprazole) is by powder filling or lyophilization.**	
498.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700
	Brand Name +Dosage Form + Strength	Cinoflox 125mg/5ml Suspension
	Composition	Each 5ml Suspension after Reconstitution Contains: Ciprofloxacin (HCl) as taste mask granules 65%…125mg
	Diary No. Date of R& I & fee	Dy.No;25466 21-12-2017 Rs. 20,000-(21-12-2017)
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	60 ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Cipro 125mg/5ml of Bayer Healthcare,(USFDA)
	Me-too status (with strength and dosage form)	Novidat 125mg/5ml of Sami Pharmaceuticals
	GMP status	Latest GMP inspection report conducted on 2 May 2018 concluded satisfactory compliance.
	Remarks of the Evaluator4	Source of pellets is vision pharmaceuticals
	Previous decision of 287th meeting	Deferred for further deliberation upon the salt form of API, in view of reference product.
	Evaluation by PEC	Firm has submitted following revised formulation along

		with fee of Rs. 5,000/- vide deposit slip# 2005138 dated 26-02-2020 for revision of formulation: "Each 5ml Suspension after Reconstitution Contains: Ciprofloxacin as taste mask granules ….. 125mg" Firm has also submitted documents of source of Ciprofloxacin pellets from M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved as per USP specifications with following composition: "Each 5ml Suspension after Reconstitution Contains: Ciprofloxacin as taste mask granules ….. 125mg"	
499.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700
	Brand Name +Dosage Form + Strength	Cinoflox 250mg/5ml Suspension
	Composition	Each 5ml Suspension after Reconstitution Contains: Ciprofloxacin (HCl) as taste mask granules 65%…250mg
	Diary No. Date of R& I & fee	Dy.No;25465 21-12-2017 Rs. 20,000-(21-12-2017)
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	60 ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Ciproxin® 250 mg/5 ml granules and solvent for oral suspension by M/s Bayer Healthcare, MHRA approved
	Me-too status (with strength and dosage form)	Novidat 250 mg/5ml of Sami Pharmaceuticals
	GMP status	Latest GMP inspection report conducted on 2 May 2018 concluded satisfactory compliance.
	Remarks of the Evaluator4	Source of pellets is vision pharmaceuticals
	Previous decision of 287th meeting	Deferred for further deliberation upon the salt form of API, in view of reference product.
	Evaluation by PEC	Firm has submitted following revised formulation along with fee of Rs. 5,000/- vide deposit slip# 2005139 dated 26-02-2020 for revision of formulation: "Each 5ml Suspension after Reconstitution Contains: Ciprofloxacin as taste mask granules ….. 250mg" Firm has also submitted documents of source of Ciprofloxacin pellets from M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved as per USP specifications with following composition: "Each 5ml Suspension after Reconstitution Contains: Ciprofloxacin as taste mask granules ….. 250mg"	

- Following applications were presented in 291st meeting of Registration board held on 2nd to 4th September, 2019 wherein Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment and confirmation of manufacturing capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, by following panel for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.

Now the cases are reproduced here for consideration of Board in the light of the report on assessment and confirmation of manufacturing capacity for contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd:

500.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Pinext 500mg IV/IM Injection
	Composition	"Each Vial Contains: Cefepime as HCl (with L-Arginine)….500mg"
	Diary No. Date of R& I & fee	Dy. No 17619 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nuxipim 500mg Injection of Bosch
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019. *Registration Board after thorough deliberation decided to allow contract manufacturing from M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore for following sections:* *i. Dry Powder Injection (Cephalosporin) Section* *ii. Dry Powder Suspension (Cephalosporin) Section* *iii. Capsule (Cephalosporin) Section* *iv. General Liquid Injection (Ampoule)* **v.** *General Liquid Injection Vials (SVP)*
	Decision: Approved.	
501.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Pinext 1000mg IV/IM Injection
	Composition	"Each Vial Contains: Cefepime as HCl (with L-Arginine)….1000mg"
	Diary No. Date of R& I & fee	Dy. No 17659 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nuxipim 1g Injection of Bosch

	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
502.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Sulbanext 1g IV/IM Injection
	Composition	"Each Vial Contains: Cefoperazone Sodium eq. to Cefoperazone …… 500mg Sulbactum Sodium eq. to Sulbactum ……..…500mg"
	Diary No. Date of R& I & fee	Dy.No 17656 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA-Japan
	Me-too status (with strength and dosage form)	2Sum Injection 1g of M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
503.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Cefinext 100mg/5ml Suspension
	Composition	"Each 5ml Contains: Cefixime as trihydrate…100mg"
	Diary No. Date of R& I & fee	Dy.No 17660 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AEMPS of Spain
	Me-too status (with strength and dosage form)	Fasxime 100mg Suspension of M/s Fassgen Pharmaceuticals, (Reg.# 053526)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
504.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ferrostar 20mg IV Injection
	Composition	"Each ml Ampoule Contains: Iron Sucrose complex eq. to elemental Iron.….20mg"
	Diary No. Date of R& I & fee	Dy. No 17649 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	5ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
505.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	D-Next 5mg/ml IV/IM Injection
	Composition	"Each 1ml Contains: Cholecalciferol (Vitamin D3)…5mg"
	Diary No. Date of R& I & fee	Dy. No 17650 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019

	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019. • Reference product is available in ampoule whereas firm has applied for vial.
	Previous Decision of 291st meeting: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment and confirmation of manufacturing capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, by following panel for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products. Moreover clarification shall be submitted regarding container closure system, since reference product is available in ampoule whereas firm has applied for vial.	
	Decision: Deferred for clarification regarding container closure system, since reference product is available in ampoule whereas firm has applied for vial.	
506.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Diazol 500mg/100ml Infusion
	Composition	"Each 100ml vial Contains: Metronidazole……500mg"
	Diary No. Date of R& I & fee	Dy. No 17652 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Imidazole derivative
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Dyrid-P 500mg Injection by M/s Medicraft Pharmaceuticals (Pvt) Ltd. (Reg#051092)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore.

		Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
507.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Alacep 400mg/100ml Infusion
	Composition	"Each vial Contains: Ciprofloxacin as lactate……400mg"
	Diary No. Date of R& I & fee	Dy. No 17655 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	100ml;As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Cinoflox 400mg/100ml Infusion by M/s S.J & G Karachi . . (Reg#076041)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
508.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Cefinext 400mg Capsule
	Composition	"Each Capsule Contains: Cefixime as trihydrate……400mg"
	Diary No. Date of R& I & fee	Dy. No 17663 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	Dispel Capsules 400 mg of M/s Fynk Pharmaceuticals (Reg.# 062702)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
509.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 500mg IV Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium eq. to ceftriaxone……500mg"
	Diary No. Date of R& I & fee	Dy.No 17667 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFD
	Me-too status (with strength and dosage form)	Rezone 500mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031982)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved	
510.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Moxiflin 400mg/250ml Infusion
	Composition	"Each Vial Contains: Moxifloxacin HCl……400mg"
	Diary No. Date of R& I & fee	Dy.No 17648 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications

	Pack size & Demanded Price	250ml;As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Moxilox 400mg Infusion by M/s Spencer Karachi (Reg.#075988)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved with innovator's specifications.	
511.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Painext 75mg/3ml IV/IM Injection
	Composition	"Each 3ml ampoule Contains: Diclofenac Sodium…75mg"
	Diary No. Date of R& I & fee	Dy. No 17651 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Adik 75mg/3ml Injection by M/s City Pharma, Karachi (Reg.#075932)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved with innovator's specifications.	
512.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By: M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Alacep 200mg/100ml Infusion
	Composition	"Each vial Contains: Ciprofloxacin as lactate……200mg"
	Diary No. Date of R& I & fee	Dy. No 17655 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	100ml;As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Cinoflox 200mg/100ml Infusion by M/s S.J & G Karachi . . (Reg#058541)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceutic als (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
513.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By: M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 250mg IM Injection
	Composition	"Each vial Contains: Ceftriaxone as sodium……250mg"
	Diary No. Date of R& I & fee	Dy. No 17664 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	El-cef Injection of M/s Linear Pharma Rawat (Reg.# 075341)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
514.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By: M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 1000mg IV Injection
	Composition	"Each vial Contains: Ceftriaxone as sodium……1000mg"
	Diary No. Date of R& I & fee	Dy.No 17668 dated 11-05-2018 Rs.20,000/- 11-05-2018

		Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Triject IV 1gm Injection of M/s Nabiqasim Industries (Pvt) Ltd., Karachi (Reg.# 058374)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
515.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By: M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 250mg IV Injection
	Composition	"Each vial Contains: Ceftriaxone as sodium……250mg"
	Diary No. Date of R& I & fee	Dy.No 17666 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Rezone 250mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031981)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	
516.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By: M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tonext 500mcg IV/IM Injection
	Composition	"Each ml Contains:

		Mecobalamin……500mcg"
	Diary No. Date of R& I & fee	Dy.No 17653 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Coenzyme Type Vitamin B12
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA of Japan
	Me-too status (with strength and dosage form)	Mexamine 500mcg/ml Injection of M/s Asian Continental (Pvt.) Ltd, Karachi(Reg. # 057864)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved with innovator's specifications.	
517.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Sulbanext 2g IV/IM Injection
	Composition	Each Vial Contains: Cefoperazone Sodium eq. to Cefoperazone …… 1000mg Sulbactum Sodium eq. to Sulbactum ……..…1000mg
	Diary No. Date of R& I & fee	Dy.No 17657 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA-Japan
	Me-too status (with strength and dosage form)	2Sum Injection 1g of M/s Sami Pharmaceuticals, Karachi (Reg.# 047003)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Approved.	

Case no. 06 Registration applications of import cases

a. Deferred cases

i. Human

518.	Name and address of Applicant	M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan
	Detail of Drug Sale License	Address: M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan Validity: 22-06-2019 Status: License to sell drugs by way of "Whole Sale"
	Name and address of manufacturer	M/s CENEXI, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France
	Name and address of marketing authorization holder	M/s Stragen Nordic A/S HelsingØrsgade 8C, HillerØd, Denmark
	Name of exporting country	**Germany**
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 30409 Dated 10-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 10-09-2018
	Brand Name +Dosage Form + Strength	Urapidil Stragen I.V 25mg/5ml (Solution for Injection)
	Composition	Each 5ml contains: Urapidil ……. 25mg
	Finished Product Specification	USP
	Pharmacological Group	Alpha-adrenoceptor antagonist
	Shelf life	18 months
	Demanded Price	Rs. 4,000/- per 5's
	Pack size	5 ampoules
	International availability	Approved by ANSM of France
	Me-too status	N/A
	Detail of certificates attached	• **Original** Legalized CoPP Certificate No: 2286/2 Certifying Authority: District Government of Cologne, Deaprtment 24, Zeughausstrae 2-10, 50667 Cologne. (The name of issuing authority is included in the WHO list of "Competent authorities of countries participating in the WHO certification scheme on the quality of pharmaceutical products moving in international commerce" https://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/contacts/en/index1.html as accessed on 19-12-2018) Issue Date: 10-07-2018 Free sale in exporting country: Yes • GMP: No • Applicant of certificate: M/s Stragen Pharma GmbH, technologie Park Koln, Eupener Strasse 135-137, 50933, Cologne, Germany • Original legalized GMP Certificate Certificate no. HPF/FR/168/2017 valid upto 22-03-2020 **Manufacturer Address:** M/s CENEXI – Fontenay Sous Bois, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France **Issued by** French National Agency for Medicines and Health Products Safety.
	Remarks of the Evaluator: • Firm has submitted a Original legalized statement from M/s Stragen Pharma SA, Switzerland declaring M/s Stragen Nordic A/S Denmark (Product License Holder) an affiliate of M/s Stragen	

	Pharma SA, Switzerland. The statement further grants the M/s Pharmatech Pakistan (Pvt.) Ltd, right to register and to commercialize, the finished product in Pakistan under Stragen Pharma's trademark. • Applicant for COPP is different from Product License Holder. • Only Long term stabilities data for three batches as per Zone IV-A conditions have been submitted by applying bracketing principle on 5ml & 20 ml ampoule.
	Decision of 289th meeting: Registration Board deferred the case for evaluation of bracketing principle applied by the firm on "long term stabilities data" in view of applicable ICH guidelines and presentation of complete details before the Board.
	Firm's response: Firm has now submitted accelerated stability data of three batches at 40°C/75% RH, while the long term stability data has already been submitted as per Zone-IV-A conditions. The results of one of the impurity i.e., 1,3-dimethylbarbituric acid are out of specifications at 6 month time point for all three batches for which firm has submitted following justification: "It is evident that product was stable till 3 months of studies at accelerated condition i.e., 40°C+2°C & 75% + 5%. Only one of the related substances is out of specification s at 6 month time point, while rest of the parameters are within specifications. Therefore it could be inferred that applied product could handle short term excursions outside the label; storage condition, e.g., during shipping or handling, since maximum time required for the shipment of stock from manufacturer to the local facility in Pakistan will be two weeks."
	Decision: Approved as per Policy for inspection of Manufacturer abroad.

Case no. 07 Registration applications of drugs for which stability study data is required to be verified (Routine)

a. Verification of stability study data

519.	Name and address of manufacturer / Applicant	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ixaban 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Apixaban…5mg"
	Diary No. Date of R& I & fee	Dy. No 32754 dated 02-10-2018 Rs.20,000/- Dated 01-10-2018, Rs. 30,000/- dated 04-02-2020.
	Pharmacological Group	Antithrombotic agents,
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	Last inspection report dated 29-01-2018, GMP are rated as Good.
	Remarks of the Evaluator[II]	
520.	Name and address of manufacturer / Applicant	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ixaban 2.5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Apixaban…2.5mg"
	Diary No. Date of R& I & fee	Dy. No 32753 dated 02-10-2018 Rs.20,000/- Dated 01-10-2018, Rs.30,000/- dated 04-02-2020
	Pharmacological Group	Antithrombotic agents,
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	--
	GMP status	Last inspection report dated 29-01-2018, GMP are rated as Good.
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA			
Drug	Ixaban Tablets		
Name of Manufacturer	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi		
Manufacturer of API	M/s CTX Life Sciences Pvt. Ltd., Block No. 251/P,252/P, 253 to 255, 256/P,258/P,276/P,277,278/P,279 to 282,283/P,284/P, GIDC, Sachi City, District surat, Gujarat state, India.		
API Lot No.	18AP00001		
Description of Pack (Container closure system)	Alu-Alu blisters packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,6 months Real Time: 0,3,6 months		
Batch No.	Batch No	Batch Size	Manufacturing Date
Ixaban 5mg	NPD-T-580-P,NPD-T-568-L, NPD-T-579-P	2500 tablets each	March-2019, April-2019
Ixaban 2.5mg	NPD-T-582-L, NPD-T-592-P, NPD-T-593-P	2500 tablets	March-2019
No. of Batches	03		
Date of Submission	12-09-2019 (Dy. No. 17318)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has provided copy of GMP certificate (Certificate#19061470) issued by FDCA Gujarat for M/s CTX Life Sciences Pvt. Ltd., Block No. 251/P,252/P, 253 to 255, 256/P,258/P,276/P,277,278/P,279 to 282,283/P,284/P, GIDC, Sachi City, District Surat, Gujarat state, India. Valid Up to 01-07-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	• Copy of invoice (Invoice No. El/3082100200) for 0.163 Kg of Apixaban has been submitted attested by Assistant Director DRAP, Karachi, dated 27-07-2018.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes

Commitment to follow Drug Specification Rules, 1978.	Yes

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Ixaban 2.5mg and 5mg (Apixaban) Tablets by M/S. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.

Reference No: F.1-2/2020-PEC : Dated 18th February, 2020.

Investigation Date and Time: 15-04-2020 (Morning).

Investigation Site: Factory premises of M/S. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi, Member Registration Board, Islamabad.
2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
3. Ms. Sanam Kausar, Assistant Director, CDL, DRAP, Karachi.

Detail of Investigation:

Sr. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API?	The firm has imported 0.163kg Apixaban API from CTX Life Sciences Pvt, Ltd India. Batch No. 18AP00001 and has taken approval from DRAP-Karachi for import.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor qualification being implemented by the firm which include an audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF, reference standard, impurity standards etc. The firm was evaluated on above mentioned criteria and selected.
3.	Do you have documents confirming the import of API reference standard and impurity standards	The firm has documents confirming the import of API of said batches and working standards of the API and major impurities.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, reference standards of API and impurities.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate no. 19061470 and validity of **01/07/2022** for Apixaban manufacturer, issued by Food and Drug Control Administration Gujrat India.
6.	Do you use API manufacturer method of testing	The firm has used API manufacturer method of testing for API.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on the API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard, and impurities standards?	The firm has remaining quantities of API, reference standards of API and impurities.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients, including: Apixaban, Lactose anhydrous,

		microcrystalline cellulose pH 102, croscarmellose sodium, sodium lauryl sulfate and magnesium stearate.
12.	Do you have documents confirming the import of the used excipients?	The firm has documents confirming the import/purchase of all excipients used.
13.	Do you have test reports and other records on the excipients used	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Ixaban 2.5/5mg tablets?	The firm has written and authorized protocols for the development of Ixaban 2.5mg/5mg tablets
15.	Have you performed Drug excipient compatibility studies?	Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies of their products against innovator products (Eliquis by M/s Pfizer, USA) and their products have shown comparable dissolution profiles.
17.	Do you have product development (R&D) section	The firm has product development (R&D) section with equipment for manufacturing of tablet dosage form. The analytical part is performed on equipment dedicated for R&D activities.
18.	Do you have necessary equipment available in product development section for development of Ixaban 2.5mg / 5mg tablets?	The firm has necessary equipment for product development of Ixaban 2.5mg / 5mg tablets. The product in question has been packed using packing machine of commercial packaging. Furthermore, the analytical part has been performed via the dedicated quality control equipment & lab.
19.	Are the equipment in product development section qualified?	The available equipment in product development section are qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has SOP for the maintenance / calibration / requalification of equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff which include One PhD Chemistry and six Pharmacists in product development section with relevant work experience.
22.	Have you manufactured three stability batches for the stability studies of Ixaban 2.5mg / 5mg tablets as required?	The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of • Ixaban (Apixaban) 2.5mg tablets with batch No. NPD-T-582-L,NPD-T-592-P,NPD-T-593-P having batch size of 2500 tablets each. The tablets are packed in Alu-Alu blisters of pack size 2x7's. • Ixaban (Apixaban) 5mg tablets with batch No. NPD-T-568-L,NPD-T-579-P,NPD-T-580-P having batch size of 2500 tablets each. The tables are packed in Alu-Alu blisters of pack size 2x7's.
23.	What was the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of tablets per testing and the number of tablets required for whole stability testing.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. Necessary logbooks of equipment used has been available with the firm.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocol for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated their own method for testing of stability batches based upon the API testing method.

27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of analytical testing has stability indicating parameters. The stability indicating nature of the testing method has been supported by forced degradation studies.
30.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit Trail reports on API and finished product testing?	The firm showed the audit trail reports on API and finished product testing.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities for real time stability studies.
33.	Do you have commitment batches kept on stability testing?	The firm has completed accelerated stability testing on the three stability batches. The real time stability testing is in progress on all the three stability batches. Currently 06 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment used in API tablets production in analysis?	The firm has valid calibration status for the equipment used in production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
36.	Do related manufacturing area, equipment, personnel, and utilities be rated as GMP compliant?	The related manufacturing area, equipment, personnel, and utilities be rated as GMP compliant.
37.	**Any Query of PEC:** Performance of content uniformity test at UV spectrophotometer, for all the trial batches of both strengths.	Since the product contains single API and lower strength of API is 2.5mg, which is easily quantifiable on UV spectrophotometery based on good absorptive at 225nm, therefore, UV spectrophotometeric method was employed due to heavy workload, for CU testing. Furthermore, the employed method was validated satisfactorily, where no interference of the excipients and diluents was noted during specificity testing as well.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Ixaban (apixaban 2.5mg and 5mg) tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel, and utilities are GMP compliant and well suited for the manufacturing of Ixaban (apixaban 2.5mg and 5mg) tablets.

Recommendations:

1. The firm may kindly be granted necessary registration of Ixaban (apixaban 2.5mg and 5mg) tablets.

Decision: Registration Board decided to approve registration of "Ixaban (Apixaban) 2.5mg tablets" and Ixaban (Apixaban) 5mg tablets by M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IV a conditions.

b. Exemption from onsite verification of stability data

521.	Name and address of manufacturer / Applicant	M/s AGP Ltd., Karachi
	Brand Name +Dosage Form + Strength	Empag Tablets 25mg
	Composition	Each film coated tablet contains:- Emagliflozin …… 25mg
	Diary No. Date of R& I & fee	Dy. No 1527, dated 01-08-2016, Rs.50,000/- 01-08-2016
	Pharmacological Group	Anti-Diaetic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	Rs. 10750/10's Rs. 15050/14's Rs. 30100/28's Rs. 32250/30's
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Emsyn 25mg tablets of M/s The Searle Company (Reg.#093089)
	GMP status	Last inspection report dated 13-05-2019, concluded good level of GMP compliance.
	Remarks of the Evaluator[II]	
522.	Name and address of manufacturer / Applicant	M/s AGP Ltd., Karachi
	Brand Name +Dosage Form + Strength	Empag Tablets 10mg
	Composition	Each film coated tablet contains:- Emagliflozin …… 10mg
	Diary No. Date of R& I & fee	Dy. No 1525, dated 01-08-2016, Rs.50,000/- 01-08-2016
	Pharmacological Group	Anti-Diaetic
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	Rs. 4300/10's Rs. 6020/14's Rs. 12040/28's Rs. 12900/30's
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Emsyn 10mg tablets of M/s The Searle Company
	GMP status	Last inspection report dated 13-05-2019, concluded good level of GMP compliance.

STABILITY STUDY DATA

Drug	Empag Tablets
Name of Manufacturer	M/s AGP (Pvt) Ltd., Karachi
Manufacturer of API	M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd. China
API Lot No.	EPG20190102
Description of Pack (Container closure system)	Alu/Alu blister in unit carton
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH
Time Period	Accelerated: 6 months Real Time: 6 months
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)

	Empag 10mg	Empag 25mg
Batch No.	TR-472, TR-473, TR-474	TR-469, TR-470, TR-471
Batch Size	2000 tablets	2000 tablets
Manufacturing Date	May-2019	Apr-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

REMARKS OF EVALUATOR

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Empag tablet and provided the following documents in conjunction with the checklist approved by the Registration Board in its 293rd Meeting of Registration Board:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved GLYZIA-XR Tablet range in its 285th Meeting of Registration Board (3rd–4th Oct. 2018), i. As per the record available with the firm their HPLC software is 21CFR Compliant. ii. Audit trail on the testing reports are available. iii. Continuous power supply and monitoring (data loggers) are available for stability chambers. The data is properly reviewed on daily basis.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	The firm has submitted certificate of analysis for API from both API Manufacturer and Finished Product manufacturer for the batch number of EPG20190102
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial invoice of Empagliflozin approved by DRAP office, Karachi has been submitted as per following details **Invoice No.** | **Quantity Imported.** | **Date of approval by DRAP** 30206691 | 1.525 Kg | 08-03-2019
4.	Method used for analysis of API from both API manufacturer and Finished Product manufacturer.	Firm has submitted method of analysis of API from both API manufacturer as well as FPP manufacturer.
5.	Stability study data of API from API manufacturer.	Firm has submitted Accelerated stability studies reports of six months and 24months Long Term stability studies reports of three batches as per the conditions of zone IVA i.e Accelerated : 40 ± 2°C and 75± 5% Long Term : 30°C±2°C and 65±5%
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP (ZJ20180032) for the M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd. issued by China Food & Drug Administration valid upto 14-03-2023.
7.	Protocols followed for conduction of stability study.	Firm has submitted protocols for conduction of stability studies.
8.	Method used for analysis of FPP.	Firm has submitted drug product testing method wherein limits of dissolution has been set as per reference product approved by US FDAi.e., NLT Q in 15 minutes.
9.	Drug-excipients compatibility studies.	Firm has submitted that their formulation is as per reference product so they do not require drug excipient compatibility studies.
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted batch manufacturing record of three batches of both strengths **Empag 10mg Tablet** Batch No. TR-472, TR-473, TR-474 **Empag 25mg Tablet**

		Batch No. TR-469, TR-470, TR-471
11.	Record of comparative dissolution data (where applicable).	Firm has submitted performed comparative dissolution profile studies of Empag 10mg & 25mg Tablet in 3 media including pH 1.2, pH 4.5, & pH 6.8 buffers with reference product JARDIANCE tablet manufactured M/s. Boehringer by Ingelheim Pharma GmbH & Co. KG Ingelheim am Rhein Germany. The results are comparable to that of the reference product
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted chromatograms, Raw data sheets, COA, summary data sheets of following batches: **Empag 10mg Tablet** Batch No. TR-472, TR-473, TR-474 **Empag 25mg Tablet** Batch No. TR-469, TR-470, TR-471
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted record of HPLC including audit trail reports for testing on the applied product
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers as mentioned below: Accelerated : 40 ± 2°C and 75± 5% Real Time: 30°C±2°C and 65±5%
Decision: Registration Board decided to approve registration of "Empag (Empagliflozin) Tablets 10mg" and "Empag (Empagliflozin) Tablets 25mg" by M/s AGP Ltd., Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.		
523.	Name and address of manufacturer / Applicant	"M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore"
	Brand Name +Dosage Form + Strength	Tapen 75mg Tablets
	Composition	"Each Film Coated Tablet Contains: Tapentadol as hydrochloride…….75mg"
	Diary No. Date of R& I & fee	Dy. No 1260 dated 27-10-2015 Rs. 50,000 Dated 26-10-2015
	Pharmacological Group	Analgesics, Opiods
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	`
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	-
	GMP status	Panel recommended issuance of GMP certificate on the basis of inspection dated 11-01-2019.
	Remarks of the Evaluator[II]	
524.	Name and address of manufacturer / Applicant	"M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore"
	Brand Name +Dosage Form + Strength	Tapen 50mg Tablets
	Composition	"Each Film Coated Tablet Contains: Tapentadol as hydrochloride…….50mg"
	Diary No. Date of R& I & fee	Dy. No 1258 dated 27-10-2015 Rs. 50,000 Dated 26-10-2015
	Pharmacological Group	Analgesics, Opiods
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Approved by USFDA

	Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	-
	GMP status	Panel recommended issuance of GMP certificate on the basis of inspection dated 11-01-2019.
	Remarks of the Evaluator[II]	

Now the firm has submitted stability data detailed as under:

STABILITY STUDY DATA

Drug	Tapen tablets
Name of Manufacturer	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
Manufacturer of API	Tapentadol: M/s Nantong Chanyoo Pharmatech Co., Ltd, Jiangsu Province China
API Lot No.	Tapentadol: 6TDL 0220518
Description of Pack (Container closure system)	10's tablets packed in alu-alu blister pack.
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 12 months Accelerated: 6 months
Frequency	Accelerated: 0,1,2,3,4 & 6 months Real Time: 0,3,6 months

Product name	Batch Nos.	Batch size	Date of Mfg.	Date of initiation
Tapen 75mg Tablets	T01,T02,T03	1000 tablets	03-2019	19-03-2019
Tapen 50mg Tablets	T02,T03,T04	1000 tablets	03-2019	19-03-2019

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Tapen 50mg tablet & Tapen 75mg tablet and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting: (Dy. No: 21950 dated 25-10-2019)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Sovir 400mg tablets", which was conducted on 06th February, 2018 and was presented in 279th meeting of Registration Board. Registration Board decided to approve registration of "Sovir tablet**"** by M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: i. The HPLC software is 21 CFR compliant. ii. Firm has demonstrated audit trail reports (assay analysis on HPLC) for the submitted stability batches.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of commercial invoice to import Tapentadol HCl (0.912Kg) attested by AD, I&E DRAP, Lahore has been submitted. Detailed as under:

Batch No.	**Invoice No.**	**Date of approval by DRAP**
6TDL 0220518	Exp/872	04-01-2018

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• Firm has submitted that “We received the reference standards along with the API, so there is no separate invoice of reference.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>• Copy of GMP certificate issued by DCA Telangana for the M/s Symed Labs Limited, Unit-VI, Survey No. 744, 745, 750, 751, 752 & 753, Mandollaguden (Village), Choutuppal (Mandal), Yadadri District, Telangana, India and valid upto 10-2021 has been submitted.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted copy of document with title “Rationale for selection of Manufacturing of the API ‘Tapentadol HCl”</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has submitted certificate of analysis for API (Batch# 6TDL 0220518) and working standard.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of R& D technical staff comprising of 7 technical members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted copy of Product Development Protocol & Stability study protocols for the Tapen 50mg & 75mg tablets.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record of three stability batches for the stability studies of Tapen 50mg & 75mg tablets such as.
<table>
<tr><th colspan="3">Tapen 50mg Tablets</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>T02</td><td>03-2019</td><td>1000 tablets</td></tr>
<tr><td>T03</td><td>03-2019</td><td>1000 tablets</td></tr>
<tr><td>T04</td><td>03-2019</td><td>1000 tablets</td></tr>
<tr><th colspan="3">Tapen 75mg Tablets</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>T01</td><td>03-2019</td><td>1000 tablets</td></tr>
<tr><td>T02</td><td>03-2019</td><td>1000 tablets</td></tr>
<tr><td>T03</td><td>03-2019</td><td>1000 tablets</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><th colspan="3">Tapen 50mg Tablets</th></tr>
<tr><th rowspan="2">Batch No.</th><th colspan="2">Remaining Quantity</th></tr>
<tr><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>T02</td><td>0 tablets</td><td>400 tablets</td></tr>
<tr><td>T03</td><td>0 tablets</td><td>400 tablets</td></tr>
<tr><td>T04</td><td>0 tablets</td><td>400 tablets</td></tr>
<tr><th colspan="3">Tapen 75mg Tablets</th></tr>
<tr><th rowspan="2">Batch No.</th><th colspan="2">Remaining Quantity</th></tr>
<tr><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>T01</td><td>0 tablets</td><td>420 tablets</td></tr>
<tr><td>T02</td><td>0 tablets</td><td>420 tablets</td></tr>
<tr><td>T03</td><td>0 tablets</td><td>420 tablets</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and</td><td>The firm has submitted photocopies of digital graphs for Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
</table>

	accelerated)	
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of raw material specifications, raw material testing procedures for Tapentadol HCl.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Testing Method of Finished Product for Tapen 50mg & 75mg tablets along with relevant analytical record for stability studies.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted stability studies reports on API as per Zone-IV-a conditions.
16.	Analysis reports for excipients used.	The firm has submitted photocopies of its Analytical reports for all excipients used in product development of Tapen tablet.
17.	Drug-excipients compatibility studies.	• The firm has submitted that drug excipient compatibility studies data is not applicable since firm has used qualitative innovator formulation.
18.	Record of comparative dissolution data.	• Firm has submitted comparative dissolution profile study for Tapen 75mg tablet against the me-too products of M/s Sami Pharmaceuticals, Karachi in three dissolution mediums of 0.1N HCl, pH 4.5 buffer and pH 6.8 buffer. • f_2 factor results are within acceptable limit • Firm has claimed exemption form the Comparative Dissolution study for Tapen 50mg tablets stating that the reference product Nucynta tablets 50mg and commercial pack of any of Pakistan brands is not available.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	• Firm has submitted audit trail reports of stability studies of applied formulations.

Remarks of Evaluator:

Sr.#	Observations	Response of firm
1	Submitted batch processing record declare the use of 2% overage in master formulation. Scientific Justification shall be submitted in for the use of 2% overage.	The 2% overage is included to compensate process losses during manufacturing. The batch size is lab scale (1000) tablets. The amount of active is 50 mg and 75 mg per tablet and 2% overage amount to 1 mg and 1.5 mg per tablet respectively. The Overage was not added to compensate any Potency loss during study.
2	Significant change (variation of more than 5% than the initial value) has been observed in the assay results of Batch # T03 of Tapen 50 mg tablets during accelerated stability studies at the 3rd and 4th month time point. Justification shall be submitted in this regard.	We request to consider the following points as justification of not performing study on intermediate conditions of stability: **1)** The assay value of 102.37% (initial time point) and 96.97% (3rd month time point) when rounded off become 102% and 97% respectively, so the net difference between assay value is 5% i.e., NMT 5%. **2)** Assay value of last time point (i.e., 6th month) is 98.57%. So the ultimate difference from initial assay (102.37%) is3.8% (i.e., NMT 5%).

Decision: Registration Board decided to approve registration of "Tapen (Tapentadol as hydrochloride) 75mg Tablets" and "Tapen (Tapentadol as hydrochloride) 50mg Tablets" by M/s Dyson Research Laboratories Pvt. Ltd. 28 km Ferozepur Road Lahore. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

525.	Name and address of manufacturer / Applicant	"M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore"
	Brand Name +Dosage Form + Strength	Obcholic 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Obetichloic Acid…….5mg"

	Diary No. Date of R& I & fee	Dy. No 21953 dated 23-11-2017 Rs. 50,000 Dated 22-11-2017
	Pharmacological Group	Bile acid preparations
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	-
	GMP status	Panel recommended issuance of GMP certificate on the basis of inspection dated 11-01-2019.
	Remarks of the Evaluator[II]	
526.	Name and address of manufacturer / Applicant	"M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore"
	Brand Name +Dosage Form + Strength	Obcholic 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Obetichloic Acid…….10mg"
	Diary No. Date of R& I & fee	Dy. No 21954 dated 23-11-2017 Rs. 50,000 Dated 22-11-2017
	Pharmacological Group	Bile acid preparations
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	-
	GMP status	Panel recommended issuance of GMP certificate on the basis of inspection dated 11-01-2019.
	Remarks of the Evaluator[II]	

Now the firm has submitted stability data detailed as under:

STABILITY STUDY DATA

Drug	Obcholic tablets
Name of Manufacturer	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
Manufacturer of API	Obeticholic acid: M/s Nantong Chanyoo Pharmatech Co., Ltd, Jjiangsu Province China
API Lot No.	Obeticholic acid: 201811001
Description of Pack (Container closure system)	10's tablets packed in alu-alu blister pack.
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 12 months Accelerated: 6 months
Frequency	Accelerated: 0,1,2,3,4 & 6 months Real Time: 0,3,6 months

Product name	Batch Nos.	Batch size	Date of Mfg.	Date of initiation
Obecholic 10mg tablets	T01, T02,T03	1500 tablets	02-2019	27-02-2019
Obecholic 5mg tablets	T01,T02,0T03	1500 tablets	02-2019	27-02-2019

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Obecholic 5mg tablet & Obecholic 10mg tablet and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting: (Dy. No: 21949 dated 25-10-2019)

<table>
<tr><th colspan="3">Administrative Portion</th></tr>
<tr><td>1.</td><td>Reference of last onsite panel inspection for instant dosage form conducted during last two years.</td><td>Firm has referred to onsite inspection report of their product “Sovir 400mg tablets”, which was conducted on 06th February, 2018 and was presented in 279th meeting of Registration Board.
Registration Board decided to approve registration of “Sovir tablet**”** by M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Following two observations were reported in the report:
i. The HPLC software is 21 CFR compliant.
ii. Firm has demonstrated audit trail reports (assay analysis on HPLC) for the submitted stability batches.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>• Copy of commercial invoice to import Obeticholic acid (90gm) attested by AD, I&E DRAP, Lahore has been submitted.
Detailed as under:<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Date of approval by DRAP</th></tr><tr><td>201811001</td><td>Cy118299</td><td>13-12-2018</td></tr></table></td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• Firm has submitted copy of declaration form M/s Nantong Chanyoo Pharmatech regarding supply of one set of impurities and working standard along with the material</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>• Copy of GMP certificate (Certificate# 2017006) issued by Nantong Food and Drug Administration, China for the M/s Nantong Chanyoo Pharmatech Co., Ltd, Jjiangsu Province China and valid upto 07-09-2020 has been submitted.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted copy of document with title “Rationale for selection of Manufacturing of the API ‘Obeticholic Acid’”</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has submitted certificate of analysis for API (Batch# 201811001), working standard and impurity standard.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of R& D technical staff comprising of 7 technical members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted copy of Product Development Protocol & Stability study protocols for the Obeticholic acid 10mg & 5mg tablets.</td></tr>
</table>

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record of three stability batches for the stability studies of Obeticholic acid 10mg & 5mg tablets such as.
<table>
<tr><th colspan="3">Obcholic 10mg Tablets</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>T01</td><td>02-2019</td><td>1500 tablets</td></tr>
<tr><td>T02</td><td>02-2019</td><td>1500 tablets</td></tr>
<tr><td>T03</td><td>02-2019</td><td>1500 tablets</td></tr>
<tr><th colspan="3">Obcholic 5mg Tablets</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>T01</td><td>02-2019</td><td>1500 tablets</td></tr>
<tr><td>T02</td><td>02-2019</td><td>1500 tablets</td></tr>
<tr><td>T03</td><td>02-2019</td><td>1500 tablets</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><th colspan="3">Obcholic 10mg Tablets</th></tr>
<tr><th rowspan="2">Batch No.</th><th colspan="2">Remaining Quantity</th></tr>
<tr><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>T01</td><td>0 tablets</td><td>600 tablets</td></tr>
<tr><td>T02</td><td>0 tablets</td><td>620 tablets</td></tr>
<tr><td>T03</td><td>0 tablets</td><td>620 tablets</td></tr>
<tr><th colspan="3">Obcholic 5mg Tablets</th></tr>
<tr><th rowspan="2">Batch No.</th><th colspan="2">Remaining Quantity</th></tr>
<tr><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>T01</td><td>0 tablets</td><td>600 tablets</td></tr>
<tr><td>T02</td><td>0 tablets</td><td>600 tablets</td></tr>
<tr><td>T03</td><td>0 tablets</td><td>600 tablets</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital graphs for Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of raw material specifications, raw material testing procedures for Obeticholic acid</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Testing Method of Finished Product for Obcholic acid 10mg & 5mg tablets along with relevant analytical record for stability studies.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on API as per Zone-IV-a conditions.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its Analytical reports for all excipients used in product development of Obcholic tablet.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has submitted that drug excipient compatibility studies data is not applicable since firm has used qualitative innovator formulation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted as under:
“It is requested to you to exempt the study of Comparative Dissolution because the reference product Ocaliva tablets for Comparative Dissolution profile is not available/marketed in Pakistan.”</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted audit trail reports of stability studies of applied formulations.</td></tr>
</table>

Remarks of Evaluator:

Sr. #	Observations	Response of firm
1	Submitted batch processing record declare the use of 3% overage in master formulation. Scientific Justification shall be submitted in for the use of 3% overage.	The assay result of API Obeticholic acid performed by us was 99.43%. So in order to compensate it to 100% we added 0.5% overage. Furthermore, the 2.5% overage is included to compensate for process losses during manufacturing. The batch size is lab scale (1500) tablets. The amount of active is 5 mg and 10 mg per tablet and 3% overage amount to 0.15 mg and 0.3 mg per tablet respectively. The Overage was not added to compensate potency loss during study.
3	Comparative dissolution profile of applied formulation with reference product shall be submitted.	Exemption claimed from study of Comparative Dissolution because the reference product Ocaliva tablets for Comparative Dissolution Profile is not available/marketed in Pakistan. DRAP already approved products of likewise cases. Firm has referred to the case of "Nib-Sol-AF tablet" of M/s Wilson Pharmaceuticals, approved in 291st meeting of Registration Board.
4	Firm has submitted Dissolution limits of 75% (Q) in 45 minutes, while the chemistry review by the CDEER of USFDA for the reference product "Ocaliva" declares the acceptance criteria of Q for dissolution at 15 minutes. Justification shall be submitted for the submitted dissolution specification in terms of time.	The firm has now submitted dissolution analysis data for two batches of each strength at both long term and accelerated stability study with the dissolution limits of NLT 75% (Q) in 15 minutes in compliance to the decision of 293rd meeting of Registration Board for rapidly dissolving drugs. Details of the newly manufactured batches are as under:

Obcholic 10mg Tablets		
Batch No.	**Date of Mfg.**	**Batch Size**
T03-B	03-2020	500 tablets
T04	03-2020	500 tablets
Obcholic 5mg Tablets		
Batch No.	**Date of Mfg.**	**Batch Size**
T03-B	03-2020	500 tablets
T04	03-2020	500 tablets

Decision: Registration Board decided to approve registration of "Obcholic (Obetichloic Acid) 5mg Tablets" and "Obcholic (Obetichloic Acid) 10mg Tablets" by M/s Dyson Research Laboratories Pvt. Ltd. 28 Km Ferozepur Road Lahore. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

Case no. 08 Miscellaneous cases

I. Registration application Under WHO Collaborative Procedure for Accelerated Registration

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

Subsequently the Registration Board in its 289th meeting held on 14-16 May, 2019, while appreciating the steps taken by DRAP for adopting internationally harmonized regulation and signing agreement with international health partners, endorsed procedure for the processing of such applications in line with WHO Technical Report Series (TRS).

Accordingly following application of a WHO prequalified product has been submitted, which is evaluated and submitted for consideration of Registration board.

527.	Name, address of Applicant / Marketing Authorization Holder	M/s The Searle Company Limited, F-319, S.I.T.E, Karachi
	Name, address of Manufacturing site.	M/s PT. SANBE FARMA Unit 3 Sterile Preparation Plant Jl. Industri Cimareme No. 8, Desa Cimareme, Kecamatan Ngamprah, Kabupaten Bandung Barat-Indonesia
	Country of origin	Republic of Indonesia
	Status of the applicant	☐ Manufacturer ☒Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.# 28302 dated 26-12-2019
	Details of fee submitted	Rs. 100,000/- vide deposit slip# 1996665 dated 26-12-209
	The proposed proprietary name / brand name	**Santocyn**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Oxytocin ….. 10 IU
	Pharmaceutical form of applied drug	Liquid Injectable
	Pharmacotherapeutic Group of (API)	Hormone ATC code: H01BB02
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	1 x 10’s
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Product: Oxytocen Manufacturer: S.J & G. Fazul Ellahie (Pvt.) Ltd. Reg.#: 021223
	Name and address of API manufacturer.	Joint Stock Company “Grindeks” 53 Krustpils Street, Riga, LV 1057, Latvia
	Details of Certification submitted	**COPP:** Original Legalized COPP Has Been Submitted. **Certificate No**. RG.01.05.32.321.08.19.0646 **Issued By:** National Agency For Drug And Food Control, Republic Of Indonesia. **Issue Date:** 05-08-2019 **GMP Status:** Endorsed **Free Sale Status In Country Of Origin:** Endorsed. **Product License Holder:** M/S PT. SANBE FARMA, Jl. Industri Cimareme No. 8, Desa Cimareme, Kecamatan Ngamprah, Kabupaten Bandung Barat-Indonesia **Letter Of Authorization:** Original Legalized Letter Of Authorization has Been Submitted From PT Sanbe Farma-

	Indonesia in the name of "The Searle Company ltd." having the registered office at 1st floor N.I.C.L Building Abbasi Shaheed Road off: Shahrah-e-e faisa Karachi-75530 for the product "Santocyn solution for injection"
WHO prequalification reference number:	RH050
Module-II (Quality Overall Summary)	Firm has module II as per WHO QOS PD template
Module-III:	Submitted.
Pharmaceutical Equivalence Data	Firm has submitted pharmaceutical equivalence data in comparison with the innovator product
Analytical method validation/verification of product	Firm has submitted analytical method verification data.
Stability study data of finished product.	The firm has submitted 36 months long term stability data at 2-8°C and 6 months accelerated stability data at 25°C/60%
Storage conditions	Store the ampoules refrigerated (2-8°C) in the original cartons protected from light. Do not freeze.
Shelf life	18 months

Remarks of Evaluator:

Exchange of following requisite documents have been done as required by the procedure decided by Registration Board in its 289th meeting, for Registration application Under WHO Collaborative Procedure for Accelerated Registration

- Appendix 3 Part A, Applicant's expression of interest in application of the procedure.
- Appendix 2, Prequalification holder's consent to information-sharing
- Fee and the complete information required under Module 1 of DRAP CTD template
- Appendix 3 Part B submitted by DRAP to WHO for communicating its decision to apply the procedure.
- WHO granted access to the WHO reports for the applied product on 26-03-2020.

Following observations were shared with WHO to seek clarification regarding assigned shelf life to which WHO replied as under:

Sr.#	Observation from PEC	WHO response
1.	When the significant change was reported in the Assay test at accelerated stability conditions, for new batches manufactured without 5% overage than how the shelf life was extrapolated to 18 months while the ICH Q1E guidelines state as under: "***2.5.1.2 Significant change at accelerated condition:*** If significant change occurs between 3 and 6 months' testing at the accelerated storage condition, the proposed retest period or shelf life should be based on the long-term data. Extrapolation is not considered appropriate. In addition, a retest period or shelf life shorter than the period covered by long-term data could be called for. If the long-term data show variability, verification of the proposed retest period or shelf life by statistical analysis can be appropriate. If significant change occurs within the first 3 months' testing at the accelerated storage condition, the proposed retest period or shelf life should be	Please note shelf life was assessed on the basis of the primary 36 months long term stability data at 2-8°C and 6 months accelerated stability data at 25°C/60% RH for the 3 batches of FPP with 5% overage and the additional supportive data on the retained samples as well as the six months accelerated and long term data reported on the three new batches manufactured without the overages. From the primary data, significant change in assay results was seen for one batch (5% decrease) with lowest assay result at 36 months for 3 batches being 101.3%. Based on this, it was concluded that assay would exceed the lower limit of 90% even in the absence of an overage at 36 months. However, since there was no 24 months stability data generated with FPP batches manufactured without the 5% overage to

	based on long-term data. Extrapolation is not considered appropriate. A retest period or shelf life shorter than the period covered by long-term data could be called for. If the long-term data show variability, verification of the proposed retest period or shelf life by statistical analysis can be appropriate. In addition, a discussion should be provided to address the effect of short-term excursions outside the label storage condition (e.g., during shipping or handling). This discussion can be supported, if appropriate, by further testing on a single batch of the drug substance or product at the accelerated condition for a period shorter than 3 months."	support the requested shelf life, it was considered prudent to assign 18 months shelf life. The applicant committed to continue stability studies on the 3 batches and to immediately report any out-of-specification results or significant changes during the study to WHO
2.	As per provided summary the short shelf-life (18 months) is appropriate for this product until significant data is provided on batches without overage, while the prequalification was granted on the 30th June 2017 and as per submitted stability schedule 18th month time point of long term was due in Feb 2017, suggesting at least 18 months data would have been available as of then, hence why the short shelf-life (18 months) wasn't extended, which was initially granted on the basis of 6 months stability data	The quality review was completed in October 2016. The final prequalification of the FPP was delayed up to June 2017 because of GMP considerations. Since the applicant did not request for extension of the shelf life, the product was prequalified with the 18 months shelf life accepted at the time of QA review.
3.	What is the current status of the shelf life of the product, when sufficient time has elapsed since the commencement of primary stability studies and also data from the commitment & ongoing stability bathes would have also been available?	The current shelf life of the FPP is 18 months. The applicant has not requested to extend the shelf life of the product. Further, there has been no communication from the applicant of any out-of-specification results or significant changes during the stability studies for batches RG3401, RG3422, RG3441 or for other ongoing stability batches.

Decision: Approved.

II. REPORT ON ASSESSMENT AND CONFIRMATION OF MANUFACTURING CAPACITY FOR CONTRACT MANUFACTURING.

General Information

Name of manufacturer	M/s. Novamed Pharmaceuticals (Pvt.) ltd.
Physical Address	28-Km Ferozepur Road, Lahore.
Manufacturing Enlistment No.	00590
Date of inspection	21-04-2020
Purpose of inspection	Assessment and confirmation of manufacturing capacity for contract manufacturing of different products with reference to DRAP, Islamabad letter No. F.1-2/2020-PEC dated 17-02-2020.
Dosage Form/Sections Included	i. Dry Powder Injection (Cephalosporin) Section ii. Dry Powder for Suspension (Cephalosporin) Section iii. Capsule (Cephalosporin) Section iv. General Liquid Injection (Ampoule) v. General Liquid Injection Vials (SVP)
Name of inspector (s)	i. Mr. Iftikhar Ahmed Chaudhry, Member Registration Board ii. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore. iii. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
Name of Firm's Representative	i. Muhammad Adnan Jamil (Production Incharge)

(s) accompanying during inspection	ii. M. Jehangir (Quality Control Manager) iii. M. Asad Malik (Assistant Manager Regulatory) iv. Mirza Rasheed Ahmed (Regulatory Executive)

Manufacturing record/data was evaluated from **January 2019 to March 2020** for the said purpose. The details of capacity calculations are as under:

SECTION WISE CAPACITY CALCULATION

Capacity of Cephalosporin Injectable Section

Step wise capacity of Cephalosporin Injectable manufacturing	Capacity
Vial Washing - Per single shiftof 8 working hours (Load per Day)	40,000 vials
Vial Washing - Per month (22 working Days) with single shift of 8 working hours	880,000 vials
Depyrogenation Capacity- Per Single shift of 8 working hours (Load per Day)	20,000 vials
Depyrogenation Capacity- Per month (22 working Days) with single shift of 8 working hours	440,000 vials
Filling and SealingCapacity – Per single shift of 8 working hours(Load per Day)	20,000 vials
Filling and SealingCapacity – Per month (22 working Days) with single shift of 8 working hours	440,000 vials
Packing Capacity – Per single shift of 8 working hours	20,000 Packs (Vials)
Packing Capacity– Per month (22 working Days) with single shift of 8 working hours	440,000 Packs (Vials)

Note: Limiting step in this process is Depyrogenationprocess for calculating Utilized Capacity.

Quarter Wise capacity utilized in Tablet Section			
Quarter	**Actual Production (Vials)**	**Capacity (Vials)**	**Capacity utilized in (%)**
1st- 2019	758,269	1,320,000	57.44%
2nd-2019	709,315	1,320,000	53.74%
3rd-2019	516,176	1,320,000	39.10%
4th -2019	935,924	1,320,000	70.90%
1st - 2020	579,698	1,320,000	43.92%
Total	3,499,382	6,600,000	--
Average per quarter	699,876	1,320,000	53.02%

Manufacturing Capacity Utilized (Average)=53.02%
Manufacturing Capacity Available (Average) = 46.98%

Capacity of Cephalosporin DryPowder Suspension

Step wise Capacity of Cephalosporin Dry Powder Suspension	Capacity
Air Blowing Capacity - Per single shift of 8 working hours (Load per Day)	20,000 Bottles
Air Blowing Capacity Per month (22 working Days) with single shift of 8 working hours	440,000 Bottles
Mixing Capacity - Per single shift of 8 workinghours (Load per Day)	300 Kg
Mixing Capacity Per month (22 working Days) with single shift of 8 workinghours	6,600 Kg
Filling Capacity –	13,000 Bottles

Per single shift of 8 workinghours (Load per Day)	
Filling Capacity – Per month (22 working Days) with single shift of 8 workinghours	286,000 Bottles
Packing Capacity – Per single shift of 8 workinghours	13,000 Packs
Packing Capacity – Per month (22 working Days) with single shift of 8 workinghours	286,000 Packs

Note: Limiting step in this process is fillingprocess for calculating Utilized Capacity.

Quarter wise Capacity utilized			
Quarter	**Actual Production (Bottles)**	**Capacity (Bottles)**	**Capacity utilized in (%)**
1st- 2019	282,960	858,000	32.98%
2nd -2019	514,696	858,000	59.99%
3rd -2019	664,009	858,000	77.39%
4th -2019	574,167	858,000	66.92%
1st - 2020	193,281	858,000	22.53%
Total	2,229,113	4,290,000	--
Average per quarter	743,038	858,000	51.96%

Manufacturing Capacity Utilized (average) : 51.96%
Manufacturing Capacity Available (average) : 48.04%

Capacity of Cephalosporin Capsule Section

Step wise capacity of Capacity of Hard Gelatin Capsule Section	**Capacity**
Mixing Capacity - Per single shift of 8 workinghours (Load per Day)	300 Kg
Mixing Capacity Per month (22 working Days) with single shift of 8 workinghours	6,600 Kg
Filling Capacity – Per single shift of 8 workinghours (Load per Day)	384,000 Capsules
Filling Capacity – Per month (22 working Days) with single shift of 8 workinghours	8,448,000 Capsules
Blistering Capacity – Per single shift of 8 working hours	48,000 Packs (Blister size 5's= 240,000 Capsules)
Blistering Capacity – Per month (22 working Days) with single shift of 8 working hours	1,056,000 Packs
Packing Capacity – Per single shift of 8 working hours	48,000 Packs
Packing Capacity – Per month (22 working Days) with single shift of 8 working hours	1,056,000 Packs

Note: Limiting step in this process is Blistering Process for calculating Utilized Capacity.

Quarter Wise Capacity of Cephalosporin Hard Gelatin Capsule Section			
Quarter	**Actual Production (Capsules)**	**Capacity (Capsules)**	**Capacity utilized in (%)**
1st - 2019	677,953	3,168,000	21.40 %
2nd -2019	1,625,000	3,168,000	51.29 %
3rd -2019	2,195,711	3,168,000	69.31 %
4th -2019	924,775	3,168,000	29.19 %
1st - 2020	833,148	3,168,000	26.30 %
Total	6,256,587	15,840,000	--
Average per	1,251,317	3,168,000	39.50%

quarter			

Manufacturing Capacity Utilized (average) : ***39.50(%)***
Manufacturing Capacity Available (average) : ***60.50 (%)***

Capacity of Liquid Injectable Section (Ampoule)

Step wise capacity of Capacity of Liquid Injectable Section (Ampoule)Section	Capacity
Ampoule Washing - Per single shift of 8 working hours (Load per Day)	100,000 Ampoules
Ampoule Washing Per month (22 working Days) with single shift of 8 working hours	2,200,000 Ampoules
Ampoule Depyrogenation – Per single shift of 8 working hours (Load per Day)	100,000 Ampoules
Ampoule Depyrogenation – Per month (22 working Days) with single shift of 8 working hours	2,200,000 Ampoules
Mixing – Per single shift of 8 working hours (Load per Day)	1000 Litres
Mixing – Per month (22 working Days) with single shift of 8 working hours	22,000 Litres
Ampoule Filling – Per single shift of 8 working hours (Load per Day)	100,000 Ampoules (5ml)
Ampoule Filling – Per month (22 working Days) with single shift of 8 working hours	2,200,000 Ampoules (5ml)
Terminal Sterilization Per single shift of 8 working hours (Load per Day)	113,000 Ampoules
Terminal Sterilization Per month (22 working Days) with single shift of 8 working hours	2,486,000 Ampoules
Packing Capacity – Per single shift of 8 working hours	1's 100,000 Packs 5's 20,000 Packs 100's- 1500 Packs
Packing Capacity – Per month (22 working Days) with single shift of 8 working hours	1's- 2,200,000 Packs 5's – 440,000 Packs 100's- 33,000 Packs

Note: Limiting step in this process is Depyrogenation and Terminal Sterilization and all batch Sizes are designed according to these limitations.

Quarter Wise Capacity of Liquid Injectable Section (Ampoule)Section			
Quarter	**Actual Production (Ampoules)**	**Capacity (Ampoules)**	**Capacity utilized in (%)**
1st - 2019	2,426,300	6,600,000	36.76 %
2nd -2019	2,551,370	6,600,000	38.66 %
3rd -2019	3,506,578	6,600,000	53.13 %
4th -2019	3,200,961	6,600,000	48.50 %
1st - 2020	2,742,329	6,600,000	41.55 %
Total	14,427,538	33,000,000	--
Average per quarter	2,885,508	33,000,000	43.72%

Manufacturing Capacity Utilized (average) : ***43.72(%)***
Manufacturing Capacity Available (average) : ***56.28 (%)***

Capacity of Liquid Injectable Section (Vials)

Step wise capacity of Capacity of Liquid Injectable Section (Vials)Section	Capacity
Vials Washing - Per single shift of 8 working hours (Load per Day)	10,000 Vials
Vials Washing Per month (22 working Days) with single shift of 8 working hours	220,000 Vials

Vials Depyrogenation – Per single shift of 8 working hours (Load per Day)	10,000 Vials
Vials Depyrogenation – Per month (22 working Days) with single shift of 8 working hours	220,000 Vials
Mixing – Per single shift of 8 working hours (Load per Day)	1000 Litres
Mixing – Per month (22 working Days) with single shift of 8 working hours	22,000 Litres
Vials Filling – Per single shift of 8 working hours (Load per Day)	10,000 Vials (100ml)
Vials Filling – Per month (22 working Days) with single shift of 8 working hours	220,000 Vials (100ml)
Terminal Sterilization Per single shift of 8 working hours (Load per Day)	10,000 Vials
Terminal Sterilization Per month (22 working Days) with single shift of 8 working hours	220,000 Vials
Packing Capacity – Per single shift of 8 working hours	10,000 Packs (Vials)
Packing Capacity – Per month (22 working Days) with single shift of 8 working hours	220,000 Packs (Vials)

Note: Limiting step in this process is Filling Process for calculating Utilized Capacity.

Quarter Wise Capacity of Liquid Injectable Section (Ampoule)Section			
Quarter	**Actual Production (Vials)**	**Capacity (Vials)**	**Capacity utilized in (%)**
1st - 2019	36,548	660,000	5.54%
2nd -2019	31,100	660,000	4.71%
3rd -2019	40,288	660,000	6.10%
4th -2019	No Batch Manufactured	660,000	-
1st - 2020	9,100	660,000	1.38%
Total	117,036	3,300,000	--
Average per quarter	23,407	660,000	3.55%

Manufacturing Capacity Utilized (average) : ***3.55(%)***

Manufacturing Capacity Available (average) : ***96.45 (%)***

CAPACITY OF QUALITY CONTROL DEPARTMENT

Quality Control Equipment Details							
S #	Equipment	Qty.	Capacity per day (tests)	Capacity per month (tests)	Average utilization/month (tests)	Capacity utilization (%age)	Capacity available (%age)
1	HPLC	3	3x4 = 12	264	178	67.42%	32.58%
2	UV Spectrophotometer	2	8x2 = 16	352	224	63.64%	36.36%
3	pH Meter	2	50	1100	300	27.27%	72.73%
4	Balance	3	--	--	--	--	--
5	Moisture Analyzer	1	50	1100	500	45.45%	54.55%
6	Melting Point Apparatus	1	16	352	300	85.23%	14.77%
7	Tablet disintegration test apparatus	2	16x2 = 32	704	500	71.02%	28.98%
8	Dissolution test apparatus	3	8x3 = 24	528	254	48.12%	51.88%
9	Liquid Particle Counter	1	48	1056	300	28.40%	71.60%
10	Cold Incubator	2	350Lx 2= 700L	--	--	--	--

11	Hot Incubator	1	350L	--	--	--	--
12	Atomic absorption spectrophotometer	1	24	1584	--	--	--

Remarks on Additional Points

Some additional points mentioned in the inspection letter that were required to be addressed are given as follows:

1. Total number of registered products and registered products in aforementioned sections:

Total registered products :223
Registered products in aforementioned sections: 99
Existing contract manufactured products in aforementioned sections: 24
Sectionwise breakup and list of products are attached. **(ANNEX 1)**

2. Manufacturing, QC and IPQC testes performed on manufactured products:

The details of QC and IPQC tests performed on the products manufactured in aforementioned sections are as given in **ANNEX 2**.

3. Installed and utilized capacity of these sections:

The installed and utilized capacity of production in these sections, as provided by the firm, has been given in detail earlier in the report.

4. Installed and utilized capacity of QC Equipment as per pharmacopoeial reference:

The installed and utilized capacity of QC equipment used for testing of products related to these sections, as provided by the firm, has been given in detail earlier in the report.
List of technical personnel **(ANNEX 3)** and list of machinery/equipment **(ANNEX 4)** is attached with the report.

CONCLUSION

The manufacturing capacity (installed, utilized and unutilized) of M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore was assessed based on the data and record provided by the firm, interview of the personnel and visit of the premises.
The details along with the additional points have been given in the report for record and further necessary action.

Decision: Registration Board discussed the inspection report in details. Deliberations were made on used and available capacity keeping in view registered product, currently applied products and future products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore for following sections:

i. **Dry Powder Injection (Cephalosporin) Section**
ii. **Dry Powder Suspension (Cephalosporin) Section**
iii. **Capsule (Cephalosporin) Section**
iv. **General Liquid Injection (Ampoule)**
v. **General Liquid Injection Vials (SVP)**

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

a. New cases

528.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Adexone 0.4mg/ml Injection
	Composition	Each ml Contains: Naloxone HCL……0.4mg
	Diary No. Date of R& I & fee	Dy.No. 33460 dated 09-10-2018 Rs.20,000/- 05-10-2018
	Pharmacological Group	Opioid antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Naloxone of MHRA approved
	Me-too status	Nalox Injection M/s Haji Sons
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
529.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Lab Pvt Limited. 149-Industrial Estate, Hayatabad, Peshawar By: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	DI-Mether Injection 80mg/ml
	Composition	Each ml contains: Artemether ……..80mg
	Diary No. Date of R& I & fee	Dy.No. 20710 dated 08-06-2018 Rs.50,000/- 07-06-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specification	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO approved formulation
	Me-too status	Artesinate Injection of M/S Gray's Pharmaceuticals
	GMP status	Last GMP inspection of Fedro Pharmaceuticals conducted on 30-01-2019 and report concludes the firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their CGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance." & Last GMP inspection Safe Pharmaceuticals conducted on 31-07-2018 and report concludes the firm was GOOD level of GMP compliance.
	Remarks of the Evaluator[IV]	• Number of sections of applicant approved by licensing Board: 07 • Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Decision: Deferred for capacity assessment report of M/s Safe Pharma Karachi by already constituted panel.	
530.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Lab Pvt Limited. 149-Industrial Estate, Hayatabad, Peshawar By M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi

	Brand Name +Dosage Form + Strength	Tramol Injection 100mg/2ml
	Composition	Each 2ml Ampoule contains: Tramadol Hcl…….100mg
	Diary No. Date of R& I & fee	Dy.No. 20712 dated 08-06-2018 Rs.50,000/- Dated 07-06-2018
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	2ml x 5's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Zamadol of (MHRA Approved)
	Me-too status	Symol Injection of M/S Indus Pharma
	GMP status	Last GMP inspection of Fedro Pharmaceuticals conducted on 30-01-2019 and report concludes the firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their CGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance." & Last GMP inspection Safe Pharmaceuticals conducted on 31-07-2018 and report concludes the firm was GOOD level of GMP compliance.
	Remarks of the Evaluator[IV]	• Number of sections of applicant approved by licensing Board: 07 • Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Decision: Deferred for capacity assessment report of M/s Safe Pharma Karachi by already constituted panel.	
531.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Itrovant 100mg Capsule
	Composition	Each Capsule Contains: Itraconazole as IR Pellets 22%...100mg
	Diary No. Date of R& I & fee	Dy.No. 41433 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	Manufacturer"s specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Itraconazole 100 mg capsules of(MHRA approved)
	Me-too status	Itrax Capsule by M/s Ferozsons Labs
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Approved with innovator's specification.	
532.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Vertox 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine Hydrobromide Eq. to Vortioxetine…10mg
	Diary No. Date of R& I & fee	Dy.No. 41432 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antidepressent
	Type of Form	Form-5

	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX 10 mg of USFDA approved
	Me-too status	Brintellix 10mg Tablet by M/s Lundbeck.
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	Submit stability studies with requisite documents.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
533.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Diclovant SR 100mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Diclofenac Sodium……100mg
	Diary No. Date of R& I & fee	Dy.No. 41422 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dicloflex Retard 100 mg of MHRA approved
	Me-too status	Sintral SR Tablets 100mg of M/s Neomedix Pharmaceuticals
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
534.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Fenovant 200mg Capsule
	Composition	Each Capsule Contains: Fenofibrate (Micronized)……200mg
	Diary No. Date of R& I & fee	Dy.No. 41431 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Lipid Regulating agent
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fenofibrate of (MHRA approved)
	Me-too status	Corfibrate 200mg Capsule by M/s OBS
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
535.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Flovant 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Fluoxetine Hcl Eq. to Fluoxetine…20mg
	Diary No. Date of R& I & fee	Dy.No. 41428 dated 07-12-2018 Rs.20,000/- 07-12-2018

	Pharmacological Group	SSRI
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fluoxetine Hydrochloride of TGA Austrailia approved
	Me-too status	Futine 20 mg Tablet by M/s Wilshire Laboratories, ,
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
536.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Amivant 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride……..…50mg
	Diary No. Date of R& I & fee	Dy.No. 41427 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Dopamine receptor antagonist
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride of (MHRA approved)
	Me-too status	Ampisol 50mg Tablet of M/s Sami
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
537.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Dexovant 20mg Capsule
	Composition	Each Capsule Contains: Enteric Coated Pellets of Duloxetine Hydrochloride Eq. to Duloxetine……..…20mg
	Diary No. Date of R& I & fee	Dy.No. 41426 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 20mg Capsule by M/s Martin Dow
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Approved.	
538.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Gentin 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Gabapentin…….600mg
	Diary No. Date of R& I & fee	Dy.No. 41425 dated 07-12-2018 Rs.20,000/- 07-12-2018

	Pharmacological Group	Anti epileptic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Neurontin 600 mg film-coated tablets of MHRA approved
	Me-too status	Gabapan 600mg Tablets of M/s Ferozsons Labs
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
539.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals.
	Brand Name +Dosage Form + Strength	Linzovant 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid……400mg
	Diary No. Date of R& I & fee	Dy.No. 41424 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 400 mg tablet of (USFDA approved)
	Me-too status	Barizold 400mg Tablet by M/s Barrett Hodgson (Reg No:076342)
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
540.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Flucovant 50mg Capsule
	Composition	Each Capsule Contains: Fluconazole…50mg
	Diary No. Date of R& I & fee	Dy.No.41430 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azocan 50mg capsule Of (MHRA Approved)
	Me-too status	Fiscon Capsules 50mg M/s Fassgen Pharmaceuticals
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
541.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Gabapil 25mg Capsule
	Composition	Each Capsule Contains: Pregabalin……25mg
	Diary No. Date of R& I & fee	Dy.No. 36374 dated 02-11-2018 Rs.20,000/- 02-11-2018

	Pharmacological Group	Anti epileptic
	Type of Form	Form 5
	Finished product Specification	Manufacutrer specifiction
	Pack size & Demanded Price	14's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Pregy 25mg Capsule of M/s Sami
	GMP status	Last GMP inspection conducted on 11-01-2019and report concludes that panel recommend the renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
542.	Name and address of manufacturer / Applicant	M/s Getz Pharma Private Limited. 29-30/27, Korangi Industrial area, Karachi
	Brand Name +Dosage Form + Strength	Indaget G DPI Capsule
	Composition	Each Capsule Contains: Indacaterol maleate eq to Indacaterol…110mcg Glycopyrronium bromide eq to Glycopyrronium…50mcg
	Diary No. Date of R& I & fee	Dy.No. 42004 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists & Cholinergic/Obstructive airway disease
	Type of Form	Form 5
	Finished product Specification	Manufacturer"s specifications
	Pack size & Demanded Price	30's ; Rs: 5000/-
	Approval status of product in Reference Regulatory Authorities	Ultibro Breezhaler of(MHRA approved)
	Me-too status	Ultibro Breezehaler of M/S Novatis (Reg# 088393) Registred in Import in 262th DRB
	GMP status	Last GMP inspection conducted on 16-12-2019, and the report concludes that the firm is considered to be operating at an acceptable level of compliance of GMP requirements.
	Remarks of the Evaluator[IV]	• Submit stability studies along with requisite documents.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
543.	Name and address of manufacturer / Applicant	M/s Getz Pharma Private Limited. 29-30/27, Korangi Industrial area, Karachi
	Brand Name +Dosage Form + Strength	Gabica Capsules 25mg
	Composition	Each Capsule Contains: Pregabalin…….25mgs
	Diary No. Date of R& I & fee	Dy.No. 42005 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Anti epileptic
	Type of Form	Form 5
	Finished product Specification	Manufacutrer specifiction
	Pack size & Demanded Price	10's ; Rs:258/- 14's ; Rs:363/- 20's ; Rs:489/- 30's ; Rs:711/-
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Pregy 25mg Capsule of M/s Sami
	GMP status	Last GMP inspection conducted on 16-12-2019, and the report concludes that the firm is considered to be operating at an acceptable level of compliance of GMP requirements.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
544.	Name and address of manufacturer / Applicant	M/s Getz Pharma Private Limited. 29-30/27, Korangi Industrial area, Karachi
	Brand Name +Dosage Form + Strength	Zolvax Powder for Oral Suspension 100mg/5ml

	Composition	Each reconstituted 5ml contains: Linezolid…….100mg
	Diary No. Date of R& I & fee	Dy.No. 42006 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	60ml ; Rs:500/- 120ml ; Rs:1000/-
	Approval status of product in Reference Regulatory Authorities	Zyvox 100 mg/5ml Granules/Powder For Oral Suspension of (USFDA approved)
	Me-too status	Linzol 100mg /5ml oral dry suspension of M/s Regal Pharmaceuticals
	GMP status	Last GMP inspection conducted on 16-12-2019, and the report concludes that the firm is considered to be operating at an acceptable level of compliance of GMP requirements.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
545.	Name and address of manufacturer / Applicant	M/s Getz Pharma Private Limited. 29-30/27, Korangi Industrial area, Karachi
	Brand Name +Dosage Form + Strength	Rival Oral Solution 1mg/ml
	Composition	Each ml contains: Risperidone…….1mg
	Diary No. Date of R& I & fee	Dy.No. 42007 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	15ml ; Rs:270/- 30ml ; Rs:540/- 60ml ; Rs:1080/- 120ml ; Rs:2160/-
	Approval status of product in Reference Regulatory Authorities.	Risperidone oral solution by Sandoz Ltd. (MHRA approved)
	Me-too status	Rislet 1mg/ml Oral Solution of M/s High-Q Pharmaceuticals
	GMP status	Last GMP inspection conducted on 16-12-2019, and the report concludes that the firm is considered to be operating at an acceptable level of compliance of GMP requirements.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
546.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Losta 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium …10mg
	Diary No. Date of R& I & fee	Dy.No. 39635 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Statin or HMG CoA Reductase Inhibitor
	Type of Form	Form -5
	Finished product Specification	Manufacturers specification
	Pack size & Demanded Price	10's, 20's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 10mg film-coated tablets by M/s AstraZeneca UK Ltd (MHRA Approved)
	Me-too status	Easetec 10mg tablet by M/s Pharmatec (Reg#067564)
	GMP status	Last GMP inspection conducted on 12-10-2017 & 12-12-2017, and the report concludes that panel are of the opinion to recoomend the grant of Drug manufacturing License for

		the following Section by the way for 1. General Tablet Section 2. General Capsule Section 3. General Dry Powder Suspension Section (General) Section 4. Liquid Syrup (General)
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
547.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Losta 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium ……20mg
	Diary No. Date of R& I & fee	Dy.No. 39636 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Statin or HMG CoA Reductase Inhibitor
	Type of Form	Form -5
	Finished product Specification	Manufacturers specification
	Pack size & Demanded Price	10's, 20's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 20mg film-coated tablets by M/s AstraZeneca UK Ltd (MHRA Approved)
	Me-too status	Easetec 20mg tablet by M/s Pharmatec (Reg#067565)
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
548.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Liplet 50/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy.No. 39637 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 14's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Galmet 50mg/500mg Table M/s Vision Pharmaceuticals,
	GMP status	As above
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
549.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Liplet 50/850 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy.No. 39638 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)

	Me-too status	Vilget-M 50mg+850mg Tablet M/s Getz
	GMP status	As above
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
550.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Liplet 50/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No. 39639 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	As above
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
551.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Pascal 25mg Capsule
	Composition	Each Capsule Contains: Pregabalin…25mg
	Diary No. Date of R& I & fee	Dy.No. 39616 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Anti epileptic
	Type of Form	Form 5
	Finished product Specification	Manufacutrer specifiction
	Pack size & Demanded Price	14's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Pregy 25mg Capsule of M/s Sami
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
552.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Lifen 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…10mg (eq to 7.5 mg solifenacin)
	Diary No. Date of R& I & fee	Dy.No. 39626 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Treatment Of Urinary Incontinence
	Type of Form	Form-5
	Finished product Specification	Innovator's Specs.
	Pack size & Demanded Price	10's, 30's, :As per SRO
	Approval status of product in	VESICARE 10 mg of MHRA approved.

	Reference Regulatory Authorities	
	Me-too status	Solifen 10mg Tablet by M/s Getz Pharmaceuticals,
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
553.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Ketin 200mg Tablet
	Composition	Each Tablet Contains: Ketoconazole…200mg
	Diary No. Date of R& I & fee	Dy.No. 39615 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10' s,As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketoconazole HRA 200 mg tablet of MHRA approved
	Me-too status	Conaz Tablets 200mg by M/s Atco Labs (Reg#026220)
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
554.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Cardilet-H 300/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…300mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 39618 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Angiotensin receptor blockers/diuretics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	AVALIDE of (USFDA approved)
	Me-too status	Irbest Plus Tablets of M/s Highnoon Laboratories
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
555.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Lakosa 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide……..200mg
	Diary No. Date of R& I & fee	Dy.No. 39617 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Nurosa 200mg Table M/s Helix Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

556.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Witadin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy.No. 39622 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's ; As per PRC
	Approval status of product in Reference Regulatory Authorities	CLARINEX of USFDA approved
	Me-too status	Larinex Tablets of M/s Getz Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
557.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Wincobal 500mcg Tablet
	Composition	Each Sugar Coated Tablet Contains: Mecobalamin……500mcg
	Diary No. Date of R& I & fee	Dy.No. 39621 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Coenzyme-type vitamin B12
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	10's, 20's, 30's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA Japan Approved
	Me-too status	Cekobal 500mcg Tablet of M/s CKD
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
558.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Fixamin 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Rifaximin…….200mg
	Diary No. Date of R& I & fee	Dy.No. 39629 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer"s specifications
	Pack size & Demanded Price	10' s, As per SRO
	Approval status of product in Reference Regulatory Authorities	XIFAXAN of(USFDA approved)
	Me-too status	Rixago 200mg Tablet of M/s OBS Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
559.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Dulet 20mg Capsule
	Composition	Each Capsule Contains: Duloxetine as Hcl (Delayed Release Pellets) …20mg
	Diary No. Date of R& I & fee	Dy.No. 40892 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 20mg Capsule by M/s Martin Dow
	GMP status	As above
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Approved.	
560.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Orila 120mg Capsule
	Composition	Each Capsule Contains: Orlistat (IR Pellets)…120mg
	Diary No. Date of R& I & fee	Dy.No. 40906 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipase inhibitor
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Beacita 120mg Capsules of (MHRA approved)
	Me-too status	Orlisat 120mg Capsules by M/s Merck Sharp & Dhome,
	GMP status	As above
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Deferred for further deliberation regarding stability of pellets.	
561.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Viget 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Vigabatrin…500mg
	Diary No. Date of R& I & fee	Dy.No. 40915 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10' s, As per SRO
	Approval status of product in Reference Regulatory Authorities	Sabril 500 mg film-coated tablets of(MHRA approved)
	Me-too status	Hilgab 500mg Tablet of M/s Hilton Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
562.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Coxera 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy.No. 40929 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacture specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ACOXXEL 60 MG of (MHRA approved)
	Me-too status	Oraxib 60mg Table M/s. Atco Lab
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

563.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Amilet Tablet
	Composition	Each Film Coated Tablet Contains: L-Isoleucin…67mg L-Leucin…101mg L-Phenylanaline…68mg L-Valine…86mg L-Methionine…59mg Lysine Acetate…105mg L-Threonine…53mg L-Tryptophan…23mg L-Histidine…38mg L-Tyrosine…30mg
	Diary No. Date of R& I & fee	Dy.No. 40938 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Calcium and analogue of essential amino acids.
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	KETOSTERIL by Fresenius Kabi, Germany.(Bfarm approved)
	Me-too status	Ketoalfa Tablets M/s Genome Pharmaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
564.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Irovit-F 100/0.35 mg Tablet
	Composition	Each Chewable Tablet Contains: Iron Elemental as Hydroxide Polymaltose Complex…100mg Folic Acid…0.35mg
	Diary No. Date of R& I & fee	Dy.No. 40916 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-anemic
	Type of Form	Form 5
	Finished product Specification	Manufacturer,s specification
	Pack size & Demanded Price	10's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Polymalt Plus Chewable Tablet Of M/S High-Q
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
565.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Viberol Tablet 450mg/35mg
	Composition	Each Tablet Contains: Paracetamol……450mg Orphenadrine Citrate……35mg
	Diary No. Date of R& I & fee	Dy.No.41783 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Analgesic, anti-pyretics, muscle relaxant
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	10×10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Norgesic by M/s iNova Pharmaceuticals, Australia(TGA)

	Me-too status	SIC Tablets of M/s Shrooq Pharmaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
566.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Winkast 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Zafirlukast……10mg
	Diary No. Date of R& I & fee	Dy.No. 40935 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form 5
	Finished product Specification	Manufacturer"s specifications
	Pack size & Demanded Price	14' s,As per SRO
	Approval status of product in Reference Regulatory Authorities	ACCOLATE of (USFDA approved)
	Me-too status	Zilesta 10mg Tablet of M/s Genix Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
567.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Ovastim 50mg Tablet
	Composition	Each Tablet Contains: Clomephine Citrate…50mg
	Diary No. Date of R& I & fee	Dy.No. 41781 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Anti-Oestrogen
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clomid of (USFDA approved)
	Me-too status	Kins Tablets by Stanley Pharmaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
568.	Name and address of manufacturer / Applicant	M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar
	Brand Name +Dosage Form + Strength	S-Zole 100mg Capsule
	Composition	Each Capsule Contains: Itraconazole Pellets 22% Eq. to Itraconazole…100mg
	Diary No. Date of R& I & fee	Dy.No. 16629 dated 07-05-2018 Rs.20,000/- 07-05-2018 (Duplicate dossier yellow slip)
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	Manufacturer"s specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Itraconazole 100 mg capsules of(MHRA approved)
	Me-too status	Itrax Capsule by M/s Ferozsons Labs
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the

		people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Approved with innovator's specification.	
569.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Agotine 25mg Tablet
	Composition	Each Film Coated Tablet contains: Agomelatine ….....25mg
	Diary No. Date of R& I & fee	Dy.No 41814 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Depressant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Agomelatine of (MHRA Approved)
	Me-too status	Valdoxan 25mg Tablet by Servier Research (Reg no. 078160)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018 and the report concludes renewal of DML
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
570.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Amride 50mg Tablet
	Composition	Each tablet contains: Amisulpride…….. 50mg
	Diary No. Date of R& I & fee	Dy.No 41815 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Psychotic
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride of (MHRA approved)
	Me-too status	Ampisol 50mg Tablet of M/s Sami
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018 and the report concludes renewal of DML
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
571.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Amride 100mg Tablet
	Composition	Each tablet contains: Amisulpride…….. 100mg
	Diary No. Date of R& I & fee	Dy.No 41816 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti-Psychotic
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride of (MHRA approved)
	Me-too status	Ampisol 100mg Tablet of M/s Sami

	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018 and the report concludes renewal of DML
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
572.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Amride 200mg Tablet
	Composition	Each tablet contains: Amisulpride…….. 200mg
	Diary No. Date of R& I & fee	Dy.No 41817 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Psychotic
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride of MHRA Approved
	Me-too status	Ampisol 200mg TABLET by Sami Karachi Reg# (076059)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018 and the report concludes renewal of DML
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
573.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Epsone 50mg Tablet
	Composition	Each Sugar Coated Tablet Contains: Eperisone Hydrochloride.…….....50mg
	Diary No. Date of R& I & fee	Dy.No 41825 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Myonal 50mg Tablet of PMDA Approved
	Me-too status	Berelax 50mg Tablet by Ray Pharma Karachi Reg# 061084
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
574.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Itrole 100mg Capsule
	Composition	Each Capsule contains: Itraconazole as IR Pellets 22% ……... 100mg
	Diary No. Date of R& I & fee	Dy.No 41829 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Fungal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Itraconazole 100 mg capsules of(MHRA approved)
	Me-too status	Zitracon 100mg Capsule by Meditech Pharma Karachi Reg# 073346
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Approved with innovator's specification.	

575.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Valzide Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan ……..……..80mg Hydrochlorothiazide……..……12.5mg
	Diary No. Date of R& I & fee	Dy.No 39687 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Diovan Of (MHRA Approved)
	Me-too status	Co-Diovan Of M/S Novartis Pharma
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
576.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Fubox 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat ……....80mg
	Diary No. Date of R& I & fee	Dy.No 41828 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Xanthine Oxidase Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 80mg Tablet of (USFDA approved)
	Me-too status	Febuxin 80mg Tablet by AGP Karachi (Reg no. 081105)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
577.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Winpine 200mg Tablet
	Composition	Each Film Coated Tablet contains: Quetiapine Fumarate eq. to Quetiapine …200mg
	Diary No. Date of R& I & fee	Dy.No 39681 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Anti-Psychotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Nubaquel 200mg Tablet of M/s Nabiqasim
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
578.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Telmi 20mg Tablet

	Composition	Each tablet contains: Telmisartan ……. 20mg
	Diary No. Date of R& I & fee	Dy.No 39688 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Angiotensin receptor blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 20mg Tab by Highnoon Laboratories Reg# (065686)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
579.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Telmi 40mg Tablet
	Composition	Each tablet contains: Telmisartan ……. 40mg
	Diary No. Date of R& I & fee	Dy.No 39689 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Angiotensin receptor blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 40mg Tab by Highnoon Laboratories Reg# (065687)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
580.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Telmi 80mg Tablet
	Composition	Each tablet contains: Telmisartan ……. 80mg
	Diary No. Date of R& I & fee	Dy.No 39690 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Angiotensin receptor blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 80mg Tab by Highnoon Laboratories Reg # (065689)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
581.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Olme Plus 20/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate eq. to Amlodipine……...5mg Olmesartan Medoxomil……..20mg
	Diary No. Date of R& I & fee	Dy.No 41833 dated 07-12-2018 Rs.20,000/- 06-12-2018

	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sevikar 20 mg/5 mg Film-Coated Tablets Of (MHRA Approved)
	Me-too status	Baritec-A 20/5 TABLET by Barret Hodgson Reg # (081442)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
582.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Olme Plus 20/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate eq. to Amlodipine……..10mg Olmesartan Medoxomil……..20mg
	Diary No. Date of R& I & fee	Dy.No 41834 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sevikar 20 mg/10 mg Film-Coated Tablets Of (MHRA Approved)
	Me-too status	Baritec-A 20/10 TABLET by Barret Hodgson Reg # (081444)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
583.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Olme Plus 40/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate eq. to Amlodipine……..5mg Olmesartan Medoxomil……..40mg
	Diary No. Date of R& I & fee	Dy.No 41834 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sevikar 40 mg/5 mg Film-Coated Tablets Of (MHRA Approved)
	Me-too status	Baritec-A 40/5 TABLET by Barret Hodgson Reg # (081443)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
584.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Ezovast 10/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Ezetimibe…….....10mg Atorvastatin Calcium eq. to Atorvastatiun……..10mg
	Diary No. Date of R& I & fee	Dy.No 41826 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipid Modifying Agent

	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Liptruzet of USFDA approved
	Me-too status	Lytron Plus Tablet (Reg# 55408) by Maple Karachi
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
585.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Ezovast 10/20mg Tablet
	Composition	Each Film Coated Tablet Contains: Ezetimibe…….....10mg Atorvastatin Calcium eq. to Atorvastatiun……..20mg
	Diary No. Date of R& I & fee	Dy.No 41827 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipid Modifying Agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Liptruzet of USFDA approved
	Me-too status	Lipiget EZ 20mg+10mg Tablet of M/S Getz Pharma
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
586.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Pastin 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Pitavastatin Calcium eq. to Pitavastatin…1mg
	Diary No. Date of R& I & fee	Dy.No 41836 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	HMG Co-A reductase inhibitor
	Type of Form	Form 5
	Finished product Specifications	JP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Livalo of USFDA approved
	Me-too status	Pitalip 1mg Tablet by Hilton Karachi (Reg no. 070655)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
587.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Pastin 2mg Tablet
	Composition	Each Film Coated Tablet Contains: Pitavastatin Calcium eq. to Pitavastatin…2mg
	Diary No. Date of R& I & fee	Dy.No 41837 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	HMG Co-A reductase inhibitor
	Type of Form	Form 5
	Finished product Specifications	JP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Livalo of USFDA approved

	Regulatory Authorities	
	Me-too status	Pitalip 2mg Tablet by Hilton Karachi (Reg no. 070756)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
588.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Pastin 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Pitavastatin Calcium eq. to Pitavastatin……4mg
	Diary No. Date of R& I & fee	Dy.No 41838 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	HMG Co-A reductase inhibitor
	Type of Form	Form 5
	Finished product Specifications	JP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Livalo of USFDA approved
	Me-too status	Pitalip 4mg Tablet by Hilton Karachi (Reg no. 070657)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
589.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	NT-Fungal 50mg
	Composition	Each 5mL Suspension Contains: Fluconazole (USP)…….50mg
	Diary No. Date of R& I & fee	Dy.No 39684 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Anti-Fungal
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diflucan 10 mg/ml powder for oral suspension by M/s Pfizer Limited (MHRA approved)
	Me-too status	Fluren 50mg/5ml Dry Suspension by Regal Pharma (Reg no. 081984)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
590.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Toxim 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Tenoxicam.…….....20mg
	Diary No. Date of R& I & fee	Dy.No 41844 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mobiflex Tablets 20mg. approved by MHRA
	Me-too status	Tobitil Tablet by Wilshire
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.

	Remarks of the Evaluator[IV]	
	Decision: Approved.	
591.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Manoclin 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Minocycline Hydrochloride eq. to Minocycline….100mg
	Diary No. Date of R& I & fee	Dy.No 41847 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Tetracycline
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Minocycline HCl 100mg, of (MHRA approved)
	Me-too status	Clin 100mg Tablet by Genix Karachi (Reg no. 075945)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
592.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Acetowin 10mg Capsule
	Composition	Each Capsule Contains: Acitretin ……..…10mg
	Diary No. Date of R& I & fee	Dy.No 41812 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antipsoriatic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Soriatane Approved by USFDA approved
	Me-too status	ACT 10mg Capsule by CIBA Pharmaceuticals Reg# (081575)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
593.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Acetowin 250mg Capsule
	Composition	Each Capsule Contains: Acitretin ……..…25mg
	Diary No. Date of R& I & fee	Dy.No 41813 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antipsoriatic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Soriatane Approved by USFDA approved
	Me-too status	Acitec 25mg Capsule by Panacea Pharma Reg# (069843)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

594.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Buspowin 5mg Tablet
	Composition	Each Uncoated Tablet contains: Buspirone Hydrochloride ….....5mg
	Diary No. Date of R& I & fee	Dy.No 41820 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anxiolytics
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BUSPIRONE 5mg TABLETS of MHRA Approved
	Me-too status	Nanzo 5mg Tab by Wilshire Reg # (065703)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
595.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Buspowin 10mg Tablet
	Composition	Each Uncoated Tablet contains: Buspirone Hydrochloride ….....10mg
	Diary No. Date of R& I & fee	Dy.No 41821 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anxiolytics
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BUSPIRONE 10mg TABLETS of MHRA Approved
	Me-too status	Nanzo 10mg Tab by Wilshire Reg # (065702)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
596.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Vigotin 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Vigabatrin…….....500mg
	Diary No. Date of R& I & fee	Dy.No 41846 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Epilepsy
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sabril 500mg film coated tablet of MHRA approved
	Me-too status	Seizril 500mg Tablet by Nabiqasim Reg # (081564)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
597.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Rozin SR 500mg Tablet
	Composition	Each Film Coated Extended Release Tablet contains: Ranolazine ….....500mg

	Diary No. Date of R& I & fee	Dy.No 39682 dated 03-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Anti-Anginal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	RANEXA of USFDA Approved
	Me-too status	Ranoline SR 500mg Tablet (Reg#078791) by Searle IV Solutions
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
598.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Bamrol 10mg Tablet
	Composition	Each Uncoated Tablet Contains: Bambuterol Hydrochloride ……..10mg
	Diary No. Date of R& I & fee	Dy.No 41885 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Long acting beta adrenoceptor agonist
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bambec Tablets 10 mg of MHRA Approved
	Me-too status	Basthma Tablet by Polyfine Chempharma Reg# (075572)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
599.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Clozer 250mg Capsule
	Composition	Each Capsule contains: Cycloserine …..... 250mg
	Diary No. Date of R& I & fee	Dy.No 41822 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti-biotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Seromycin of USFDA Approved
	Me-too status	Egycerine 250mg by Werrick Pharmaceuticals. Capsule (Reg# 082049)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
600.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Megron 25mg Tablet
	Composition	Each Extended Released Film Coated Tablet contains: Mirabegron……..... 25mg
	Diary No. Date of R& I & fee	Dy.No 41830 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Beta-3 adrenergic agonists

	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ of USFDA APPROVED
	Me-too status	Not found
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	Submitt Stability studies with differential fee..
	Decision:Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, or else application on form-5D along with differential fee.	
601.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Megron 50mg Tablet
	Composition	Each Extended Released Film Coated Tablet contains: Mirabegron……..... 50mg
	Diary No. Date of R& I & fee	Dy.No 41831 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Beta-3 adrenergic agonists
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ of USFDA APPROVED
	Me-too status	Not found
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	Stability studies required with differential fee.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, or else application on form-5D along with differential fee.	
602.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Dexfin 50mg XR Tablet
	Composition	Each Extended Release Film Coated Tablet Contains: Desvenlafaxine Succinate eq. to Desvenlafaxine…....50mg
	Diary No. Date of R& I & fee	Dy.No 41823 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Depressant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PRISTIQ of USFDA Approved
	Me-too status	Qrist 50mg Tab by NabiQasim Karachi Reg # (079528)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
603.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Dexfin 100mg XR Tablet
	Composition	Each Extended Release Film Coated Tablet Contains: Desvenlafaxine Succinate eq. to Desvenlafaxine…....100mg
	Diary No. Date of R& I & fee	Dy.No 41824 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Depressant

	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PRISTIQ of USFDA Approved
	Me-too status	Qrist 100mg Tab by NabiQasim Karachi Reg # (079527)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
604.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Naxin 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Naltrexone Hydrochloride….50mg
	Diary No. Date of R& I & fee	Dy.No 41832 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Opioid Antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Naltrexone Hydrochloride of MHRA Approved
	Me-too status	E-Track 50mg Tablet by Eklo Karachi (070791)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
605.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Irbiotan Tablet 75mg
	Composition	Each Film Coated Tablet Contains: Irbesartan…75mg
	Diary No. Date of R& I & fee	Dy.No. 39913 dated 04-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Angiotensin-II receptor antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's & 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Aprovel 75 mg film-coated tablets of (MHRA approved)
	Me-too status	Irbest Tablets 75mg of M/s. Highnoon Laboratories,
	GMP status	Last GMP inspection conducted on **09-07-2019**, and the report concludes that the Overall GMP of the firm is rated as good, based on the area inspected, the people met and the documents reviewed.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
606.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Irbiotan Tablet 150mg
	Composition	Each Film Coated Tablet Contains: Irbesartan…150mg
	Diary No. Date of R& I & fee	Dy.No. 39914 dated 04-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Angiotensin-II receptor antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's & 30's ; As per SRO

	Approval status of product in Reference Regulatory Authorities	Aprovel 150 mg film-coated tablets of (MHRA approved)
	Me-too status	Irbest Tablets 150mg of M/s. Highnoon Laboratories,
	GMP status	Last GMP inspection conducted on **09-07-2019**, and the report concludes that the Overall GMP of the firm is rated as good, based on the area inspected, the people met and the documents reviewed.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
607.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Irbiotan Tablet 300mg
	Composition	Each Film Coated Tablet Contains: Irbesartan…300mg
	Diary No. Date of R& I & fee	Dy.No. 39915 dated 04-12-2018 Rs.20,000/- 03-12-2018
	Pharmacological Group	Angiotensin-II receptor antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's & 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Aprovel 300 mg film-coated tablets of (MHRA approved)
	Me-too status	Irbest Tablets 300mg of M/s. Highnoon Laboratories,
	GMP status	Last GMP inspection conducted on **09-07-2019**, and the report concludes that **the** Overall GMP of the firm is rated as good, based on the area inspected, the people met and the documents reviewed.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
608.	Name and address of manufacturer / Applicant	M/s Oval Pharmaceuticals,112/11, Quaid-e-Azam Industrial Estate, kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Reodene Solution 100mg/ml (Povidone-Iodine)
	Composition	Each ml contains: Povidone-Iodine…100mg(10%)
	Diary No. Date of R& I & fee	Dy.No 4768 dated 09-02-2018 Rs. 20,000/- 09-02-2018
	Pharmacological Group	Antiseptic, germicidal
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	60ml,450ml; Rs : 77/60ml & 377/450ml
	Approval status of product in Reference Regulatory Authorities	BETADINE ANTISEPTIC TOPICAL SOLUTION povidone-iodine 100mg/mL solution
	Me-too status (with strength and dosage form)	PYODINE 10% solution by Brookes Pharma.
	GMP status	Last GMP inspection conducted on **07-01-2020.**, and the report concludes that " In view of above findings of inspection, areas checked, documents, documents reviewed,the panel of the opinion that firm had rectified most of the previous observation. Hence the firm allowed to resume the production activities. The management assured that they would follow the Drug act 1976 for GMP compliance
	Remarks of the Evaluator[IV]	Firm applied for regularization of layout in which external preparation section is also mentioned.(Section still not approved)
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
609.	Name and address of manufacturer / Applicant	M/s Saffon Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad

	Brand Name +Dosage Form + Strength	Zolmi 2.5mg Tablet
	Composition	Each film coated Tablet Contains: Zolmitriptan…….2.5mg
	Diary No. Date of R& I & fee	Dy.No. 39650 dated 03-12-2018 Rs.20,000/- 30-11-2018
	Pharmacological Group	Selective serotonin (5HT1) agonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	3' s, Rs:1000/-
	Approval status of product in Reference Regulatory Authorities	Zomig 2.5 mg Tablets of USFDA approved
	Me-too status	Migzor 2.5mg Tablet of M/s Hilton Pharma
	GMP status	Last GMP inspection conducted on 08-10-2019, and the report concludes that the firm is considered to be operating at Good level of compliance with GMP guidelines
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
610.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Brand Name +Dosage Form + Strength	Zolmi 5mg Tablet
	Composition	Each film coated Tablet Contains: Zolmitriptan…5mg
	Diary No. Date of R& I & fee	Dy.No. 39651 dated 03-12-2018 Rs.20,000/- 30-11-2018
	Pharmacological Group	Selective serotonin (5HT1) agonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	3' s, Rs:1200/-
	Approval status of product in Reference Regulatory Authorities	Zomig 5 mg Tablets of USFDA approved
	Me-too status	Migzor 5mg Tablet of M/s Hilton Pharma
	GMP status	Last GMP inspection conducted on 08-10-2019, and the report concludes that the firm is considered to be operating at Good level of compliance with GMP guidelines
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
611.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Brand Name +Dosage Form + Strength	Zolmi 2.5mg Nasal Spray
	Composition	Each spray contains: Zolmitriptan…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 39649 dated 03-12-2018 Rs.20,000/- 30-11-2018
	Pharmacological Group	Selective serotonin (5HT1) agonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1' s, Rs:1000/-
	Approval status of product in Reference Regulatory Authorities	Zomig 2.5 mg Nasal Spray of (USFDA approved)
	Me-too status	Zolmpine 2.5mg Nasal spray of M/s Graton Pharma (Reg# 088394**)** Registred in Import in 262th DRB
	GMP status	Last GMP inspection conducted on 08-10-2019, and the report concludes that the firm is considered to be operating at Good level of compliance with GMP guidelines
	Remarks of the Evaluator[IV]	Nasal Spray section (Steriodal) available. Submitt on for 5D with differential fee and stability studies.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	

612.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Brand Name +Dosage Form + Strength	Valpro 500mg Tablet
	Composition	Each enteric coated tablet contains: Divalproex sodium eq to Valproic Acid 500mg
	Diary No. Date of R& I & fee	Dy.No. 43345 dated 19-12-2018 Rs.20,000/- 19-12-2018
	Pharmacological Group	Antiepileptic & Anticonvulsant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	100's / Rs:1200/-
	Approval status of product in Reference Regulatory Authorities	Depakote tablet USFDA Approved
	Me-too status	Valrox Tab by Polyfine Chemical
	GMP status	Last GMP inspection conducted on 08-10-2019, and the report concludes that the firm is considered to be operating at Good level of compliance with GMP guidelines
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
613.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name +Dosage Form + Strength	Cefowen 2g Injection IM/IV
	Composition	Each Vial Contains: Cefotaxime as Sodium…..2g
	Diary No. Date of R& I & fee	Dy.No. 36645 dated 06-11-2018 Rs.20,000/- 06-11-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefotaxime 2g Powder for solution for injection or infusion of MHRA approved
	Me-too status	Claforan 2.0g Injection of M/s Sanofi Aventis
	GMP status	Last GMP inspection conducted on 30-09-2018 & 29-10-2018 and report concludes that Firm is compliant to current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management; panel unanimously recommends the grant of GMP certificate.
	Remarks of the Evaluator[IV]	Firm revise their formulation from Cefotaxime HCl with L-Arginin to Cefotaxime as Sodium with submission of fee of RS: 5000/- Deposit Slip No: 2018379 Dated:14-02-2020
	Decision: Approved.	
614.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name +Dosage Form + Strength	Valpo 250mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Divalporex Sodium Eq. to Valporic Acid…250mg
	Diary No. Date of R& I & fee	Dy.No. 36647 dated 06-11-2018 Rs.20,000/- 06-11-2018
	Pharmacological Group	Antiepileptic & Anticonvulsant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Depakote tablet USFDA Approved
	Me-too status	Valrox Tab of M/s Polyfine Chemical
	GMP status	Last GMP inspection conducted on 30-09-2018 & 29-10-2018 and report concludes that Firm is compliant to current

		Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management; panel unanimously recommends the grant of GMP certificate.
	Remarks of the Evaluator[IV]	Firm Change formulation from film coated to enteric coated with submission of fee of RS: 5000/- Deposit Slip No: 2018380 Dated:14-02-2020
	Decision: Approved.	
615.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name +Dosage Form + Strength	Valpo 500mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Divalporex Sodium Eq. to Valporic Acid…500mg
	Diary No. Date of R& I & fee	Dy.No. 36648 dated 06-11-2018 Rs.20,000/- 06-11-2018
	Pharmacological Group	Antiepileptic & Anticonvulsant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Depakote tablet USFDA Approved
	Me-too status	Valrox Tab by Polyfine Chemical
	GMP status	Last GMP inspection conducted on 30-09-2018 & 29-10-2018 and report concludes that Firm is compliant to current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management; panel unanimously recommends the grant of GMP certificate.
	Remarks of the Evaluator	Firm Change formulation from film coated to enteric coated with submission of fee of RS: 5000/- Deposit Slip No: 2018381 Dated:14-02-2020
	Decision: Approved.	
616.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Brand Name +Dosage Form + Strength	Weforide 0.9% Injection
	Composition	Each 5ml Contains: Sodium Chloride…..45mg
	Diary No. Date of R& I & fee	Dy.No. 366442 dated 06-11-2018 Rs.20,000/- 06-11-2018
	Pharmacological Group	Electrolyte
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml x 1's : As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Sacro Injection of Macter Intr. Karachi. (Reg.#079756)
	GMP status	Last GMP inspection conducted on 30-09-2018 & 29-10-2018 and report concludes that Firm is compliant to current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management; panel unanimously recommends the grant of GMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
617.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Exor 5/80 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate Eq. to Amlodipine…5mg

		Valsartan…….80mg
	Diary No. Date of R& I & fee	Dy.No. 41600 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 28's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Exforge Tablet of M/s Novartis Pharma (Reg.#047569)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections "Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
618.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Exor 5/160 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate Eq. to Amlodipine…5mg Valsartan…….160mg
	Diary No. Date of R& I & fee	Dy.No. 41589 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Calcium antagonist/Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 28's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Of (USFDA Approved)
	Me-too status	Co-Valzaar 5mg/160mg Tablet by M/s Vision Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections "Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
619.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Exor 10/160 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate Eq. to Amlodipine…10mg Valsartan…….160mg
	Diary No. Date of R& I & fee	Dy.No. 41602 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Calcium antagonist/Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Of (USFDA Approved)
	Me-too status	Co-Valzaar 10mg/160mg Tablet by M/s Vision Pharma
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections "Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

620.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Ecox 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib.…60mg
	Diary No. Date of R& I & fee	Dy.No. 41529 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacture specification
	Pack size & Demanded Price	2's, 7's, 10's, 14's, 20's, 28's, 49's & 98'sAs per SRO
	Approval status of product in Reference Regulatory Authorities	ARCOXIA 60 mg film-coated tablets of (MHRA approved)
	Me-too status	Oraxib 60mg Table M/s. Atco Lab
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections "Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
621.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gastrolux 20mg Oral Sachet
	Composition	Each Sachet Contains: Esomeprazole as Magnesium Trihydrate Enteric Coated Pellets 7%...20mg
	Diary No. Date of R& I & fee	Dy.No. 41100 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	PPIs
	Type of Form	Form 5
	Finished product Specification	Manufacture specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	NEXIUM For Delayed-Release Oral Suspension of (USFDA approved)
	Me-too status	Somezol 20mg Sache M/s Bosch
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	Source of Pellets: Vision
	Decision: Approved with innovator's specification.	
622.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gastrolux 40mg Oral Sachet
	Composition	Each Sachet Contains: Esomeprazole as Magnesium Trihydrate Enteric Coated Pellets 7%...40mg
	Diary No. Date of R& I & fee	Dy.No. 41085 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	PPIs
	Type of Form	Form 5
	Finished product Specification	Manufacture specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	NEXIUM For Delayed-Release Oral Suspension of (USFDA approved)
	Me-too status	Somezol 40mg Sache M/s Bosch
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections

		" Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	Source of Pellets: Vision
	Decision: Approved with innovator's specification.	
623.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Espasevit 8mg/4ml Injection
	Composition	Each 4ml Ampoule Contains: Ondansetron as Hydrochloride dihydrate…8mg
	Diary No. Date of R& I & fee	Dy.No. 40216 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form -5
	Finished product Specification	USP
	Pack size & Demanded Price	4ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 2 mg/ml Injection of (MHRA approved)
	Me-too status	Doston 8mg Injection by M/s Vision Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
624.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Flagex 400mg Tablet
	Composition	Each Film Coated Contains: Metronidazole…400mg
	Diary No. Date of R& I & fee	Dy.No. 41603 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's x 10's, 10's x 10, 50's x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Flagyl tablet of (MHRA approved)
	Me-too status	Flagyl tablet of M/s Sanofi Aventis
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
625.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Flagex 200mg/5ml Suspension
	Composition	Each 5ml Contains: Metronidazole Benzoate Eq. to Metronidazole…200mg
	Diary No. Date of R& I & fee	Dy.No. 41091 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antiprotozoal/Antiinfective/Antiamebic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	60ml, 90ml, 120ml, & 450ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Mogel 200mg Suspension of M/s Metro Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval

		of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
626.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Epilap 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Dy.No. 41581 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Nurosa 100mg Table M/s Helix Pharma
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
627.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Epilap 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…200mg
	Diary No. Date of R& I & fee	Dy.No. 41569 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 14's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Nurosa 200mg Table M/s Helix Pharma
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
628.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Artex 0.4mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Naloxone HCL…0.4mg
	Diary No. Date of R& I & fee	Dy.No. 40223 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Opioid antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, 10's, 100's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status	NALOXONE INJECTION 0.4MG of M/s REHMAN MEDICINES CO (Reg.# 019587)

	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
629.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Evotex 2.5mg/5ml Liquid Syrup
	Composition	Each 5ml Contains: Levocetirizine dihydrochloride…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 41066 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacture's specification
	Pack size & Demanded Price	30ml, 60ml, 120ml ;As per SRO
	Approval status of product in Reference Regulatory Authorities	Xyzal of (USFDA approved)
	Me-too status	Concidol-L Syrup of M/s Convell Laboratories
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
630.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Alpha Plus 2mcg/ml Oral Drops
	Composition	Each ml Contains: Alfacalcidol…2mcg
	Diary No. Date of R& I & fee	Dy.No. 41126 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Vitamin D Analogue
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	One-Alpha of MHRA approved
	Me-too status	Vitamin D Analogue
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
631.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Arizol 15mg Tablet
	Composition	Each Tablet Contains: Aripiprazole…….15mg
	Diary No. Date of R& I & fee	Dy.No. 41579 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Abilify uncoated of USFDA approved.

	Me-too status	Mactril Tablet 15mg of M/s Wilshire Laboratories
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	Firm change formulation from film coated to uncoated tablet with submission of fee of Rs: 5000/- Deposit slip No# 2017880, Dated:19-02-2020
	Decision: Approved.	
632.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Brutex 100mg/5ml Liquid Suspension
	Composition	Each 5ml Contains: Ibuprofen…100mg
	Diary No. Date of R& I & fee	Dy.No. 41079 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	60ml, 90ml,120ml, 450ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ibuprofen of MHRA approved
	Me-too status	Brufen Oral Suspension by M/s Abbot Laboratories
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
633.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Brutex 200mg/5ml DS Liquid Suspension
	Composition	Each 5ml Contains: Ibuprofen…200mg
	Diary No. Date of R& I & fee	Dy.No. 41092 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	NSAID, Antipyretic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 90ml,120ml, 450ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	IBuprofen 200mg/5ml Oral Suspension of MHRA approved
	Me-too status	Kata-DS Suspension M/s Cibex Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
634.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fenorate 67mg Capsule
	Composition	Each Capsule Contains: Fenofibrate…67mg
	Diary No. Date of R& I & fee	Dy.No. 41058 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipid Regulating agent
	Type of Form	Form 5
	Finished product Specification	USP

	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Fenofibrate 67mg Capsule of (MHRA approved)
	Me-too status	Corfibrate 67mg Capsule by M/s OBS
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	Physical form of API either micronized or not could not be confirmed.
	Decision: Deferred for the clarification of Physical form of API either micronized or not could not be confirmed.	
635.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fenorate 200mg Capsule
	Composition	Each Capsule Contains: Fenofibrate…200mg
	Diary No. Date of R& I & fee	Dy.No. 41117 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipid Regulating agent
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipantil Micro 200 mg, capsules of (MHRA approved)
	Me-too status	Felip 200mg Capsule of M/s Bosch Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	Physical form of API either micronized or not could not be confirmed.
	Decision: Deferred for the clarification of Physical form of API either micronized or not could not be confirmed.	
636.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Hemorox 150mg Capsule
	Composition	Each Capsule Contains: Iron Polysaccharide Complex Eq. to Elemental Iron…50mg
	Diary No. Date of R& I & fee	Dy.No. 41082 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-anaemic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Fastcure 150mg Capsule of M/s Faas Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
637.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Actim 800mg Tablet

	Composition	Each Film Coated Tablet Contains: Piracetam……..800mg
	Diary No. Date of R& I & fee	Dy.No. 41574 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, 60's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Nootropil 800 mg film-coated tablets of MHRA approved
	Me-too status	Cibrotam Tablets 800mg of M/s Visio Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
638.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Baclo 10mg Tablet
	Composition	Each Tablet Contains: Baclofen……..10mg
	Diary No. Date of R& I & fee	Dy.No. 41592 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Muscle Relaxant and antispastic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	3 x 10's, 6 x 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Baclofen of (MHRA approved)
	Me-too status	Baclin Tablets Of M/S Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
639.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bupon SR 150mg Tablet
	Composition	Each Sustained Release Film Coated Tablet Contains: Bupropion Hydrochloride…150mg
	Diary No. Date of R& I & fee	Dy.No. 41598 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antidrepressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 20's, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	WELLBUTRIN XL of USFDA approved ACT BUPROPION XL 150mg tablets of Canada approved
	Me-too status	Prop Ropion SR 150mg of M/S Searle Pak
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	In reference (diffusion controlled tablets) membrane control system to sustain the tablet ,while firm use matrix control system.. Firm did not revise its master formulation and method of manufacturing.

	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities	
640.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bupon SR 300mg Tablet
	Composition	Each Sustained Release Film Coated Tablet Contains: Bupropion Hydrochloride…300mg
	Diary No. Date of R& I & fee	Dy.No. 41571 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antidrepressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 20's, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	WELLBUTRIN XL of USFDA approved ACT BUPROPION XL300mg tablets of Canada approved.
	Me-too status	Propin SR 300mg of M/S Genix Pharma
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	In reference (diffusion controlled tablets) membrane control system to sustain the tablet ,while firm use matrix control system.. Firm did not revise its master formulation and method of manufacturing.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities	
641.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Diaend 2mg Capsule
	Composition	Each Capsule Contains: Loperamide Hydrochloride…2mg
	Diary No. Date of R& I & fee	Dy.No. 41114 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antidiarrheal Agent
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 50's, 60's, 100's As per SRO
	Approval status of product in Reference Regulatory Authorities	Imodium Classic 2 mg Capsules. of MHRA approved
	Me-too status	Repol Capsules of M/S Genome Pharmaceutical
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
642.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Clozox 25mg Tablet
	Composition	Each Tablet Contains: Clozapine…….25mg
	Diary No. Date of R& I & fee	Dy.No. 41572 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Denzapine 25 mg Tablets of MHRA approved

	Me-too status	Zydex -25 Tablets of M/S Genome Pharmaceutical
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16,new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	Firm change formulation from film coated to uncoated tablet with submission of fee of Rs: 5000/- Deposit slip No# 2017878, Dated:19-02-2020
	Decision: Approved.	
643.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Clozox 100mg Tablet
	Composition	Each Tablet Contains: Clozapine…….100mg
	Diary No. Date of R& I & fee	Dy.No. 41597 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, 5 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Denzapine 100 mg Tablets of MHRA approved
	Me-too status	Zydex -100 Tablets of M/S Genome Pharmaceutical
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	Firm change formulation from film coated to uncoated tablet with submission of fee of Rs: 5000/- Deposit slip No# 2017879, Dated:19-02-2020
	Decision: Approved.	
644.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Flerox 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Cyclobenzaprine HCL…10mg
	Diary No. Date of R& I & fee	Dy.No. 41564 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Muscle relaxant, Centrally acting agent
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30,s: As per SRO
	Approval status of product in Reference Regulatory Authorities	Flexeril 10mg Tablets of USFDA approved
	Me-too status	Dysoprin Tablets 10mg of M/S Dyson Research Labs.
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
645.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Finride 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Finasteride……5mg
	Diary No. Date of R& I & fee	Dy.No. 41533 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	5-Alpha reductase Inhibitor

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 42's, 56's, 84,s: As per SRO
	Approval status of product in Reference Regulatory Authorities	PROSCAR 5mg Tablets of USFDA approved
	Me-too status	Prostryl Tablets 5mg of M/S Novins International
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved. Firm will follow protective measures for workers.	
646.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Deox 250mg/5ml Liquid Suspension
	Composition	Each 5ml Contains: Ursodeoxycholic Acid…250mg
	Diary No. Date of R& I & fee	Dy.No. 41118 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Bile-acid
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	60ml, 120ml /As per SRO
	Approval status of product in Reference Regulatory Authorities	Ursofalk 250mg/5ml Suspension Of MHRA Approved
	Me-too status	Urso Suspension by AGP (Reg. No. 076152)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
647.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cita-P 1mg/5ml Liquid Syrup
	Composition	Each 5ml Contains: Cinitapride Acid Tartrate Eq. to Cinitapride…1mg
	Diary No. Date of R& I & fee	Dy.No. 41084 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Gastrointestinal prokinetic
	Type of Form	Form-5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	60ml, 120ml /As per SRO
	Approval status of product in Reference Regulatory Authorities	Cidine 1 mg / 5 ml Oral solution by ALMIRALL, SA (Spain Approved)
	Me-too status	Cidine of M/s Highnoon (Reg. No. 069457)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
648.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Divel 250mg/5ml Syrup
	Composition	Each 5ml Contains: Divalproex Sodium Eq. to Valporic Acid…250mg
	Diary No. Date of R& I & fee	Dy.No. 41112 dated 06-12-2018 Rs.20,000/- 06-12-2018

	Pharmacological Group	Antiepileptics
	Type of Form	Form-5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	60ml, 120ml /As per SRO
	Approval status of product in Reference Regulatory Authorities	Valproic Acid of USFDA approved
	Me-too status	Epinil 250mg Syrup of M/s Platinum Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16,new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
649.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Galon-4 4mg/5ml Oral Solution
	Composition	Each 5ml Contains: Galantamine as Hydrobromide…4mg
	Diary No. Date of R& I & fee	Dy.No. 41099 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anticholinesterases
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 120ml /As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by Registration Board in 275th meeting • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
650.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fortycin 1gm IV Injection
	Composition	Each Vial Contains: Sterile Powder of Fosfomycin Sodium Eq. to Fosfomycin Sodium…1gm
	Diary No. Date of R& I & fee	Dy.No. 40209 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	FOSFOCINE 1 g IV, powder for solution for infusion of ANSM france approved
	Me-too status	Fosfomycin Sodium Injection Of M/S United International,
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report

		concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Deferred for confirmation of manufacturing facility.	
651.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Douro 12.5mg/ml Injection (20ml)
	Composition	Each ml Contains: Dobutamine Hcl Eq. to Dobutamine…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 40218 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Sympathomimetics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20ml x 1's, 20ml x 5's, & 20ml x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Dobutamine 12.5 mg/ml concentrate for solution for infusion of MHRA approved
	Me-too status	Dobutamine Injection 250mg of Haji medicine (Reg#027345)
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
652.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Flunate 25mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Fluphenazine Deconate…25mg
	Diary No. Date of R& I & fee	Dy.No. 41095 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antipsychotic agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1ml x 5's, 1ml x 5's, 1ml x 10's, 1ml x 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Fluphenazine Deconate of USFDA approved
	Me-too status	Xzine Injection of M/s Global Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	Master formula and method of manufacturing not submitted in line with reference product(sesame oil as vehicle in reference).
	Decision: Registration Board deferred for submission of method of manufacturing as per Innovator's formulation.	
653.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Drotex 40mg/2ml Injection
	Composition	Each 2ml Contains: Drotaverine Hydrochloride…40mg
	Diary No. Date of R& I & fee	Dy.No. 41098 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications

	Pack size & Demanded Price	2ml x 25's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Three European countries Bulgaria**,** Romania**,** Hungary
	Me-too status	Hi-Spa 40mg/2ml Injection of M/s Helix
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
654.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gratex 3mg/3ml Injection
	Composition	Each 3ml Ampoule Contains: Granisetron as Hydrochloride…3mg
	Diary No. Date of R& I & fee	Dy.No. 41096 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	5HT3-antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3ml x 1's, 3ml x 5's, 3ml x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Granisetron 1mg/ml concentrate for solution for injection or infusion (MHRA approved)
	Me-too status	Xzine Injection of M/s Global Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
655.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Burok-F Rotacaps
	Composition	Each Rotacap Contains: Budesonide…100mcg Formoterol Fumarate…6mcg
	Diary No. Date of R& I & fee	Dy.No. 41074 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Adrenergics, Inhalants (Adrenergics in combination with corticosteroids or other drugs, excl. Aticholinergics)
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Symbicort 100/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Venticort Rotacaps 100mcg+6mcg Capsule of M/s Macter Intr.
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	**Section for DPIs is not available.** Evidence of rotacaps is not found in Reference Regulatory Authorities. This formulation is available as Symbicort available in a multidose inspiratory flow driven, metered dose dry powder inhaler (Turbuhaler).
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	

656.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Burok-F Rotacaps
	Composition	Each Rotacap Contains: Budesonide…200mcg Formoterol Fumarate…6mcg
	Diary No. Date of R& I & fee	Dy.No. 41076 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Adrenergics, Inhalants (Adrenergics in combination with corticosteroids or other drugs, excl. Aticholinergics)
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Symbicort 200/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Venticort Rotacaps 200mcg+6mcg Capsule of M/s Macter Intr.
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	**Section for DPIs is not available.** Evidence of rotacaps is not found in Reference Regulatory Authorities. This formulation is available as Symbicort available in a multidose inspiratory flow driven, metered dose dry powder inhaler (Turbuhaler).
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
657.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Paratine CR 12.5mg Tablet
	Composition	Each Enteric, film Coated Controlled Release Tablet Contains: Paroxetine as Hydrochloride…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 33476 dated 09-10-2018 Rs.20,000/- 14-09-2018
	Pharmacological Group	Selective serotonin-reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR of (USFDA approved)
	Me-too status	Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
658.	Name and address of manufacturer / Applicant	**M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi**
	Brand Name +Dosage Form + Strength	Paratine CR 25mg Tablet
	Composition	Each Enteric, film Coated Controlled Release Tablet Contains: Paroxetine as Hydrochloride…..25mg
	Diary No. Date of R& I & fee	Dy.No. 33477 dated 09-10-2018 Rs.20,000/- 14-09-2018
	Pharmacological Group	Selective serotonin-reuptake inhibitors

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR of (USFDA approved)
	Me-too status	Panox CR Tablet 25 mg M/s Regal Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
659.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Lincovant 500mg Capsule
	Composition	Each Capsule Contains: Lincomycin Hydrochloride Monohydrate Eq. to Lincomycin…500mg
	Diary No. Date of R& I & fee	Dy.No. 41423 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lincocine 500 mg Capsule by M/s Pfizer Holding France (ANSM approved)
	Me-too status	F-Linco 500mg capsule by M/s Fresh Pharmaceuticals
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	The USP has specified Raman spectroscopy for dissolution study of Lincomycin capsules. However, upon clarification, the firm did not provide proof of provision of Raman Spectrophotometer
	Decision: Deferred for confirmation of required equipment i.e. Raman spectroscopy.	
660.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Prevant 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R& I & fee	Dy.No. 41429 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

661.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals.Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Laviga Capsule 50mg
	Composition	Each hard gelatin capsule contains: Pregabalin…….50mg
	Diary No. Date of R& I & fee	Dy.No 40719 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's, , 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma
	GMP status	Panel Inspection for renewal of DML conducted on 12-11-2018 & 02-01-2019 unanimously recommends the renewal of DML for Crystolite Islamabad for following sections. 1- Tablet section (gen) 2- Capsule section (gen) 3- Cream/ointment section (gen) 4- Topical lotion section (gen) 5- Cream/Ointment section (steroid) 6- Topical lotion section (steroid) 7- Oral Sachet (gen) 8- Soft gelatin capsule (gen) 9- Syrup section (gen)
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
662.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals.Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ceetalite 250mg Tablets
	Composition	Each Film Coated Tablet Contains: Levetiracetam……250mg
	Diary No. Date of R& I & fee	Dy.No 40722 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's : RS: 40/- tablet
	Approval status of product in Reference Regulatory Authorities	Levetiracetam zentiva 250 mg of MHRA approved
	Me-too status	Levep 250mg Tablet by Hilton Pharma (Reg. No. 053348)
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
663.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ceetalite 500mg Tablets
	Composition	Each Film Coated Tablet Contains: Levetiracetam……500mg
	Diary No. Date of R& I & fee	Dy.No 40723 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's : RS: 65/- tablet
	Approval status of product in Reference Regulatory Authorities	Levetiracetam zentiva 500 mg of MHRA approved
	Me-too status	Levep 500mg Tablet by Hilton Pharma (Reg.No. 053349)

	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
664.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals.Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Q-Win 100mg Tablets
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…100mg
	Diary No. Date of R& I & fee	Dy.No. 40721 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Nubaquel 100mg Tablet of M/s Nabiqasim
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
665.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Tiraline 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Sertraline as Hydrochloride…100mg
	Diary No. Date of R& I & fee	Dy.No. 40720 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti depressant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zoloft Tablet Of (USFDA Approved)
	Me-too status	Ertalin 100 mg Tablets M/s Genome Pharmaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
666.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Speridon 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone…1mg
	Diary No. Date of R& I & fee	Dy.No. 40724 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Sedative
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 1mg of (MHRA approved)
	Me-too status	Rislet 1mg Tablet M/s. High-Q Pharmaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
667.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Flowmax-D Capsule
	Composition	Each Capsule Contains: Dutasteride (Soft gelatin capsule)…0.5mg

		Tamsulosin HCL (Extended release pellets)…0.4mg
	Diary No. Date of R& I & fee	Dy.No. 41071 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Drugs Used In Benign Prostatic Hyperplasia
	Type of Form	Form 5
	Finished product Specification	Manufacturers specification
	Pack size & Demanded Price	7's, 1 x 10's, 2 x 10's, 3 x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Combodart 0.5 mg / 0.4 mg hard capsules of MHRA approved
	Me-too status	BPH CapsulesOf M/S CCL
	GMP status	Last GMP inspection conducted on 19 -09-2018 And report concludes that panel Unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of Inspection report is rated as Good".
	Remarks of the Evaluator[IV]	• Source of tamsulosin pellets: Vision • Source of dutasteride (soft gel) capsule: Novel Pharmaceuticals Laboratories, Indonesia • Fee of Rs: 100000/- for Dutasteride 0.5mg (soft gel) submitted through deposit slip# 2017864 Dated: 07-02-2020 • Accelerated stability studies for 6 month & Long term Stability studies for 12 months according to Zone IV-A of dutasteride soft gel capsules for 3 batches submitted. • Certificate of analysis of dutasteride soft gelatin capsule submitted. • For Manufacturing facility and equipment for manufacturing, firm reply that they modified their semiautomatic hard gelatin capsule filling machine for encapsulation of soft gel capsule of dutasteride and tamsulosin HCl SR pellets. • Original legalized COPP not submitted. • GMP certificate of Source of dutasteride soft gelatin capsule not submitted • Complete method of manufacturer of • tamsulosin and dutasteride soft gel capsule into final dosage form not submitted.
	Decision: Deferred for following: • **Original legalized COPP of dutasteride soft gelatin capsule** • **GMP certificate of Source of dutasteride soft gelatin capsule** • **Complete method of manufacturer of tamsulosin and dutasteride soft gel capsule into final dosage form**	
668.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Telzide 40/12.5mg Tablet
	Composition	Each of bi-layered Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No. 42068 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's & 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)

	Me-too status	Cresar–H 40/12.5mg Tablet of M/S Tabros Pharma
	GMP status	Last GMP inspection conducted on 11-01-2019 and report concludes that panel recommend the renewal of DML.
	Remarks of the Evaluator[IV]	Applied formulation is film coated tablet while Innovator product is bilayered uncoated tablet. In reply firm revised their formulation without submission of fee and said that it is a typographical error and mistakenly typed For evidence of bi-layered machine firm replied that they are already manufacturing bi-layered tablet Lopizan (Clopidogrel 75mg & Aspirin 75mg)
	Decision: Deferred for submission of fee for revision of formulation and confirmation of bi-layered tablet machine.	
669.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Folan 6/25mg Capsules
	Composition	Each Capsule Contains: Fluoxetine as HCL…25mg Olanzapine…6mg
	Diary No. Date of R& I & fee	Dy.No. 42064 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antidepressant, Anti-Psychotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's; As per PRC
	Approval status of product in Reference Regulatory Authorities	SYMBYAX capsule Of (USFDA Approved)
	Me-too status	Olanzo – F 6/25 Capsule by M/s Regal Pharmaceuticals
	GMP status	Last GMP inspection conducted on 11-01-2019 and report concludes that panel recommend the renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
670.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Telmine 5/40mg Tablet
	Composition	Each of bi-layered Tablet Contains: Amlodipine as besylate…5mg Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy.No. 42066 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Telam 40mg/5mg Tablet of M/s Macter
	GMP status	Last GMP inspection conducted on 11-01-2019 and report concludes that panel recommend the renewal of DML.
	Remarks of the Evaluator[IV]	Applied formulation is film coated tablet while Innovator product is bilayered uncoated tablet. In reply firm revisedtheir formulation without submission of fee and said that it is a typographical error and mistakenly typed For evidence of bi-layered machine firm replied that they are already manufacturing bi-layered tabler Lopizan (Clopidogrel 75mg & Aspirin 75mg)
	Decision: Deferred for submission of fee for revision of formulation and confirmation of bi-layered tablet machine.	

671.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Telmine 5/80mg Tablet
	Composition	Each of bi-layered Tablet Contains: Amlodipine as besylate…5mg Telmisartan…80mg
	Diary No. Date of R& I & fee	Dy.No. 42065 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Telam 80mg/5mg Tablet of M/s Macter
	GMP status	Last GMP inspection conducted on 11-01-2019 and report concludes that panel recommend the renewal of DML.
	Remarks of the Evaluator[IV]	Applied formulation is film coated tablet while Innovator product is bilayered uncoated tablet. In reply firm revised their formulation without submission of fee and said that it is a typographical error and mistakenly typed For evidence of bi-layered machine firm replied that they are already manufacturing bi-layered tabler Lopizan (Clopidogrel 75mg & Aspirin 75mg)
	Decision: Deferred for submission of fee for revision of formulation and confirmation of bi-layered tablet machine.	
672.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Naptan 85/500mg
	Composition	Each film coated Tablet Contains: Sumatriptan succinate eq to Sumatriptan…85mg Naproxen Sodium eq to Naproxen…500mg
	Diary No. Date of R& I & fee	Dy.No. 42067 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	5 HT receptor, NSAID
	Type of Form	Form- 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	2's, 6's, 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	TREXIMET 85/500 mg of USFDA Approved
	Me-too status	Imtaxen Tablet of M/s Shaigan Pharmaceuticals
	GMP status	Last GMP inspection conducted on 11-01-2019 and report concludes that panel recommend the renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
673.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar By M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Citil 250mg/2ml Injection
	Composition	Each Ampoule (2ml) Contains: Citicoline as Sodium…250mg
	Diary No. Date of R& I & fee	Dy.No. 39861 dated 04-12-2018 Rs.50,000/- 30-11-2018
	Pharmacological Group	Psychostimulants, Agents Used For ADHD And Nootropics (Other psychostimulants and nootropics)
	Type of Form	Form 5
	Finished product Specification	Manufacturers specification

	Pack size & Demanded Price	2ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	ITICOLINE PANPHARMA 250 mg/ 2ml, solution injectable (IM,IV) ampoule by M/s PANPHARMA (ANSM, France Approved)
	Me-too status	Neurotec Injection. 250mg/2ml by M/s Schazoo Laboratories,
	GMP status	Last GMP inspection of welmark conducted on 04-09-2018 & 26-09-2018 and report concludes overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation." & Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	Number of sections of applicant approved by Licensing Board : 09 Number of products already registered/approved on contract manufacturing in the name of applicant: 05
	Decision: Approved with innovator's specification.	
674.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Ethin 2mg/35mcg Tablets
	Composition	Each Film Coated Tablet Contains: Cyproterone Acetate…2mg Ethinyloestradiol…35mcg
	Diary No. Date of R& I & fee	Dy.No. 41776 dated 07-12-2018 Rs.50,000/- 07-12-2018
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specificartions
	Pack size & Demanded Price	3 x 7's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-cyprindiol 2000/35 microgram Film-coated Tablets of MHRA approved
	Me-too status	Acne-Heal Tablet by M/s OBS (Reg# 073476)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator[IV]	Tablet hormone section available (but steroidal or non steroidal not confirm and Steroidal hormone tablet section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Decision: Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
675.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore

	Brand Name +Dosage Form + Strength	MC-Day Tablets 5mg
	Composition	Each Tablet Contains: Norethisterone Acetate…5mg
	Diary No. Date of R& I & fee	Dy.No. 41774 dated 07-12-2018 Rs.50,000/- 07-12-2018
	Pharmacological Group	Progestogen
	Type of Form	Form -5
	Finished product Specifications	BP
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Primolut N of MHRA approved
	Me-too status	Postpon-M Tablet by M/s OBS, (Reg# 073532)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator[IV]	Tablet hormone section available (but steroidal or nonsteriodal not confirm and Steriodal hormone section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Decision: Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
676.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Ster 25mg Tablets
	Composition	Each Tablet Contains: Mesterolon…25mg
	Diary No. Date of R& I & fee	Dy.No. 41773 dated 07-12-2018 Rs.50,000/- 07-12-2018
	Pharmacological Group	Androgen (5-androstanon (3) derivative)
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	2 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Pro-viron of MHRA approved
	Me-too status	Androviron 25mg Tablets by M/s Global (Reg# 030471)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator[IV]	Tablet hormone section available (but steroidal or nonsteriodal not confirm and Steriodal hormone section is required) Number of sections of applicant approved by Licensing Board : 05

		Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Decision: Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
677.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Lone 2.5mg Tablets
	Composition	Each Tablet Contains: Tibolone…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 41775 dated 07-12-2018 Rs.50,000/- 07-12-2018
	Pharmacological Group	Estrogens
	Type of Form	Form -5
	Finished product Specifications	BP
	Pack size & Demanded Price	3 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Livial 2.5 mg tablets of MHRA approved
	Me-too status	Tibopause Tablets 2.5mg by M/s Zafa Pharmaceuticals (Reg# 024213)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator[IV]	Tablet hormone section available (but steroidal or nonsteriodal not confirm and Steriodal hormone section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Decision: Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
678.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Nest 500mcg Tablet
	Composition	Each Tablet Contains: Lynestrenol …500mcg
	Diary No. Date of R& I & fee	Dy.No. 41772 dated 07-12-2018 Rs.50,000/- 07-12-2018
	Pharmacological Group	Progestogen
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	3 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Exluton, 0.5 mg tablet by M/s N.V. Organon (Netherland approved)
	Me-too status	Minipyl 500mcg Table by M/s Zafa Pharmaceuticals (Reg# 081463)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant

		of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator[IV]	Tablet hormone section available (but steroidal or nonsteriodal not confirm and Steriodal hormone section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Decision: Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
679.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura By: M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Ges 0.02mg/0.075mg Tablets
	Composition	Each Film Coated Tablet Contains: Ethinylestradiol…0.2mg Gestodene…0.075mg
	Diary No. Date of R& I & fee	Dy.No. 41771 dated 07-12-2018 Rs.50,000/- 07-12-2018
	Pharmacological Group	Hormonal contraceptives for systemic use (Progestogens and estrogens, fixed Combinations)
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	21's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Aidulan 20/75 microgram film-coated tablets of MHRA approved
	Me-too status	Meliane Tablets of M/s Medipharm Reg# 024076
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator[IV]	Tablet hormone section available (but steroidal or nonsteriodal not confirm and Steriodal hormone section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Decision: Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
680.	Name and address of manufacturer / Applicant	M/s Karsons Pharmaceuticals.Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad BY: M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road
	Brand Name +Dosage Form + Strength	Piptex 2.25gm Injection
	Composition	Each Vial Contains: Piperacillin as sodium …2gm

		Tazobactam as sodium...0.25gm
	Diary No. Date of R& I & fee	Dy.No. 39679 dated 03-12-2018 Rs.50,000/- 03-12-2018
	Pharmacological Group	Penicillin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN 2.25 g of US-FDA approved
	Me-too status	Tanzo Injection of M/s Bosch Pharmaceutical,
	GMP status	Last GMP inspection conducted on 17-12-2019 and report concludes that : Keeping in view the stated observations during inspection,areas visited, documents reviewed it is concluded that firm requires ti improve the Pharmaceutical Qulaity System in general. However, in the opininon of the undersigned basic elements of GMP compliance reference to the schedule B-II are in place and complied with & Certificate of GMP Issued on 17 & 18-01-2019.
	Remarks of the Evaluator[IV]	• Number of sections of applicant approved by Licensing Board :04 • Number of products already registered/approved on contract manufacturing in the name of applicant:06 • Dry powder injection (penicillin) section of M/s English Pharmaceutical available
	Decision: Approved.	
681.	Name and address of manufacturer / Applicant	M/s Karsons Pharmaceuticals.Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad BY M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road
	Brand Name +Dosage Form + Strength	Piptex 4.5gm Injection
	Composition	Each Vial Contains: Piperacillin as sodium ...4gm Tazobactam as sodium...0.5gm
	Diary No. Date of R& I & fee	Dy.No. 39680 dated 03-12-2018 Rs.50,000/- 03-12-2018
	Pharmacological Group	Penicillin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOSYN 4.5 g of US-FDA approved
	Me-too status	Tanzo Injection of M/s Bosch Pharmaceutical,
	GMP status	Last GMP inspection conducted on 17-12-2019 and report concludes that : Keeping in view the stated observations during inspection,areas visited, documents reviewed it is concluded that firm requires ti improve the Pharmaceutical Qulaity System in general. However, in the opininon of the undersigned basic elements of GMP compliance reference to the schedule B-II are in place and complied with & Certificate of GMP Issued on 17 & 18-01-2019.
	Remarks of the Evaluator[IV]	• Number of sections of applicant approved by Licensing Board :04 • Number of products already registered/approved on contract manufacturing in the name of applicant:06 • Dry powder injection (penicillin) section of M/s

		English Pharmaceutical available
	Decision: Approved.	
682.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Myxzine Tulle
	Composition	Each Gauze Tulle Contains: Polymyxin B Sulphate…10,000 IU/gm Bacitracin Zinc…500 iu/gm
	Diary No. Date of R& I & fee	Dy.No. 26422 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10cm x 10cm x 10's 15cm x 20cm x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 23-02-2018 & 26-02-2018and report concludes that firm has maintained a satisfactory level of GMP compliance."
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) along with registration number, brand name and name of firm
	Decision: Registration Board deferred the case for further deiberation	
683.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals.Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ricofib 5mg/145mg Tablet
	Composition	Each film-coated tablet contains: Rosuvastatin (as Calcium)……5mg Fenofibrate……....145mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :30-12-2014 ; Rs.50,000/- (Duplicate)
	Pharmacological Group	HMG-Coa Reductase Inhibitor, Fibrate
	Type of Form	Form-5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the cGMP
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by Registration Board in 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies**	

	which were declared/approved by the Registration Board.	
684.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Mebcap 200mg MR Capsule
	Composition	Each Modified Release Capsule Contains: Mebeverine HCL as SR Pellets…200mg
	Diary No. Date of R& I & fee	Dy.No 7894 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	10's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Mebever MR capsule of M/s Getz Pakistan (050747)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Source of pellets: Surge laboratoried
	Decision: Approved with innovator's specification.	
685.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	GT-CIP 125mg Suspension
	Composition	Each 5ml contains: Ciprofloxacin (as taste mask granules 35%)…125mg
	Diary No. Date of R& I & fee	Dy.No 5306 dated 14-02-2018 Rs. 20,000/- 14-02-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cipro 250mg/5ml of USFDA approved
	Me-too status (with strength and dosage form)	Novidate 125mg/5ml Dry Suspension of M/s Sami Pharmaceuticals
	GMP status	Last GMP inspection conducted on 08-08-2017, and the report concludes that the firm maintained confirmance to GMP compliance.
	Remarks of the Evaluator[IV]	• GMP certificate of source of granules not provided • Stability study of 3 batches of granules not provided • Certificate of analysis of granules not provided. • Clarify it is ciprofloxacin HCl granules or only ciprofloxacin
	Decision: Deferred for source of granules, along with stability studies data, GMP certificate of supplier and differential fee in case of import of granules.	
686.	Name and address of manufacturer / Applicant	M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Coagbon 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…..…10mg
	Diary No. Date of R& I & fee	Dy.No. 17066 dated 08-05-2018 Rs.20,000/- 08-05-2018
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer,s specification
	Pack size & Demanded Price	10's, 14's 20's & 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 10mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 10mg Tablet Of M/S Bayer

	GMP status	Last GMP inspection conducted on 19-05-2017. And report concludes that overall firm has fair GMP compliance
	Remarks of the Evaluator[IV]	Covering letter and challan form of different product submitted.
	Decision: Deferred for submission of fee.	
687.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Param Injection
	Composition	Each 2ml Vial Contains: Paracetamol…300mg
	Diary No. Date of R& I & fee	Dy.No. 1063 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Pharmacological Group	Analgesic/Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 (2ml) x 05's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Fermol 300 mg Injection of Caraway Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 15-09-2017 and report concludes firm was Overall the firm was GMP Compliant as per DRAP Guidelines."
	Remarks of the Evaluator[IV]	Firm initially applied Each 2ml Vial Contains: Paracetamol…300mg Now firm change its formulation with revised form-5, master formulation along with method of manufacturing Fee for revision of Rs: 20000/- Deposit slip No #2002911 , Dated: 15-04-2020 Now applied formulation is as follows Param 1000mg/100mlInfusion Each 100ml contains: Paracetamol…….1000mg(10mg/ml) Reference regulatory authority status: Paracetamol 10mg/ml Solution for Infusion of MHRA approved Me-Too status: Paedal Infusion of M/S Regal Pharmaceutical
	Decision: Approved with innovator's specification As following: **Param 1000mg/100mlInfusion** **Each 100ml contains:** **Paracetamol…….1000mg(10mg/ml)**	
688.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Amika 50mg/2ml Injection
	Composition	Each Vial (2ml) Contains: Amikacin as Sulfate…50mg
	Diary No. Date of R& I & fee	Dy.No. 1100 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Grasil Of Sami Pharmaceuticals (Pvt) Ltd.
	GMP status	Last GMP inspection conducted on 15-09-2017 and report concludes firm was Overall the firm was GMP Compliant as per DRAP Guidelines."

	Remarks of the Evaluator[IV]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
689.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Telmi-H 40/12.5mg Tablet
	Composition	Each Bilayered Tablet Contains: Telmisartan…….40mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy.No. 1099 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2 x 7's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 40/12.5mg Tablet of M/S Tabros Pharma
	GMP status	Last GMP inspection conducted on 15-09-2017 and report concludes firm was Overall the firm was GMP Compliant as per DRAP Guidelines."
	Remarks of the Evaluator[IV]	Bilayered compression machine evidence not provided.
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.	
690.	Name and address of manufacturer / Applicant	M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan
	Brand Name +Dosage Form + Strength	Omson 40mg Capsule
	Composition	Each Capsule Contains: Omeprazole enteric coated pellets …40mg
	Diary No. Date of R& I & fee	Dy.No. 36407 dated 02-11-2018 Rs.20,000/- 02-11-2018
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2 x 7's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Losec capsule Of (MHRA Approved)
	Me-too status	Losec 40mg capsule by M/s Barrett Hodgson
	GMP status	Last GMP inspection conducted on 19-11-2019.and report concludes that the panel of inspectors recommend the renewal of DML.
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision:Approved	
691.	Name and address of manufacturer / Applicant	M/s Searl Company Limited F-319 SITE Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Nuberol P Injection 300mg/2ml
	Composition	Each 2ml Contains: Paracetamol…..300mg
	Diary No. Date of R& I & fee	Dy.No. 447 dated 03-03-2015 Rs.20,000/- 31-03-2015 (Duplicate dossier)
	Pharmacological Group	Analgesics
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	2ml x 1's : As per SRO

	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Bofalgan 300mg/2ml Injection of M/s Bosch-II. (Reg.# 070616)
	GMP status	GMP certificate issued based on the inspection conducted on 11-07-2019
	Remarks of the Evaluator[IV]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Method of manufacturing not submitted.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
692.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vorix 10mg Tablet
	Composition	Each film coated Tablet Contains: Vortioxetine Hydrobromide Eq. to Vortioxetine…10mg
	Diary No. Date of R& I & fee	Dy.No. 44513 dated 31-12-2018 Rs.20,000/- 31-12-2018
	Pharmacological Group	Antidepressent
	Type of Form	Form-5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRINTELLIX 10 mg of USFDA approved
	Me-too status	Brintellix 10mg Tablet by M/s Lundbeck.
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	The applied drug has been approved as "film coated" while you have applied for the drug without film coating, justification/clarification is required in this required. Otherwise revise your formulation to film coated tablet with submission of requisite fee. Submit stability studies with requisite documents.
	Decision: Registration Board deferred the case for following: • **Deferred for revision of formulation as per reference product along with submission of requisite fee.** • **Submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.**	
693.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Siovena 3gm Sachet
	Composition	Each sachet contains: L-Ornithine L-Aspartate…3g
	Diary No. Date of R& I & fee	Dy.No. 40497 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Hepatoprotectant
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Hepa-Merz Sachet containing ornithine aspartate (granules for solution). AGES approved
	Me-too status	Couthy 3gm Sachet of M/s Martin Dow
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices

	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
694.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lomogin 25mg Tablet
	Composition	Each Tablet Contains: Lamotrigine …..25mg
	Diary No. Date of R& I & fee	Dy.No. 40512 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	LAMICTAL 25mg Tablets (USFDA approved)
	Me-too status	Epictal 25mg Tablet of M/s Bosch
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
695.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lomogin 50mg Tablet
	Composition	Each Tablet Contains: Lamotrigine …..50mg
	Diary No. Date of R& I & fee	Dy.No. 40513 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamicta 50mg (MHRA approved)
	Me-too status	Epictal 50mg Tablet of M/s Bosch
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
696.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lomogin 100mg Tablet
	Composition	Each Tablet Contains: Lamotrigine …..100mg
	Diary No. Date of R& I & fee	Dy.No. 40514 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamicta 100mg (MHRA approved)
	Me-too status	Epictal 100mg Tablet of M/s Bosch
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good

		manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
697.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tarcit 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Cetirizine Dihydrochloride…10mg
	Diary No. Date of R& I & fee	Dy.No. 40501 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's,30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Zirtek tablet of (MHRA approved)
	Me-too status	Serzine 10mg Tablets of M/s Qintar Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
698.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Apritus 40mg Capsule
	Composition	Each Capsule Contains: Aprepitant…….40mg
	Diary No. Date of R& I & fee	Dy.No. 40509 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, 2's / As per SRO
	Approval status of product in Reference Regulatory Authorities	EMEND Capsule of USFDA
	Me-too status	Apritus 40mg Capsule of M/s S.J&G
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
699.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Apritus 80mg Capsule
	Composition	Each Capsule Contains: Aprepitant…….80mg
	Diary No. Date of R& I & fee	Dy.No. 40510 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, 2's / As per SRO
	Approval status of product in Reference Regulatory Authorities	EMEND Capsule of USFDA
	Me-too status	Apritus 80mg Capsule of M/s S.J&G
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating

		at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
700.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Apritus 125mg Capsule
	Composition	Each Capsule Contains: Aprepitant…….125mg
	Diary No. Date of R& I & fee	Dy.No. 40511 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, 2's / As per SRO
	Approval status of product in Reference Regulatory Authorities	EMEND Capsule of USFDA
	Me-too status	Apritus 125mg Capsule of M/s S.J&G
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
701.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Pequit 25mgTablet
	Composition	Each film coated tablet contains: Quetiapine as fumarate eq to Quetiapine…25mg
	Diary No. Date of R& I & fee	Dy.No. 40515 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Nubaquel 25mg Tablet of M/s Nabiqasim
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
702.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Pequit 100mgTablet
	Composition	Each film coated tablet contains: Quetiapine as fumarate eq to Quetiapine…100mg
	Diary No. Date of R& I & fee	Dy.No. 40516 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Nubaquel 100mg Tablet of M/s Nabiqasim
	GMP status	Last GMP inspection conducted on 10-04-18, and the

		report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
703.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Pequit 200mgTablet
	Composition	Each film coated tablet contains: Quetiapine as fumarate eq to Quetiapine…200mg
	Diary No. Date of R& I & fee	Dy.No. 40517 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Nubaquel 200mg Tablet of M/s Nabiqasim
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
704.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Pequit 300mgTablet
	Composition	Each film coated tablet contains: Quetiapine as fumarate eq to Quetiapine…300mg
	Diary No. Date of R& I & fee	Dy.No. 40518 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Pine Tablet 300mg of M/s Werrick Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
705.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Diarin 50mg Capsule
	Composition	Each Capsule Contains: Diacerein…….50mg
	Diary No. Date of R& I & fee	Dy.No. 41488 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Anti- Rheumatic
	Type of Form	Form 5
	Finished product Specification	Manufacturer,s specification
	Pack size & Demanded Price	1's, 10's & 30's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Diacerein Biogaran 50 mg Hard Capsule by M/s Biogaran (ANSM, France approved).
	Me-too status	Dycerin 50mg Capsule of M/s S.J &G. Fazul Ellahie

	GMP status	Last GMP inspection conducted on 10-04-18, and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
706.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Sitawil Tablets 50/500mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate…50mg Metformin HCL …500mg
	Diary No. Date of R& I & fee	Dy.No. 41806 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antihyperglycemic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, & 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet tablets of (TGA approved)
	Me-too status	S-Gliptin Plus Tablets of M/s Barrett Hodgson
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
707.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Sitawil Tablets 50/1000mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate…50mg Metformin HCL …1000mg
	Diary No. Date of R& I & fee	Dy.No. 41807 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antihyperglycemic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, & 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet tablets of (TGA approved)
	Me-too status	Silmax-M 50mg/1000mg Tablet by M/s High-Q Pharma
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
708.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Diagesic DS Tablets 75mg/650mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCL…75mg Paracetamol…650mg
	Diary No. Date of R& I & fee	Dy.No. 41808 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	USP

	Pack size & Demanded Price	10's, 20's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol/Paracetamol 75 mg / 650 mg tablets of MHRA approved
	Me-too status	Tonoflex-P Forte of M/S Sami
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	• The applied drug has been approved as "uncoated" while firm have applied for the drug with "film coating", • Submitt stability data along with requisite documents
	Decision: Deferred for: • **Revision of formulation from uncoated tablet to film coated tablet along with submission of applicable fee.** • **submission of stability study data as per the guidelines provided in 278th meeting of Registration Board**	
709.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Algicon Suspension 1000mg/200mg
	Composition	Each 10ml of suspension contains: Sodium Alginate…1000mg Potassium Hydrogen Carbonate…200mg
	Diary No. Date of R& I & fee	Dy.No. 41803 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antacid
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	90ml, 120ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	Gaviscon Advance Peppermint Flavour of (MHRA approved)
	Me-too status	Gasicol Advance Suspension of M/s Sami Pharmaceutical
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
710.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Sinazin Surup 100mg/2.5mg
	Composition	Each 5ml of syrup contains Carbocisteine …100mg Promethazine HCL…2.5mgs
	Diary No. Date of R& I & fee	Dy.No. 41802 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antacid
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	90ml, 120ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	RHINATHIOL PROMETHAZINE, syrup of ANSM France approved
	Me-too status	Muflex Pro Syrup of M/s Kaizen Pharmaceuticals
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

711.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Butasone Dry Powder Inhaler 100/200mcg
	Composition	Each Capsule Contains: Salbutamol as Sulphate…200mcg Beclomethasone Dipropionate…100mcg
	Diary No. Date of R& I & fee	Dy.No. 40982 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Corticosteroid, Adrenergics Inhalants
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Aerotec-B Rotacaps of M/s Highnoon Laboratories,
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • DPI section could not be confirmed.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Deferred for confirmation of required manufacturing facility / section from Licensing Division.**	
712.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Butasone Dry Powder Inhaler 200/400mcg
	Composition	Each Capsule Contains: Salbutamol as Sulphate…400mcg Beclomethasone Dipropionate…200mcg
	Diary No. Date of R& I & fee	Dy.No. 40983 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Corticosteroid, Adrenergics Inhalants
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Aerotec-B Forte Rotacaps of M/s Highnoon Laboratories,
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • DPI section could not be confirmed.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Deferred for confirmation of required manufacturing facility / section from Licensing Division.**	

713.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Butamol Dry Powder Inhaler 200mcg
	Composition	Each Capsule Contains: Salbutamol…200mcg
	Diary No. Date of R& I & fee	Dy.No. 40984 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Selective beta2-adrenoreceptor agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Aerotec 200 capsules of highnoon Labs (Reg # 044593)
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • DPI section could not be confirmed.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Deferred for confirmation of required manufacturing facility / section from Licensing Division.**	
714.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Agomine 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Agomelatine…25mg
	Diary No. Date of R& I & fee	Dy.No. 41252 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Agomelatine of (MHRA Approved)
	Me-too status	Valdoxan tablet by Servier
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
715.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Orliwrd 60mg Capsule
	Composition	Each Capsule Contains: Orlistat…60mg
	Diary No. Date of R& I & fee	Dy.No. 41255 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipase inhibitor
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Beacita 60mg Capsules of (MHRA approved)

	Me-too status	Orlisat 60mg Capsules by M/s Merck Sharp & Dhome,
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	Source of pellets not provided.
	Decision: Deferred for further deliberation regarding stability data of pellets	
716.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Atowel 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin Calcium Trihydrate Eq. to Atorvastatin…….10mg
	Diary No. Date of R& I & fee	Dy.No. 41248 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Hypolipidamic(Statin)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor tablets by Pfizer (MHRA Approved)
	Me-too status	Lipitor of M/s parke-davis
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
717.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Atowel 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin Calcium Trihydrate Eq. to Atorvastatin…….40mg
	Diary No. Date of R& I & fee	Dy.No. 41249 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Hypolipidamic(Statin)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor tablets by Pfizer (MHRA Approved)
	Me-too status	Lipitor of M/s parke-davis
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
718.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Buspol 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate …….5mg
	Diary No. Date of R& I & fee	Dy.No. 41243 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-hypertensive (Selective B1 adrenergic receptor blocker)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Cardicor 5mg tablet Of (MHRA Approved)

	Reference Regulatory Authorities	
	Me-too status	Biscot 5mg Tablet Of M/S Scotmann Pharmaceuticals,
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
719.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Buspol 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate …….10mg
	Diary No. Date of R& I & fee	Dy.No. 41244 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-hypertensive (Selective B1 adrenergic receptor blocker)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cardicor 10mg tablet Of (MHRA Approved)
	Me-too status	Biscot 10mg Tablet Of M/S Scotmann Pharmaceuticals,
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
720.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Itazol 100mg Capsule
	Composition	Each Capsule Contains: Itraconazole IR Pellets 22%...100mg
	Diary No. Date of R& I & fee	Dy.No. 41247 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	Manufacturer‟s specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Itraconazole 100 mg capsules of(MHRA approved)
	Me-too status	Itrax Capsule by M/s Ferozsons Labs
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Approved with innovator's specification.	
721.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Flowrd 50mg Capsule
	Composition	Each Capsule Contains: Fluconazole…50mg
	Diary No. Date of R& I & fee	Dy.No. 41254 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azocan 50mg capsule Of (MHRA Approved)

	Me-too status	Fiscon Capsules 50mg M/s Fassgen Pharmaceuticals
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
722.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Vigoo 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Vigabatrin…500mg
	Diary No. Date of R& I & fee	Dy.No. 41251 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10' s, As per SRO
	Approval status of product in Reference Regulatory Authorities	Sabril 500 mg film-coated tablets of(MHRA approved)
	Me-too status	Hilgab 500mg Tablet of M/s Hilton Pharma
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
723.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Amide 100mg Tablet
	Composition	Each Uncoated Tablet Contains: Amisulpride…100mg
	Diary No. Date of R& I & fee	Dy.No. 41241 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Dopamine receptor antagonist
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride of (MHRA approved)
	Me-too status	Ampisol 100mg Tablet of M/s Sami
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
724.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Amide 400mg Tablet
	Composition	Each film coated Tablet Contains: Amisulpride……..400mg
	Diary No. Date of R& I & fee	Dy.No. 41242 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Dopamine receptor antagonist
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride of (MHRA approved)
	Me-too status	Phrenic 400mg Tabletsof M/s Sami
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018

		and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	Firm revise formulation from uncoated to film coated with submission of fee of Rs: 5000/- Deposit slip No: 2018385 Dated: 26-02-2020
	Decision: Approved.	
725.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Alendrol Tablet
	Composition	Each Uncoated Tablet Contains: Alendronate Sodium Trihydrate Eq. to Alendronic Acid…70mg Cholecalciferol Eq. to 2800 IU…70mcg
	Diary No. Date of R& I & fee	Dy.No. 41253 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Drugs for treatment of bone diseases (Bisphosphonates)
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FOSAVANCE 70 mg/2,800 IU tablets of MHRA approved
	Me-too status	Osto-D Tablet of M/S Nabiqasim
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
726.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Fudate 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Sodium Fusidate…250mg
	Diary No. Date of R& I & fee	Dy.No. 41245 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-infective
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fucidin 250 mg Tablets of MHRA approved
	Me-too status	Pandate 250mg Tablets of M/S Panacea Pharmaceuticals
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
727.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Otomide 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Otilonium Bromide…40mg
	Diary No. Date of R& I & fee	Dy.No. 41235 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Synthetic anticholinergics, quaternary ammonium compounds
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Otilonio Teva 40 mg tablets of Spain approved

	Reference Regulatory Authorities	
	Me-too status	Otomin Tablet by Genome Pharma (Reg # 059407)
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
728.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Parowrd 10mg/ml Injection
	Composition	Each ml Contains: Paracetamol……..10mg
	Diary No. Date of R& I & fee	Dy.No. 41257 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Analgesic, Antipyretic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Paracetamol 10mg/ml Solution for Infusion of MHRA approved
	Me-too status	Paedal Infusion of M/S Regal Pharmaceutical
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	Type of primary packaging not mentioned.
	Decision: Deferred for clarification regarding type of primary packaging material.	
729.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Faltose 50mg/ml Injection
	Composition	Each ml Contains: Iron as Ferric Carboxymaltose…….50mg
	Diary No. Date of R& I & fee	Dy.No. 41258 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	15ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Injectafer 750 mg iron / 15 mL of USFDA approved
	Me-too status	Ferinject Injectabl of M/s R.GPharmaceutica (Reg#072548) (10ml)
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	• Type of primary packaging not mentioned. • Evidence of applied formulation/drug in 15ml already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Clarification regarding type of primary packaging material.** • **Evidence of applied formulation/drug in 15ml already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
730.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Eztatin 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Ezetimibe…10mg Atorvastatin Calcium Eq. to Atorvastatin…20mg

	Diary No. Date of R& I & fee	Dy.No. 41238 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipid lowering Agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Liptruzet of USFDA approved
	Me-too status	Lipiget EZ 20mg+10mg Tablet of M/S Getz Pharma
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
731.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Simtibe 10/10 mg Tablet
	Composition	Each Uncoated Tablet Contains: Ezetimibe…10mg Simvastatin…10mg
	Diary No. Date of R& I & fee	Dy.No. 41239 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	HMG Co-A reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN of USFDA approved
	Me-too status	Vivo-Plus Tablets of M/S Scotmann Pharmaceuticals
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
732.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Simtibe 10/20 mg Tablet
	Composition	Each Uncoated Tablet Contains: Ezetimibe…10mg Simvastatin…20mg
	Diary No. Date of R& I & fee	Dy.No. 41240 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	HMG Co-A reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN of USFDA approved
	Me-too status	Vivo-Plus Tablets of M/S Scotmann Pharmaceuticals
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and report concludes are considered to be operating at satisfactory level of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
733.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Odetro 4mg/5ml Injection
	Composition	Each 5ml Injection Contains:

		Ondansetron…4mg
	Diary No. Date of R& I & fee	Dy.No. 39917 dated 04-12-2018 Rs.20,000/- 04-12-2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form -5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 08-08-2019, and the report concludes that thefirm was operating at an acceptable compliance of cGMP.
	Remarks of the Evaluator[IV]	Firm initially applied Each 5ml Injection Contains: Ondansetron…4mg Now firm change its formulation with revised form-5, master formulation along with method of manufacturing Fee for revision of Rs: 20000/- Deposit slip No #2026511 , Dated: 05-05-2020 Now applied formulation is as follows Odetro 4mg/2ml Injection Each 2ml Injection Contains: Ondansetron…4mg Reference Regulatory Authorities status: Ondansetron 2 mg/ml Injection of (MHRA approved) (2ml) Me-too status: Adosetron 4mg Injection by M/s Searle IV Solutions
	Decision: Approved with following formulation: **Odetro 4mg/2ml Injection** **Each 2ml Injection Contains:** **Ondansetron…4mg**	
734.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Odetro 8mg/5ml Injection
	Composition	Each 5ml Injection Contains: Ondansetron…8mg
	Diary No. Date of R& I & fee	Dy.No. 40368 dated 07-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form -5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 08-08-2019, and the report concludes that thefirm was operating at an acceptable compliance of cGMP.
	Remarks of the Evaluator[IV]	Firm initially applied Each 5ml Injection Contains: Ondansetron…8mg Now firm change its formulation with revised form-5, master formulation along with method of manufacturing Fee for revision of Rs: 20000/- Deposit slip No #2026510 , Dated: 05-05-2020 Now applied formulation is as follows Odetro 8mg/4ml Injection

		Each 4ml Injection Contains: Ondansetron…8mg Reference Regulatory Authorities status: Ondansetron 2 mg/ml Injection of (MHRA approved) (4ml) Me-too status: Doston 8mg Injection by M/s Vision Pharmaceuticals
	Decision: Approved with following formulation: **Odetro 8mg/4ml Injection** **Each 4ml Injection Contains:** **Ondansetron…8mg**	
735.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Iromalt Injection 50mg/ml
	Composition	Each Vial Contains: Ferric carboxymaltose …50mg/ml
	Diary No. Date of R& I & fee	Dy.No. 41223 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Haematinic
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specificartions
	Pack size & Demanded Price	10ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ferinject 50 mg iron/mL solution for injection/infusion of MHRA approved
	Me-too status	Ferinject 500mg/10ml by M/s RG. Pharmaceuticals (Reg#072548)
	GMP status	Last GMP inspection conducted on 08-08-2019, and the report concludes that thefirm was operating at an acceptable compliance of cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specifications. Registration letter will be issued after comments of Legal Affairs Division, about patent issue of applied formulation.	
736.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Iromalt Injection 100mg/2ml
	Composition	Each Vial Contains: Ferric carboxymaltose …100mg/2ml
	Diary No. Date of R& I & fee	Dy.No. 41223 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Haematinic
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specificartions
	Pack size & Demanded Price	2ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ferinject 50 mg iron/mL solution for injection/infusion of MHRA approved
	Me-too status	Ferinject 500mg/10ml by M/s RG. Pharma (Reg#072548)
	GMP status	Last GMP inspection conducted on 08-08-2019, and the report concludes that thefirm was operating at an acceptable compliance of cGMP.
	Remarks of the Evaluator[IV]	Fermax-Plus Injection (2ml) of M/s Cirin Pharmaceuticals (approved in 269 meeting)
	Decision: Approved with innovator's specifications. Registration letter will be issued after comments of Legal affairs division, about patent issue of applied formulation.	
737.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Ironext 800mg/15ml Syrup
	Composition	Each 15ml Solution Contains: Iron Protein Succinylate .....800mg (Eq. to 40mg Elemental Iron)

	Diary No. Date of R& I & fee	Dy.No. 41355 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antianemic preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ferplex 40mg oral solution of Spain approved
	Me-too status	Fero-slim Syrup by M/s Fynk Pharma (Reg#062725)
	GMP status	Last GMP inspection conducted on 22-02-2018, and the report concludes that the was operating under satisfactory compliance of cGMP on the day of inspection.
	Remarks of the Evaluator[IV]	
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
738.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Gavinext 250/133.5/80/5ml Oral supension
	Composition	Each 5ml Suspension contains: Sodium alginate…250mg Sodium bicarbonate…133.5mg Calcium carbonate…80mg
	Diary No. Date of R& I & fee	Dy.No. 41347 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antacid
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specificartions
	Pack size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Gaviscon Peppermint Liquid Relief of MHRA approved
	Me-too status	Ul-Nil Suspension by M/s Z-JANS Pharma (Reg# 052470)
	GMP status	Last GMP inspection conducted on 22-02-2018, and the report concludes that the was operating under satisfactory compliance of cGMP on the day of inspection.
	Remarks of the Evaluator[IV]	Firm initially applied as syrup and now firm change formulation as Ora suspension with submission of fee of Rs: 20000/- Deposit Slip No# 2009161,Dated; 22-04-2020
	Decision: Approved with innovator's specification.	
739.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Irofit 1/90mg Tablet
	Composition	Each Film Coated Tablet Contains: Folic Acid…1mg Iron as Dried Ferrous Sulphate…….90mg
	Diary No. Date of R& I & fee	Dy.No. 41349 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Anti-anemic
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specificartions
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 22-02-2018, and the report concludes that the was operating under satisfactory compliance of cGMP on the day of inspection.
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Firm submitted fee of RS; 5000/- Deposit No# 1905802, dated: 22-04-2020 for change of salt form from Iron salt to Iron as Dried Ferrous Sulphate.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
740.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Trimanext 10% w/w cream
	Composition	Each unit contains: Clotrimazole….. 10% w/w
	Diary No. Date of R& I & fee	Dy.No. 41342 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	5gm, 10gm, 15gm; As per DPC
	Approval status of product in Reference Regulatory Authorities	Canesten 10% w/w Vaginal Cream of (MHRA approved)
	Me-too status	Vaginex-1 Cream of M/s Global Pharmaceuticals
	GMP status	Last GMP inspection conducted on 22-02-2018, and the report concludes that the was operating under satisfactory compliance of cGMP on the day of inspection.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
741.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Lignonext 2% Gel
	Composition	Each gm of gel contains: Lignocaine Hcl….. 2%
	Diary No. Date of R& I & fee	Dy.No. 41350 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Local Anaesthetic.
	Type of Form	Form -5
	Finished product Specifications	BP
	Pack size & Demanded Price	20gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lignocaine 2% of TGA Austraila approved
	Me-too status	Ruscain Gel by M/s Fynk Pharmaceuticals
	GMP status	Last GMP inspection conducted on 22-02-2018, and the report concludes that the was operating under satisfactory compliance of cGMP on the day of inspection.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
742.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Centron 8mg Tablet
	Composition	Each film coatedTablet Contains: Ondansetron as Hcl…8mg
	Diary No. Date of R& I & fee	Dy.No 513 dated 04-01-2019 Rs.20,000/- 04-01-2019
	Pharmacological Group	Selective serotonin 5-HT3 receptor antagonist
	Type of Form	Form 5

	Finished product Specifications	USP
	Pack size & Demanded Price	10's,; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRAN Of (USFDA Approved)
	Me-too status	Ondonix 8mg Tablet M/s Genix Pharma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
743.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Centron 8mg/4ml Injection
	Composition	Each 4ml Contains: Ondansetron as Hcl dihydrate…8mg
	Diary No. Date of R& I & fee	Dy.No 514 dated 04-01-2019 Rs.20,000/- 04-01-2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form -5
	Finished product Specifications	USP
	Pack size & Demanded Price	4ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 2 mg/ml Injection of (MHRA approved)
	Me-too status	Doston 8mg Injection by M/s Vision Pharmaceuticals
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
744.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Norline 1mg/ml Injection
	Composition	Each ml Contains: Noradrenaline Acid Tartrate (eq to Noradrenaline 1mg/ml) ……..2mg
	Diary No. Date of R& I & fee	Dy.No 512 dated 04-01-2019 Rs.20,000/- 04-01-2019
	Pharmacological Group	Sympathomimetic
	Type of Form	Form -5
	Finished product Specifications	BP
	Pack size & Demanded Price	2ml x5's , 2ml x10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Noradrenaline (Norepinephrine) 1 mg / ml Concentrate for solution for infusion of MHRA approved
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP."
	Remarks of the Evaluator[IV]	Adrenaline 1mg/ml Injection of M/s Safe Pharmaceuticals, but applied formulation is Noradrenaline.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
745.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Adecain 10mg/ml Injection
	Composition	Each ml Contains: Lignocaine Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No 510 dated 04-01-2019 Rs.20,000/- 04-01-2019
	Pharmacological Group	Local anaesthetic
	Type of Form	Form 5

	Finished product Specifications	USP
	Pack size & Demanded Price	2ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lidocaine Injection 1% w/v (MHRA approved)
	Me-too status	Lacain 1% Injection of M/s. Pulse Pharmaceuticals
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
746.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Lopride 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Dy.No 752 dated 07-01-2019 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 50's & 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Levopraid 25 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	Certificate of current Good Manufacturing practices on the basis of inspection conducted on 19-03-2020
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
747.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Lopride 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R& I & fee	Dy.No 753 dated 07-01-2019 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's,20's,30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Levopraid 50 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	Certificate of current Good Manufacturing practices on the basis of inspection conducted on 19-03-2020
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
748.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Lopride 100mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…100mg uncoated
	Diary No. Date of R& I & fee	Dy.No 754 dated 07-01-2019 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's,20's,30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Levopraid 100 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma

	GMP status	Certificate of current Good Manufacturing practices on the basis of inspection conducted on 19-03-2020
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
749.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Megafenac k 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…75mg
	Diary No. Date of R& I & fee	Dy.No 1881 dated 15-01-2019 Rs.20,000/- 14-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Dicgesic-K Tablets M/s Alen Pharmaceuticals
	GMP status	Certificate of current Good Manufacturing practices on the basis of inspection conducted on 19-03-2020
	Remarks of the Evaluator[IV]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting because Diclofenac Potassium is not registered in any reference country in dose more than 50mg.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
750.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Megafenac SR 100mg Tablet
	Composition	Each film coated Sustained Release Tablet Contains: Diclofenac Sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 1882 dated 15-01-2019 Rs.20,000/- 14-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dicloflex Retard 100mg prolonged released tablet by M/s Dexcel®-Pharma Ltd, MHRA Approved
	Me-too status	Sintral SR Tablets 100mg of M/s Neomedix (R.# 081413)
	GMP status	Certificate of current Good Manufacturing practices on the basis of inspection conducted on 19-03-2020
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
751.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Avepram 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram as Oxalate…5mg
	Diary No. Date of R& I & fee	Dy.No 3706 dated 28-01-2019 Rs.20,000/- 28-01-2019
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors (SSRIs)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Escitalopram 5 mg Of (MHRA Approved)

	Me-too status	Gentle 5mg Tablet Of M/S Wilson's Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
752.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Trazol 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Trazodone Hcl…100mg
	Diary No. Date of R& I & fee	Dy.No 3705 dated 28-01-2019 Rs.20,000/- 28-01-2019
	Pharmacological Group	Anti -depressant (serotonin antagonist and reuptake inhibito
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DESYREL Of (USFDA Approved)
	Me-too status	Dazod 100 Tablet Of M/S Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 07-12-2017, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
753.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Etocox 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy.No 3704 dated 28-01-2019 Rs.20,000/- 28-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ARCOXIA 60 MG of (MHRA approved)
	Me-too status	Oraxib 60mg Table M/s. Atco Lab
	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
754.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
	Brand Name +Dosage Form + Strength	Lecoz 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…200mg
	Diary No. Date of R& I & fee	Dy.No 3707 dated 28-01-2019 Rs.20,000/- 28-01-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Atcomid 200mg Tablet M/s Atco Lab

	GMP status	Last GMP inspection conducted on 07-12-17, and the report concludes that the Overall rating of GMP was found good at the time of inspection
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
755.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatab, Peshwar
	Brand Name +Dosage Form + Strength	Emeran 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron Hcl Dihydrate eq to Ondansetron…8mg
	Diary No. Date of R& I & fee	Dy.No 1238 dated 10-01-2019 Rs.20,000/- 10-01-2019
	Pharmacological Group	Selective serotonin 5-HT3 receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 12's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRAN Of (USFDA Approved)
	Me-too status	Ondonix 8mg Tablet M/s Genix Pharma
	GMP status	Last GMP inspection of conducted on 26-07-2018, and the report concludes that the firm is operating at good level of GMP compliance**.** panel unanimously recommends the grant of renewal of DML by way of formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
756.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatab, Peshwar
	Brand Name +Dosage Form + Strength	Emeran 4mg/5ml Syrup
	Composition	Each 5ml contains: Ondansetron Hcl Dihydrate eq to Ondansetron…4mg
	Diary No. Date of R& I & fee	Dy.No 1239 dated 10-01-2019 Rs.20,000/- 10-01-2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form -5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ml :As per SRO
	Approval status of product in Reference Regulatory Authorities	Zofran oral Solution 4mg/5mlof USFDA approved
	Me-too status	Dantron Syrup of M/s Sharooq Pharma Reg No# 077076
	GMP status	Last GMP inspection of conducted on 26-07-2018, and the report concludes that the firm is operating at good level of GMP compliance**.** panel unanimously recommends the grant of renewal of DML by way of formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
757.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatab, Peshwar
	Brand Name +Dosage Form + Strength	Irofer Plus Syrup 100mg
	Composition	Each 5ml contains: Iron Polysaccharide complex eq to elemental Iron …100mg
	Diary No. Date of R& I & fee	Dy.No 1240 dated 10-01-2019 Rs.20,000/- 10-01-2019
	Pharmacological Group	Anti-anemic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	30ml, 60ml, 120ml, 240ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A

	Me-too status	Medifer Syrup Of M/S Meditech Pharmaceutical
	GMP status	Last GMP inspection of conducted on 26-07-2018, and the report concludes that the firm is operating at good level of GMP compliance**.** panel unanimously recommends the grant of renewal of DML by way of formulation
	Remarks of the Evaluator[IV]	
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
758.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Widamet Tablets 50/500mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…500mg
	Diary No. Date of R& I & fee	Dy.No 750 dated 07-01-2019 Rs.20,000/- Dated 07-01-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Galmet 50mg/500mg Table M/s Vision Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
759.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Widamet Tablets 50/850mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…850mg
	Diary No. Date of R& I & fee	Dy.No 751 dated 07-01-2019 Rs.20,000/- Dated 07-01-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+850mg Tablet M/s Getz
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
760.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad

	Brand Name +Dosage Form + Strength	Widamet Tablets 50/1000mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…1000mg
	Diary No. Date of R& I & fee	Dy.No 1241 dated 10-01-2019 Rs.20,000/- 10-01-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	Last GMP inspection conducted on 24-01-2018 and report concludes firm was Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
761.	Name and address of manufacturer / Applicant	**M/s Werrick Pahrmaceuticals.** **216-217,I-10/3, Industrial Area, Islamabad**
	Brand Name +Dosage Form + Strength	Epitab 200mg Tablet
	Composition	Each Compressed Tablet Contains: Carbamazepine…200mg
	Diary No. Date of R& I & fee	Dy.No 3698 dated 28-01-2019 Rs.20,000/- 28-01-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Tegretol Of (MHRA Approved)
	Me-too status	Carbawel 200 mg Tablets of M/s Welmark Pharmaceuticals
	GMP status	Certificate of GMP on the basis of inspection conducted on 09-11-2018 andvalid till 08-11-2021
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
762.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi By M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cefrion Injection 250mg IV
	Composition	Each Vial Contains: Ceftriaxone as sodium…250mg
	Diary No. Date of R& I & fee	Dy.No 3673 dated 28-01-2019 Rs.50,000/- 28-01-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Rocephin I.V injection of (MHRA approved)
	Me-too status	Wincef 250 mg IV Injection M/s Wel Wink Pharmaceuticals,
	GMP status	Last GMP inspection of Noa Hemis Pharmaceuticals

		conducted on 28-02-2019 and the report concludes that the Overall Evaluation of the panel inspection rating is Good. & GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached. • Number of sections of applicant approved by Licensing Board:11 • Number of products already registered/approved on contract manufacturing in the name of applicant :Nil • Cephalosporin dry vial Section of seraph pharmavceuticals available
	Decision: Deferred for capacity assessment of M/s Seraph Pharma Islamabad.	
763.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi By M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cefrion Injection 500mg IV
	Composition	Each Vial Contains: Ceftriaxone as sodium…500mg
	Diary No. Date of R& I & fee	Dy.No 3674 dated 28-01-2019 Rs.50,000/- 28-01-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Rocephin I.V injection of (MHRA approved)
	Me-too status	Wincef 500 mg IV Injection M/s Wel Wink Pharmaceuticals,
	GMP status	Last GMP inspection of Noa Hemis Pharmaceuticals conducted on 28-02-2019 and the report concludes that the Overall Evaluation of the panel inspection rating is Good. & GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached. • Number of sections of applicant approved by Licensing Board:11 • Number of products already registered/approved on contract manufacturing in the name of applicant :Nil • Cephalosporin dry vial Section of seraph pharmaceuticals available
	Decision: Deferred for capacity assessment of M/s Seraph Pharma Islamabad.	
764.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi By: M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cefrion Injection 1000mg IV
	Composition	Each Vial Contains: Ceftriaxone as sodium…1000mg
	Diary No. Date of R& I & fee	Dy.No 3675 dated 28-01-2019 Rs.50,000/- 28-01-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Rocephin I.V injection of (MHRA approved)
	Me-too status	Trivolive 1gm Injection I.V M/s Olive Pharmaceuticals
	GMP status	Last GMP inspection of Noa Hemis Pharmaceuticals

		conducted on 28-02-2019 and the report concludes that the Overall Evaluation of the panel inspection rating is Good. & GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached. • Number of sections of applicant approved by Licensing Board:11 • Number of products already registered/approved on contract manufacturing in the name of applicant :Nil • Cephalosporin dry vial Section of seraph pharmaceuticals available
	Decision: Deferred for capacity assessment of M/s Seraph Pharma Islamabad.	
765.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi By M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fixime Capsule 400mg
	Composition	Each hard gelatin capsule contains: Cefixime as Trihydrate…400mg
	Diary No. Date of R& I & fee	Dy.No 3678 dated 28-01-2019 Rs.50,000/- 28-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	JP
	Pack size & Demanded Price	5's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Suprax of (USFDA approved)
	Me-too status	Maxophine Capsules of M/s Global Pharmaceuticals,
	GMP status	Last GMP inspection of Noa Hemis Pharmaceuticals conducted on 28-02-2019 and the report concludes that the Overall Evaluation of the panel inspection rating is Good. & GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached. • Number of sections of applicant approved by Licensing Board:11 • Number of products already registered/approved on contract manufacturing in the name of applicant :Nil • Cephalosporin Capsule Section of seraph pharmaceuticals available.
	Decision: Deferred for capacity assessment of M/s Seraph Pharma Islamabad.	
766.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi By: M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fixime DS 100mg/5ml
	Composition	Each 5ml contains: Cefixime as Trihydrate…100mg
	Diary No. Date of R& I & fee	Dy.No 3676 dated 28-01-2019 Rs.50,000/- 28-01-2019
	Pharmacological Group	Antibiotic (cephalosporin)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	30ml after reconstitution: As per SRO
	Approval status of product in Reference Regulatory Authorities	Suprax Of USFDA Approved
	Me-too status	Gyala Suspension Of M/S Epoch Pharmaceuticals
	GMP status	Last GMP inspection of Noa Hemis Pharmaceuticals conducted on 28-02-2019 and the report concludes that the

		Overall Evaluation of the panel inspection rating is Good. & GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached. • Number of sections of applicant approved by Licensing Board:11 • Number of products already registered/approved on contract manufacturing in the name of applicant :Nil • Cephalosporin dry powder for oral suspension Section of seraph pharmaceuticals available
	Decision: Deferred for capacity assessment of M/s Seraph Pharma Islamabad.	
767.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi By M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fixime DS 200mg/5ml
	Composition	Each 5ml contains: Cefixime as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 3677 dated 28-01-2019 Rs.50,000/- 28-01-2019
	Pharmacological Group	Antibiotic (cephalosporin)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	30ml after reconstitution: As per SRO
	Approval status of product in Reference Regulatory Authorities	Suprax Of USFDA Approved
	Me-too status	Gyala Suspension Of M/S Nexus Pharma
	GMP status	Last GMP inspection of Noa Hemis Pharmaceuticals conducted on 28-02-2019 and the report concludes that the Overall Evaluation of the panel inspection rating is Good. & GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached. • Number of sections of applicant approved by Licensing Board:11 • Number of products already registered/approved on contract manufacturing in the name of applicant :Nil • Cephalosporin dry powder for oral suspension Section of seraph pharmaceuticals available
	Decision: Deferred for capacity assessment of M/s Seraph Pharma Islamabad.	
768.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Amipride 200mg Tablet
	Composition	Each Uncoated Tablet Contains: Amisulpride…200mg
	Diary No. Date of R& I & fee	Dy.No 8922 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Dopamine receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride of (MHRA approved)
	Me-too status	Ampisol 200mg Tablet of M/s Sami
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

769.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Zine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Cetirizine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 8915 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cetirizine 10mg film coated tablet of (MHRA approved)
	Me-too status	Winzim 10mg Tablets of M/s Wnsfeild Pharmaceutical,
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
770.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Zine 5mg/5ml Syrup
	Composition	Each 5ml Contains: Cetirizine Hcl…5mg
	Diary No. Date of R& I & fee	Dy.No 8914 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ziralton Allergy Relief for Children 5mg/5ml Oral Solution of (MHRA approved)
	Me-too status	Rizox 5mg/5ml Syrup of M/s Espoir
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
771.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	D-Lor 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy.No 8928 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	CLARINEX of USFDA approved
	Me-too status	Larinex Tablets of M/s Getz Pharma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

772.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	D-Lor 0.5mg/ml Syrup
	Composition	Each ml of syrup contains: Desloratadine…0.5mg
	Diary No. Date of R& I & fee	Dy.No 8927 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	120 ml , 60 ml ,30ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarinex of (USFDA approved)
	Me-too status	Desora Syrup by M/s S.J &G. Fazul Ellahie
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
773.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Dexi 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…300mg
	Diary No. Date of R& I & fee	Dy.No 8933 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	NSIADs
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	30's : As Per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen of (MHRA approved)
	Me-too status	Obsprufen 300mg Tablet by M/s OBS
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
774.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Dexi 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…400mg
	Diary No. Date of R& I & fee	Dy.No 8918 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	NSIADs
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	30's : As Per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen of (MHRA approved)
	Me-too status	Obsprufen 400mg Tablet by M/s OBS
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

775.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Feno-K 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R& I & fee	Dy.No 8905 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac Potassium of (MHRA approved)
	Me-too status	Dicota 50 Tablet by M/s Linz
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
776.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Fenotab 50mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Diclofenac Sodium…50mg
	Diary No. Date of R& I & fee	Dy.No 8923 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's, 30's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac Sodium 50mg Gastro-Resistant Tablets of MHRA Approved
	Me-too status	Dicmaf 50mg Tablet of M/s Mafins (R.# 079884)
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
777.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Fenotab 100mg SR Tablet
	Composition	Each Sustained Release (film coated)Tablet Contains: Diclofenac Sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 8924 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's, 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Dicloflex Retard 100mg prolonged released tablet by M/s Dexcel®-Pharma Ltd, MHRA Approved
	Me-too status	Sintral SR Tablets 100mg of M/s Neomedix (R.# 081413)
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

778.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Peri-Dew 10mg Tablet
	Composition	Each film coated Tablet Contains: Domperidone Maleate eq to Domperidone…10mg
	Diary No. Date of R& I & fee	Dy.No 8921 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form -5
	Finished product Specifications	Manufacturers specification BP
	Pack size & Demanded Price	30's, 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Motilium 10 Mg Tablets of M/s (TGA approved)
	Me-too status	Stomacol of M/s High-Q
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	• The firm change formulation from uncoated to film coated along with submission of fee of Rs. 5000/- (deposit slip # 2041831) dated 08-06-2020.
	Decision: Approved with BP specifications.	
779.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	E-Pram 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram Oxalate Eq. to Ecitalopram…10mg
	Diary No. Date of R& I & fee	Dy.No 8920 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors (SSRIs)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's ; As per DPC
	Approval status of product in Reference Regulatory Authorities	Escitalopram 10 mg Of (MHRA Approved)
	Me-too status	Gentle 10mg Tablet Of M/S Wilson's Pharmaceuticals,
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
780.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Dew-Fam 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Famotidine…20mg
	Diary No. Date of R& I & fee	Dy.No 8908 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	H2-receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Pepcid of (USFDA Approved)
	Me-too status	Famotric 20mg Tablet Of M/S Klifton Pharma,
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

781.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Dew-Fam 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Famotidine…40mg
	Diary No. Date of R& I & fee	Dy.No 8909 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	H2-receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Pepcid of (USFDA Approved)
	Me-too status	Famotric 40mg Tablet Of M/S Klifton Pharma,
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
782.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Flur 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Flurbiprofen…100mg
	Diary No. Date of R& I & fee	Dy.No 8906 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form -5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Froben Tablets 100 mg of (MHRA Approved)
	Me-too status	Flurin 100 mg Tablet of M/s Mafins
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator	
	Decision: Approved.	
783.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd.Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Gemx 320mg Tablet
	Composition	Each Film Coated Tablet Contains: Gemifloxacin mesylate Eq. to Gemifloxacin…320mg
	Diary No. Date of R& I & fee	Dy.No 8919 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	7's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Factive tablet of USFDA approved
	Me-too status	Ifactiv 320mg Tablet M/s Hilton
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
784.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan

	Brand Name +Dosage Form + Strength	Laxtol 667mg/ml Syrup
	Composition	Each ml of Syrup Contains: Lactitol Monohydrate…667mg
	Diary No. Date of R& I & fee	Dy.No 8925 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Osmotically acting laxative
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	60ml, 90ml, 120ml, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Importal Syrup by (Swiss Medica) Switzerland Approved
	Me-too status	Lacasil 10g/15ml syrup by M/s Sami Pharma (Reg#070552)
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
785.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Levot 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Levofloxacin Hemihydrate Eq. to Levofloxacin…250mg
	Diary No. Date of R& I & fee	Dy.No 8910 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antibiotics (Fluoroquinolones)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Evoxil 250 mg film-coated tablets by M/s Beacon Pharm (MHRA approved)
	Me-too status	Leoflox 250mg Tablet by M/s Bryon Pharma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulations.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
786.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Levot 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levofloxacin Hemihydrate Eq. to Levofloxacin…500mg
	Diary No. Date of R& I & fee	Dy.No 8911 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antibiotics (Fluoroquinolones)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Evoxil 500 mg film-coated tablets by M/s Beacon Pharm (MHRA approved)
	Me-too status	Leoflox 5o0mg Tablet by M/s Bryon Pharma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
787.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Suride 25mg Tablet

	Composition	Each Tablet Contains: Levosulpiride…25mg\
	Diary No. Date of R& I & fee	Dy.No 8932 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 20's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Levopraid 25 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
788.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Suride 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R& I & fee	Dy.No 8926 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Levopraid 50 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
789.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Hi-Gyl 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Metronidazole…200mg
	Diary No. Date of R& I & fee	Dy.No 8912 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Flagyl tablet of (MHRA approved)
	Me-too status	Raygyl tablet of M/s Ray Pharma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
790.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Hi-Gyl 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Metronidazole…400mg

	Diary No. Date of R& I & fee	Dy.No 8913 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Flagyl tablet of (MHRA approved)
	Me-too status	Flagyl tablet of M/s Sanofi Aventis
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
791.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Air-Ez 5mg Chewable Tablet
	Composition	Each chewable tablet Contains: Montelukast Sodium Eq. to Montilukast…5mg
	Diary No. Date of R& I & fee	Dy.No 8903 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 7's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair 5mg chewable of (USFDA approved)
	Me-too status	Lontuka 5mg Chewable Tablet M/s Linz Pharmaceuticals.
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
792.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Air-Ez 10mg Tablet
	Composition	Each film coated tablet Contains: Montelukast Sodium Eq. to Montilukast…10mg
	Diary No. Date of R& I & fee	Dy.No 8904 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 7's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair Of (MHRA Approved)
	Me-too status	Mecost 10mg Tablet M/s Sigma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
793.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Nime 100mg Tablet
	Composition	Each UnCoated Tablet Contains: Nimesulide…100mg
	Diary No. Date of R& I & fee	Dy.No 8907 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	NSAID Cox-2 Inhibitor

	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's ,20's 30's /As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status	Nims Tablet by Sami Reg. No. 026657
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	The firm change formulation from film coated to uncoated tablet alongwith submission of fee of Rs. 5000/- (deposit slip #2041832) dated 08-06-2020.
	Decision: Approved with innovator's specifications.	
794.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Orfal 450/35 mg Tablet
	Composition	Each Uncoated Tablet Contains: Paracetamol…450mg Orphenadrine Citrate…35mg
	Diary No. Date of R& I & fee	Dy.No 8931 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Analgesic /Muscle Relaxant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	30's, 100's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Norgesic tablets (uncoated) M/s iNova Pharmaceuticals Australia Pvt. Ltd. approved by TGA of Australia
	Me-too status	Nuberol Tablet by M/s Searle Pakistan Ltd,, Reg.No.020373
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
795.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd.Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Tel-H 40/12.5 mg Tablet
	Composition	Each Bi-layered uncoated Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 8929 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 40/12.5mg Tablet of M/S Tabros Pharma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	• The firm change label calim from plain tablet to bilayer uncoated tablet without submission of fee & did not revise master formulation and method of manufacturing for bilayer tablet. • For evidence of bilayer machine firm reply that they have no such facility and will purchase machine

		before launching of this product(Undertaking attached on stamp paper)
	Decision:Deferred for following: • **Revision of master formulation and method of manufacturing for bilayer tablet.** • **Deferred for submission of fee for revision of formulation** • **Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.**	
796.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd.Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Tel-H 80/12.5 mg Tablet
	Composition	Each Bi-layered uncoated Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 8930 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 80/12.5mg Tablet of M/S Tabros Pharma
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	• The firm change label calim from plain tablet to bilayer uncoated tablet without submission of fee & did not revise master formulation and method of manufacturing for bilayer tablet. • For evidence of bilayer machine firm reply that they have no such facility and will purchase machine before launching of this product(Undertaking attached on stamp paper)
	Decision:Deferred for following: • **Revision of master formulation and method of manufacturing for bilayer tablet.** • **Deferred for submission of fee for revision of formulation** • **Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.**	
797.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd.Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Tiz 2mg Tablet
	Composition	Each Tablet Contains: Tizanidine Hcl Eq. to Tizanidine…2mg
	Diary No. Date of R& I & fee	Dy.No 8916 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine of MHRA approved
	Me-too status	Tandolax 2mg Tablet M/s High-Q Pharmaceuticals
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

798.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd.Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Tiz 4mg Tablet
	Composition	Each Tablet Contains: Tizanidine Hcl Eq. to Tizanidine…4mg
	Diary No. Date of R& I & fee	Dy.No 8917 dated 28-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine of MHRA approved
	Me-too status	Tandolax 4mg Tablet M/s High-Q Pharmaceuticals
	GMP status	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
799.	Name and address of manufacturer / Applicant	M/s Stanley Pharmaceuticals Pvt Ltd 84-B, Industrial Estate, Hayatabad, peshawar
	Brand Name +Dosage Form + Strength	Briska Tablets 5mg
	Composition	Each enteric coated tablet contains: Serratiopeptidase…5mg
	Diary No. Date of R& I & fee	Dy.No 3182 dated 23-01-2019 Rs.20,000/- 23-01-2019
	Pharmacological Group	Anti-inflammatory proteolytic enzyme
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	20's,; As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not found
	Me-too status	Korzen tablet of M/s ST.John karachi
	GMP status	Last GMP inspection of conducted on 09-05-18, and the report concludes that the Overall GMP compliance was found satisfactory and panel decided to issue theGMPn certificate to the firm.
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting (According to 245th meeting, Serratiopeptidase is a proteolytic enzyme present in silkworm gut which helps it to dissolve the cocoon. It has been used as an anti-inflammatory agent without any scientific evidence of efficacy. Takeda Pharmaceuticals, the brand leader Japanese company, had agreed for voluntary withdrawal from market in 2011.Not recommended for registration)
	Decision:Deferred for further deliberation for registration as drug or otherwise	
800.	Name and address of manufacturer / Applicant	M/s Stanley Pharmaceuticals Pvt Ltd 84-B, Industrial Estate, Hayatabad, peshawar
	Brand Name +Dosage Form + Strength	Perl DS Capsules
	Composition	Each Capsule Contains: Omeprazole Enteric coated pellets eq to Omeprazole…40mg
	Diary No. Date of R& I & fee	Dy.No 3185 dated 23-01-2019 Rs.20,000/- 23-01-2019
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Losec capsule Of (MHRA Approved)
	Me-too status	Losec 40mg capsule by M/s Barrett Hodgson
	GMP status	Last GMP inspection of conducted on 09-05-18, and the report concludes that the Overall GMP compliance was found satisfactory and panel decided to issue theGMPn certificate to the firm.
	Remarks of the Evaluator	Source of pellets :M/s Ocean Pharmacoat Pvt Ltd. Fee of Rs: 80000/- submitted Deposit slip No#0784356 Dated : 12-05-2020 GMP certificate No# L. Dis. No.26206/TS/2019 dated: 01-07-2019 Stability study of 3 batches of pellets was not according to Zone IV- A or B
	Decision: Deferred for submission of Stability studies according to Zone IV-A. or IV-B	
801.	Name and address of manufacturer / Applicant	M/s Pharmatec Pakistan Pvt Ltd. D-86/A, S.I.T.E. Karachi-75700
	Brand Name +Dosage Form + Strength	Empazin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy.No 2692 dated 21-01-2019 Rs.20,000/- 21-01-2019
	Pharmacological Group	Antidiabetic (Sodium-glucose cotransporter 2 (SGLT2) inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's,14's, 28's, 30's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	JARDIANCE tablets (USFDA) approved
	Me-too status	Empa 10mg of M/s CCL pharmaceuticals
	GMP status	Last GMP inspection of conducted on 30-01-2018, and the report concludes that the Based on the above observations their overall GMP compliance is rated as Good."
	Remarks of the Evaluator[IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
802.	Name and address of manufacturer / Applicant	M/s Pharmatec Pakistan Pvt Ltd. D-86/A, S.I.T.E. Karachi-75700
	Brand Name +Dosage Form + Strength	Empazin 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Dy.No 2693 dated 21-01-2019 Rs.20,000/- 21-01-2019
	Pharmacological Group	Antidiabetic (Sodium-glucose cotransporter 2 (SGLT2) inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's,14's, 28's, 30's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	JARDIANCE tablets (USFDA) approved
	Me-too status	
	GMP status	Last GMP inspection of conducted on 30-01-2018, and the report concludes that the Based on the above observations their overall GMP compliance is rated as Good."
	Remarks of the Evaluator[IV]	Submit Stability studies with requisite documents
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	

803.	Name and address of manufacturer / Applicant	M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Kilcam Oral Drops
	Composition	Each reconstituted 5ml coontains: Clarithromycin as taste masked granules 27.5%……125mg
	Diary No. Date of R& I & fee	Dy.No 3668 dated 28-01-2019 Rs.20,000/- 28-01-2019
	Pharmacological Group	Antibiotic (Macrolide)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	25ml ;As per SRO
	Approval status of product in Reference Regulatory Authorities	Biaxin granules for oral suspension 125mg/5ml by M/s Abbvie, USFDA approved.
	Me-too status	Rethro 125mg/5ml Dry Suspension by M/s Regal Pharmaceuticals.
	GMP status	Last GMP inspection of avant Pharmaceutical conducted on 16-04-2019, and the report concludes that the firm was considered to be operating at an acceptable level of Compliance of GMP requirments.
	Remarks of the Evaluator[IV]	Source of granules : Surge
	Decision: Approved.	
804.	Name and address of manufacturer / Applicant	M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Welday 400mg/250ml IV Infusion
	Composition	Each vial of 250ml contains: Moxifloxacin as HCL…400mg
	Diary No. Date of R& I & fee	Dy.No 3667 dated 28-01-2019 Rs.20,000/- 28-01-2019
	Pharmacological Group	AntiBiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Avelox solution for infusion of (MHRA approved)
	Me-too status	Moximed solution for infusion of M/s Medimarker's
	GMP status	Last GMP inspection of avant Pharmaceutical conducted on 16-04-2019, and the report concludes that the firm was considered to be operating at an acceptable level of Compliance of GMP requirments.
	Remarks of the Evaluator[IV]	Evidence of large volume parenterals section not provided.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
805.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Glipsyn Tablet 50mg/500mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…500mg
	Diary No. Date of R& I & fee	Dy.No 4401 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Galmet 50mg/500mg Table M/s Vision Pharmaceuticals,
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory

		level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
806.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Glipsyn Tablet 50mg/850mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…850mg
	Diary No. Date of R& I & fee	Dy.No 4403 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+850mg Tablet M/s Getz
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
807.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Glipsyn Tablet 50mg/1000mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…1000mg
	Diary No. Date of R& I & fee	Dy.No 4402 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/ aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
808.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Crazmed 50mg Tablet

	Composition	Each Film Coated Tablet Contains: Amisulpride…50mg
	Diary No. Date of R& I & fee	Dy.No 4409 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	3 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Solian 50 mg Tablets Of (MHRA Approved)
	Me-too status	Ampisol 50mg Tablet M/s Sami
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	Applied as film coated while in reference available as uncoated tablet.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
809.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Diplosyn Tablets 5mg/80mg
	Composition	Each Film Coated Tablet Contains: Amlodipine besylate eq to Amlodipine…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Dy.No 4399 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge of MHRA approved
	Me-too status	Exforge Tablet of M/s Novartis Pharma (Reg.#047569)
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
810.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telpin Plus Tablet 5/40mg
	Composition	Each bilayer unCoated Tablet Contains: Amlodipine besylate eq to Amlodipine…5mg Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy.No 4397 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Telam 40mg/5mg Tablet of M/s Macter
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory

		level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised label claim in line with the reference product (bilayer tablet) with out revision of master formulation, manufacturing outlines and without submission of fee.
	Decision:Deferred for following: • **Revision of master formulation and method of manufacturing for bilayer tablet.** • **Deferred for submission of fee for revision of formulation.** • **Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.**	
811.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telpin Plus Tablet 10/40mg
	Composition	Each bilayer unCoated Tablet Contains: Amlodipine besylate eq to Amlodipine…10mg Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy.No 4413 dated 31-01-2019 Rs.20,000/- 29-02-2019
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Ezitab-AM 10/40mg TABLET Werrick (Reg no. 082045)
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised label claim in line with the reference product (bilayer tablet) with out revision of master formulation, manufacturing outlines and without submission of fee.
	Decision:Deferred for following: • **Revision of master formulation and method of manufacturing for bilayer tablet.** • **Deferred for submission of fee for revision of formulation.** • **Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.**	
812.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telpin Plus Tablet 5/80mg
	Composition	Each bilayer unCoated Tablet Contains: Amlodipine besylate eq to Amlodipine…5mg Telmisartan…80mg
	Diary No. Date of R& I & fee	Dy.No 4395 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Telam 80mg/5mg Tablet of M/s Macter
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have

		been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised label claim in line with the reference product (bilayer tablet) with out revision of master formulation, manufacturing outlines and without submission of fee.
	Decision:Deferred for following: • **Revision of master formulation and method of manufacturing for bilayer tablet.** • **Deferred for submission of fee for revision of formulation.** • **Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.**	
813.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telpin Plus Tablet 10/80mg
	Composition	Each bilayer unCoated Tablet Contains: Amlodipine besylate eq to Amlodipine…10mg Telmisartan…80mg
	Diary No. Date of R& I & fee	Dy.No 4365 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Telam 80mg/5mg Tablet of M/s Macter
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised label claim in line with the reference product (bilayer tablet) with out revision of master formulation, manufacturing outlines and without submission of fee.
	Decision:Deferred for following: • **Revision of master formulation and method of manufacturing for bilayer tablet.** • **Deferred for submission of fee for revision of formulation.** • **Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.**	
814.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Logrel 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Clopidogrel bisulfate eq to Clopidogrel…75mg
	Diary No. Date of R& I & fee	Dy.No 4407 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Antiplatelet/Anticoagulant
	Type of Form	Form- 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	PLAVIX of USFDA Approved
	Me-too status	Ducati Tablet of M/s NOA Hemis Pharmaceuticals,
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.

	Remarks of the Evaluator[IV]	
	Decision: Approved.	
815.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Torsyn 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy.No 4410 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	1x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ARCOXIA 60 MG of (MHRA approved
	Me-too status	Oraxib 60mg Table M/s. Atco Lab
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
816.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Spazdic Tablet 80/80mg
	Composition	Each Sugar coated Tablet Contains: Hydrated phloroglucinol 80mg eq to anhydrous phloroglucinol…62.333mg Trimethylphloroglucinol…80mg
	Diary No. Date of R& I & fee	Dy.No 4390 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Gastrointestinal nticholinergics/Antispasmodics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	3 x 10's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Spasfon Tablet (ANSM Approved)
	Me-too status	Spasrid Tablet of M/s Barrett Hodgson Pakistan
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised formulation as sugar coated tablet without submission of fee.
	Decision: Deferred for submission of fee for revision of formulation.	
817.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Mecsyn 6mg Tablet
	Composition	Each Film Coated Tablet Contains: Ivermectin…6mg
	Diary No. Date of R& I & fee	Dy.No 4411 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Semisynthetic anthelmintic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found

	Me-too status	I-Mec Tablets t of M/s Alen Pharmaceuticals
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• Stromectol 6mg (Uncoated) of USFDA Discontinued (submitted by firm) • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
818.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Biosyn 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…600mg
	Diary No. Date of R& I & fee	Dy.No 4414 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Oxazoldone Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	12's, ;As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 400 mg tablet of (USFDA approved)
	Me-too status	Ecasil 600mg tablet by M/s Sami (Reg#066904)
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
819.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Torment 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy.No 4394 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too status	Lorfix 8mg Tablet of M/s AGP
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
820.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Toplet 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate…25mg
	Diary No. Date of R& I & fee	Dy.No 4392 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019

	Pharmacological Group	Antiepileptic agent
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax Of (USFDA Approved)
	Me-too status	Lowseiz 25mg Tablets of M/S Helix Pharma
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
821.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Toplet 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate…50mg
	Diary No. Date of R& I & fee	Dy.No 4393 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Antiepileptic agent
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax Of (USFDA Approved)
	Me-too status	Lowseiz 50mg Tablets of M/S Helix Pharma
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
822.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Colsid 4mg Capsule
	Composition	Each Capsule Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy.No 4404 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Muscle relaxants
	Type of Form	Form 5
	Finished product Specifications	Manufacturer"s specifications
	Pack size & Demanded Price	1 x 10' s, As per SRO
	Approval status of product in Reference Regulatory Authorities	Thiocolchicoside capsules of(ANSM approved)
	Me-too status	Muscor Capsules. by M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
823.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Prostek 0.4mg Capsuls
	Composition	Each Capsule Contains: Tamsulosin HCL…0.4mg

	Diary No. Date of R& I & fee	Dy.No 4408 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Anti- adrenergic
	Type of Form	Form-5
	Finished product Specifications	USP Specs.
	Pack size & Demanded Price	3 x 10's::As per PRC .
	Approval status of product in Reference Regulatory Authorities	FLOMAX 0.4 mg of USFDA approved
	Me-too status	Tamsolin 0.4mg Capsule by M/s Getz Pharma
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Approved.	
824.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Rosu 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium…5mg
	Diary No. Date of R& I & fee	Dy.No.4406 dated 31-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	HMG CoA reductase inhibitor/Antihyprlipidemic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	CRESTOR tablet of (USFDA approved)
	Me-too status	RosuBar 5mg Tablet by M/s Barrett Hodgson
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
825.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Rosu 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium…10mg
	Diary No. Date of R& I & fee	Dy.No 4405 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Statin or HMG CoA Reductase Inhibitor
	Type of Form	Form -5
	Finished product Specifications	Manufacturers specification Specifications
	Pack size & Demanded Price	10's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 10mg film-coated tablets by M/s AstraZeneca UK Ltd (MHRA Approved)
	Me-too status	Easetec 10mg tablet by M/s Pharmatec (Reg#067564)
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
826.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Quitpin XR 150mg Tablet

	Composition	Each Extended release Film Coated Tablet Contains: Quetiapine Fumarate eq to Quetiapine …150mg
	Diary No. Date of R& I & fee	Dy.No 4389 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel XR of USFDA approved.
	Me-too status	Qusel XR 150mg Tablet of M/s Hilton Pharma
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised formulation as Extended release Film Coated Tablet without Submission of fee.
	Decision: Deferred for submission of fee for revision of formulation.	
827.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Quitpin XR 300mg Tablet
	Composition	Each Extended release Film Coated Tablet Contains: Quetiapine Fumarate eq to Quetiapine …300mg
	Diary No. Date of R& I & fee	Dy.No 4400 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel XR of USFDA approved.
	Me-too status	Qusel XR 300mg Tablet of M/s Hilton Pharma
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised formulation as Extended release Film Coated Tablet without Submission of fee.
	Decision: Deferred for submission of fee for revision of formulation.	
828.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Crisp CR 12.5mg Tablets
	Composition	Each Enteric, film Coated Controlled Release Tablet: Paroxetine as HCl…12.5mg
	Diary No. Date of R& I & fee	Dy.No 4398 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Selective serotonin-reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR of (USFDA approved)
	Me-too status	Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals,
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised formulation as Enteric, film coated tablet without Submission of fee.

	Decision: Deferred for submission of fee for revision of formulation.	
829.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Crisp CR 25mg Tablets
	Composition	Each Enteric, film Coated Controlled Release Tablet Paroxetine as HCl…25mg
	Diary No. Date of R& I & fee	Dy.No 4412 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Selective serotonin-reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR of (USFDA approved)
	Me-too status	Panox CR Tablet 25 mg M/s Regal Pharmaceuticals,
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	• The firm revised formulation as Enteric, film coated tablet without Submission of fee.
	Decision: Deferred for submission of fee for revision of formulation.	
830.	Name and address of manufacturer / Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Zapsyn 30mg Tablets
	Composition	Each Film Coated Tablet Contains: Mirtazapine…30mg
	Diary No. Date of R& I & fee	Dy.No 4391 dated 31-01-2019 Rs.20,000/- 29-01-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Mirtazapine of (MHRA Approved)
	Me-too status	Tazemir 30mg Tablet of M/s Lisko
	GMP status	Last GMP inspection of conducted on 01-03-2019 and the report concludes that thefirm is operating at satisfactory level of GMP as of today, suggestion for improvement have been agreed upon by management.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
831.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Demet 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No 7070 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Anti-dementia drugs
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's, 28's, 56's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Ebixa 10 mg of MHRA Approved
	Me-too status	Memura Tablet by Pharmevo (Reg. No. 055485)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.

	Remarks of the Evaluator[IV]	
	Decision: Approved.	
832.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Vilmet 50/500 mg Tablet
	Composition	Each film coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy.No 7072 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Galmet 50mg/500mg Table M/s Vision Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
833.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Vilmet 50/850 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…850mg
	Diary No. Date of R& I & fee	Dy.No 7073 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+850mg Tablet M/s Getz
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/ aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
834.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Adica 75mg Capsule
	Composition	Each Capsule Contains: Pregabalin…75mg
	Diary No. Date of R& I & fee	Dy.No 7076 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference	Lyrica of (USFDA approved)

	Regulatory Authorities	
	Me-too status	Gabica Capsule by M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
835.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Adica 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R& I & fee	Dy.No 7077 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
836.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Atrum 10mg/ml Injection
	Composition	Each ml contains: Atracurium Besylate…10mg
	Diary No. Date of R& I & fee	Dy.No 8694 dated 27-02-2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Non-depolarizing skeletal muscle relaxant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5ml x 5's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Atracurium Besilate 10 mg/ml Solution for Injection of MHRA approved
	Me-too status	Atrium Injections of M/s Searle
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
837.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Fina 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Finasteride…5mg
	Diary No. Date of R& I & fee	Dy.No 7897 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	5-Alpha reductase Inhibitor
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Proscar Tablet Of (USFDA Approved)
	Me-too status	Proscar Tablet of M/S Muller &Phipps
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	

	Decision: Approved with protective measures for woekers	
838.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Adetose Tablet 100mg/0.35mg
	Composition	Each Chewable Tablet Contains Iron III Hydroxide Polymaltose Complex eq to elemental iron…100mg Folic Acid…0.35mg
	Diary No. Date of R& I & fee	Dy.No 8692 dated 27-02-2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Anti-anemic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	10's, 20's,; As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Polymalt Plus Chewable Table Of M/S High-Q
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
839.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Levet Injection500mg/5ml
	Composition	Each ml of injection contains: Levetiracetam…100mg
	Diary No. Date of R& I & fee	Dy.No 8695 dated 27-02-2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Anti epileptic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	5ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA 500mg/5ml Injection of USFDA approved
	Me-too status	Lumark Injection M/s Searle Pak
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
840.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Lanzec 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…600mg
	Diary No. Date of R& I & fee	Dy.No 8691 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Oxazoldone Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	10's, ;As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 400 mg tablet of (USFDA approved)
	Me-too status	Ecasil 600mg tablet by M/s Sami (Reg#066904)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

841.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Rirox 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…10mg
	Diary No. Date of R& I & fee	Dy.No 7891 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	14's, 28's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 10mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 10mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
842.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Rirox 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
	Diary No. Date of R& I & fee	Dy.No 7892 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	14's, 28's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 15mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 15mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
843.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Rirox 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…20mg
	Diary No. Date of R& I & fee	Dy.No 7893 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer,s specification
	Pack size & Demanded Price	14's, 28's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 20mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 20mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
844.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Amtel 5/40 mg Tablet
	Composition	Each bilayer uncoated Tablet Contains:

		Telmisartan…40mg Amlodipine as besylate…5mg
	Diary No. Date of R& I & fee	Dy.No 7074 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	Type of Form	Form- 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Telam 40mg/5mg Tablet of M/s Macter
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Firm change formulation from film coated to bilayer uncoated tablet with submission of fee of Rs: 5000/- Deposit slip No# 0788371 dated: 02-06-2020 As evidence of bilayer machine firm submitted purchase order, commercial Invoice, Packing list and delivey note.
	Decision: Deferred for submission of IQ, OQ and PQ of bi-layered tablet machine	
845.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Tenvir 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Tenofovir disoproxil fumarate ……300mg (eq. to Tenofovir disoproxil 245mg)
	Diary No. Date of R& I & fee	Dy.No 8698 dated 27-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Viread 300mg Tablets by Gilead Sciences Inc, approved by US-FDA
	Me-too status	Hilten 300mg Tablet of Hilton Reg# 073735
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
846.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Kolsid 4mg/2ml Injection
	Composition	Each ml of injection contains: Thiocolchicoside…2mg
	Diary No. Date of R& I & fee	Dy.No 8697 dated 27-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Skeletal Muscle Relaxant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2ml x 6's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Coltramyl Injection by M/s Sanofi Aventis ANSM France
	Me-too status	Myovi 4mg/2ml Injection by Macter International (Reg. No. 058692)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

847.	Name and address of manufacturer / Applicant	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura
	Brand Name +Dosage Form + Strength	Magnesium sulfate 50% w/v
	Composition	Each ml contains: Magnesium sulphate heptahydrate…500mg
	Diary No. Date of R& I & fee	Dy.No 7988 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Anticonvulsant or Electrolyte Replenisher
	Type of Form	Form 5
	Finished product Specifications	IP
	Pack size & Demanded Price	10ml x 1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Magnesium Sulfate 50%w/v Solution for Injection (of MHRA approved)
	Me-too status	Magnesium Sulphate Injection of M/s. Zafa Reg# 023767
	GMP status	Last GMP inspection conducted on 21-02-2018 and report concludes Overall hygienic condition of firm was satisfactory at time of Inspection. They were advised to improve further their documentation as mentioned above. They agreed.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
848.	Name and address of manufacturer / Applicant	M/s The Schazoo Zaka Pvt Ltd. Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Qutin 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine as fumarate eq to Quetiapine…25mg
	Diary No. Date of R& I & fee	Dy.No 9207 dated 28-02-2019 Rs.20,000/- 28-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Quit 25mg Tablets of M/s Navegal Laboratories, (Reg.# 068244)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
849.	Name and address of manufacturer / Applicant	M/s The Schazoo Zaka Pvt Ltd.Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Qutin XR 200mg Tablet
	Composition	Each extended release tablet contains: Quetiapine as fumarate eq to Quetiapine…200mg
	Diary No. Date of R& I & fee	Dy.No.9209 dated 28-02-2019 Rs.20,000/- 28-02-2019
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SEROQUEL XR (of USFDA approved)
	Me-too status	Pine XR Tablet of M/s. Werrick Pharmaceuticals
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

850.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Aldocal 0.5mcg
	Composition	Each Tablet Contains: Alfacalcidol…0.5mcg
	Diary No. Date of R& I & fee	Dy.No 8309 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished product Specifications	Manufacturerspecification
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	one alpha tablet 0.5 µg PMDA approved
	Me-too status	D3A 0.5 mcg Tablet of M/s. High-Q
	GMP status	Panel Inspection for renewal of DML conducted on 12-11-2018 & 02-01-2019 unanimously recommends the renewal of DML for Crystolite Islamabad for following sections. 1- Tablet section (gen) 2- Capsule section (gen) 3- Cream/ointment section (gen) 4- Topical lotion section (gen) 5- Cream/Ointment section (steroid) 6- Topical lotion section (steroid) 7- Oral Sachet (gen) 8- Soft gelatin capsule (gen)
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
851.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals.Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Aprenil 80mg Capsule
	Composition	Each Capsule Contains: Aprepitant…80mg
	Diary No. Date of R& I & fee	Dy.No 8191 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2's , 6's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Emend capsule of USFDA
	Me-too status	Apritus 80mg Capsule of M/s S.J&G
	GMP status	Same asabove
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
852.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Aprenil 125mg Capsule
	Composition	Each Capsule Contains: Aprepitant…125mg
	Diary No. Date of R& I & fee	Dy.No 8192 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	6's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Emend Capsule of USFDA
	Me-too status	Apritus 125mg Capsule of M/s S.J&G
	GMP status	Same as above

	Remarks of the Evaluator[IV]	
	Decision: Approved.	
853.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dericin 1mg Tablet
	Composition	Each uncoated tablet contains: Cinitapride as Acid Tartrate…1mg
	Diary No. Date of R& I & fee	Dy.No 8306 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 30's, 50's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Cidine 1 mg Tablet of Spain approved
	Me-too status	Cint 1mg Tablet M/s High-Q Pharmaceutical
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
854.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clarilite 500mg Tablets
	Composition	Each Film Coated Tablet Contains: Clarithromycin…500mg
	Diary No. Date of R& I & fee	Dy.No 8311 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Klaricid of (MHRA approved)
	Me-too status	Respect tablet M/s Spencer Pharmaceutical
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
855.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dalofen-P 50mg Tablets
	Composition	Each film coated tablet contains: Diclofenac potassium…50mg
	Diary No. Date of R& I & fee	Dy.No 8294 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac Potassium of (MHRA approved)
	Me-too status	Dicota 50 Tablet by M/s Linz
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
856.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Hospilid 400mg Tablets
	Composition	Each Film Coated Tablet Contains: Linezolid…400mg
	Diary No. Date of R& I & fee	Dy.No 8303 dated 25-02-2019 Rs.20,000/- 25-02-2019

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	12's;As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 400 mg tablet of (USFDA approved)
	Me-too status	Barizold 400mg Tablet by M/s Barrett Hodgson(R#076342)
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
857.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Naxotil 550mg Tablet
	Composition `	Each Film Coated Tablet Contains: 550mg Naproxen Sodium eq to Naproxen……500mg
	Diary No. Date of R& I & fee	Dy.No 8314 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Health Canada approved
	Me-too status	Fougera Tablet of M/s Hiranis Reg # 076489
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
858.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Renamer 400mg Tablets
	Composition `	Each Film Coated Tablet Contains: Sevelamer HCL…400mg
	Diary No. Date of R& I & fee	Dy.No 8190 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Phosphate binder
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	3x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Renagel tablet of (USFDA approved)
	Me-too status	Renavel Tablets 400mg M/s Genome Pharmaceuticals
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
859.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Urisin 0.4mg SR Capsules
	Composition `	Each prolonged release capsule contains: Tamsulosin HCL…0.4mg
	Diary No. Date of R& I & fee	Dy.No 8299 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Anti- adrenergic
	Type of Form	Form-5
	Finished product Specifications	USP Specs.
	Pack size & Demanded Price	10's, 30's :As per PRC .
	Approval status of product in Reference Regulatory Authorities	FLOMAX 0.4 mg of USFDA approved
	Me-too status	Tamsolin 0.4mg Capsule by M/s Getz Pharma
	GMP status	Same as above

	Remarks of the Evaluator[IV]	Source of pellets : Vision
	Decision: Approved.	
860.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Zitadine 2mg Tablet
	Composition `	Each Tablet Contains: Tizanidine as HCL…2mg
	Diary No. Date of R& I & fee	Dy.No 8534 dated 26-02-2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine of MHRA approved
	Me-too status	Tandolax 2mg Tablet M/s High-Q Pharmaceuticals
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
861.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Adomat 50mg/ml Solution for injection or infusion
	Composition `	Each 1ml contains Tramadol HCL……50mg
	Diary No. Date of R& I & fee	Dy.No 8217 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2ml x 5's , 2ml x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol 50mg/ml Solution for Injection or Infusion. of MHRA approved
	Me-too status	Acugesic Injection 50Mg by M/S Al-Hameed Agencies
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
862.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Metvida 50mg/850mg Tablet
	Composition `	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…850mg
	Diary No. Date of R& I & fee	Dy.No 8307 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 30's:As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+850mg Tablet M/s Getz
	GMP status	Same as above
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	

863.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Metvida 50mg/1000mg Tablet
	Composition `	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…1000m
	Diary No. Date of R& I & fee	Dy.No 8321 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	Same as above
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
864.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Vorazin 200mg Tablet
	Composition `	Each Film Coated Tablet Contains: Voriconazole…200mg
	Diary No. Date of R& I & fee	Dy.No 8304 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Anti- fungal agent
	Type of Form	Form 5
	Finished product Specifications	JP
	Pack size & Demanded Price	10's, 30's, : As per SRO
	Approval status of product in Reference Regulatory Authorities	VFEND Tablets of USFDA approved
	Me-too status	Voricon Tablets of M/s Genome Pharmaceuticals
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
865.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dalofen SR Tablets 100mg
	Composition	Each prolonged release tablet contains: Diclofenac Sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 8319 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Dicloflex Retard 100mg prolonged released tablet by M/s Dexcel®-Pharma Ltd, MHRA Approved
	Me-too status	Sintral SR Tablets 100mg of M/s Neomedix (R.# 081413)
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
866.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dalofen 50mg Tablets
	Composition	Each gastro resistant tablet contains:

		Diclofenac Sodium…50mg
	Diary No. Date of R& I & fee	Dy.No 8300 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac Sodium 50mg Gastro-Resistant Tablets of MHRA approved
	Me-too status	Dicmaf 50mg Tablet of Mafin Reg # 79884 sodium
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
867.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Cetolite Injection 125mg/ml
	Composition	Each ampule of 1ml contains: Citicoline as Sodium…125mg
	Diary No. Date of R& I & fee	Dy.No 8301 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Psychostimulants, Agents Used For ADHD And Nootropics (Other psychostimulants and nootropics)
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	2ml x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	CITICOLINE PANPHARMA 250 mg/ 2 ml, solution injectable (IM,IV) ampoule. ANSM approved
	Me-too status	CT-Nol of M/s Uni-Tiech Pharmaceutials, (Reg.#047049)
	GMP status	Same as above
	Remarks of the Evaluator[IV]	
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
868.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi BY: M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cefrion Injection 250mg IM
	Composition	Each Vial Contains: Ceftriaxone as sodium…250mg
	Diary No. Date of R& I & fee	Dy.No 7717 dated 21-02-2019 Rs.50,000/- 21-02-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin I.M injection of (MHRA approved)
	Me-too status	Accucef 250 mg IM Injection M/s Wel Wink Pharma,
	GMP status	Last GMP inspection of Noa Hemis Pharmaceuticals conducted on 28-02-2019 and the report concludes that the Overall Evaluation of the panel inspection rating is Good. & GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached. • Number of sections of applicant approved by Licensing Board:11 • Number of products already registered/approved on contract manufacturing in the name of applicant :Nil • Cephalosporin dry vial Section of seraph

		pharmaceuticals available
	Decision: Deferred for capacity assessment of M/s Seraph Pharma.	
869.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals. Plot No. 154, Sector-23, Korangi Industrial Area, Karachi BY M/s Seraph Pharmaceuticals pvt Ltd Plot # 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Cefrion Injection 500mg IM
	Composition	Each Vial Contains: Ceftriaxone as sodium…500mgs
	Diary No. Date of R& I & fee	Dy.No 7718 dated 21-02-2019 Rs.50,000/- 21-02-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin I.M injection of (MHRA approved)
	Me-too status	Wixone 500 mg Injection IM M/s Wise Pharmaceuticals,
	GMP status	Last GMP inspection of Noa Hemis Pharmaceuticals conducted on 28-02-2019 and the report concludes that the Overall Evaluation of the panel inspection rating is Good. & GMP certificate issued on 03-07-2018."
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached. • Number of sections of applicant approved by Licensing Board:11 • Number of products already registered/approved on contract manufacturing in the name of applicant :Nil • Cephalosporin dry vial Section of seraph pharmaceuticals available
	Decision: Deferred for capacity assessment of M/s Seraph Pharma.	
870.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Fercari 50mg/ml Solution for Injection/Infusion
	Composition	Each ml contains: Iron as ferric carboxymaltose…50mg
	Diary No. Date of R& I & fee	Dy.No 6194 dated 12-02-2019 Rs.20,000/- 01-02-2019
	Pharmacological Group	Haematinic
	Type of Form	Form -5
	Finished product Specifications	Manufacturer specificartions
	Pack size & Demanded Price	1ml x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ferinject 50 mg iron/mL solution for injection/infusion of MHRA approved
	Me-too status	Ferinject 500mg/10ml by M/s RG. Pharma (Reg#072548) Carefer injection 50mg/ml of M/s S.J. & G. Fazul Ellahie (Approved in 269th meeting)
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."."
	Remarks of the Evaluator[IV]	In reference agency fill volume startts from 2ml
	Decision: Deferred for evidence of approval of applied fill volume i.e Iron (as ferric carboxymaltose) 50mg/ml in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
871.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Xcite Tablets 20mg
	Composition	Each filmcoated tablet contains: Escitalopram Oxalate eq to Escitalopram…20mg

	Diary No. Date of R& I & fee	Dy.No 8736 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors (SSRIs)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, 10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Escitalopram 20 mg Of (MHRA Approved)
	Me-too status	Gentle 20mg Tablet Of M/S Wilson's Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
872.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Ranarazine 25mg Tablet
	Composition	Each Tablet Contains: Cinnarizine…25mg
	Diary No. Date of R& I & fee	Dy.No 8733 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Stugeron25mgTablets of HPRA Ireland approved
	Me-too status	Novertige Tablet 25mg by Medisure Laboratories R.#29248
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
873.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Rakanox Capsule 100mg
	Composition	Each Capsule Contains: Itraconazole as immediate release pellets…100mg
	Diary No. Date of R& I & fee	Dy.No 8739 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer"s specifications
	Pack size & Demanded Price	4's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Itraconazole 100 mg capsules of(MHRA approved)
	Me-too status	Itrax Capsule by M/s Ferozsons Labs
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	Source of pellets: Vision
	Decision: Approved with innovator's specification.	
874.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Motrigine 50mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…50mg

	Diary No. Date of R& I & fee	Dy.No 8732 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamotrigine Accord 50 mg Tablets (MHRA approved)
	Me-too status	Epictal 50mg Tablet of M/s Bosch
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
875.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Motrigine 100mg Tablet
	Composition	Each Tablet Contains: Lomotrigine…100mg
	Diary No. Date of R& I & fee	Dy.No 8734 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamotrigine Accord 100 mg Tablets (MHRA approved)
	Me-too status	Epictal 100mg Tablet of M/s Bosch
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
876.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Rakalor 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy.No 8735 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	5's, 10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too status	Lorfix 8mg Tablet of **M/s** AGP
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
877.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Raxatine 20mg Tablets
	Composition	Each Film Coated Tablet Contains: Paroxetine as HCl…20mg
	Diary No. Date of R& I & fee	Dy.No 8731 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors (SSRIs)

	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities	Paroxetine 20mg Tablets of (MHRA approved)
	Me-too status	Paroxiwel 20 mg Tablets of M/s Welwrd Pharmaceuticals
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
878.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Prebalin 75mg Capsule
	Composition	Each Capsule Contains: Pregabalin……75mg
	Diary No. Date of R& I & fee	Dy.No 8730 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	7's, 10's, 14's, 28's,; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
879.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Raximin 200mg Tablets
	Composition	Each film coated tablet contains: Rifaximin…200mg
	Diary No. Date of R& I & fee	Dy.No 8737 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Anti biotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, 14's, 28's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	XIFAXAN Of (USFDA Approved)
	Me-too status	Nimixa 200mg Tablet M/s Getz
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
880.	Name and address of manufacturer / Applicant	M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Raximin 550mg Tablets
	Composition	Each film coated tablet contains: Rifaximin…550mg
	Diary No. Date of R& I & fee	Dy.No 8738 dated 27-02-2019 Rs.20,000/- 27-02-2019
	Pharmacological Group	Anti biotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications

	Pack size & Demanded Price	10's, 14's, 28's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	XIFAXAN Of (USFDA Approved)
	Me-too status	Nimixa 550mg Tablet M/s Getz
	GMP status	Last GMP inspection conducted on 19-09-2018 and the report concludes that the panel recommend the grant ofcGMP certificate.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
881.	Name and address of manufacturer / Applicant	M/s The Schazoo Zaka Pvt Ltd. Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Dexlanz 30mg Capsule
	Composition	Each Capsule Contains: Dual Delayed Release Pellets of Dexlansoprazole Eq. to Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy.No 929 dated 08-01-2019 Rs.20,000/- 07-01-2019
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexilant Delayed Release Capsule 30mg of USFDA approved
	Me-too status	Lansodex Capsule 30mg of M/S Getz Pharma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Source of pellets (In case of imported source remaining Rs: 80000/- fee) Submit Stability studies along with requisite documents Submit complete manufacturing method
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
882.	Name and address of manufacturer / Applicant	M/s The Schazoo Zaka Pvt Ltd. Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Dexlanz 60mg Capsule
	Composition	Each Capsule Contains: Dual Delayed Release Pellets of Dexlansoprazole Eq. to Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy.No 930 dated 08-01-2019 Rs.20,000/- 07-01-2019
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexilant Delayed Release Capsule 30mg of USFDA approved
	Me-too status	Lansodex Capsule 30mg of M/S Getz Pharma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Source of pellets (In case of imported source remaining Rs: 80000/- fee) Submit Stability studies along with requisite documents Submit complete manufacturing method
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
883.	Name and address of manufacturer / Applicant	M/s The Schazoo Zaka Pvt Ltd. Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Zalast 250mcg Tablets

	Composition	Each Tablet Contains: Roflumilast…250mcg
	Diary No. Date of R& I & fee	Dy.No 927 dated 08-01-2019 Rs.20,000/- 07-01-2019
	Pharmacological Group	Phosphodiesterase-4 Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Daliresp 250mcg tablet of USFDA approved
	Me-too status	
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Submit Stability studies along with requisite document Submit complete manufacturing method Differential fee.
	Decision: Registration Board deferred the case for: • **Submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.** • **Differential fee.**	
884.	Name and address of manufacturer / Applicant	M/s The Schazoo Zaka Pvt Ltd. Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura
	Brand Name +Dosage Form + Strength	Zalast 500mcg Tablets
	Composition	Each Tablet Contains: Roflumilast…500mcg
	Diary No. Date of R& I & fee	Dy.No 928 dated 08-01-2019 Rs.20,000/- 07-01-2019
	Pharmacological Group	Phosphodiesterase-4 Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Daliresp 500mcg tablet of USFDA approved
	Me-too status	
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Submit Stability studies along with requisite documents Submit complete manufacturing method Differential fee.
	Decision: Registration Board deferred the case for: • **Submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.** • **Differential fee.**	
885.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cansartan 8mg Tablet
	Composition	Each Tablet Contains: Candesartan cilexitil…8mg
	Diary No. Date of R& I & fee	Dy.No 7741 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, 28's : As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND of USFDA approved
	Me-too status	Canex 8mg Tablets of Wellborne Pharmachem and Biologicals,

	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
886.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cansartan 16mg Tablet
	Composition	Each Tablet Contains: Candesartan cilexitil……16mg
	Diary No. Date of R& I & fee	Dy.No 7742 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, 28's : As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND of USFDA approved
	Me-too status	Canex 16mg Tab. of Wellborne Pharmachem & Biologicals,
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
887.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cansartan 32mg Tablet
	Composition	Each Tablet Contains: Candesartan cilexitil……32mg
	Diary No. Date of R& I & fee	Dy.No 7743 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, 28's : As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND of USFDA approved
	Me-too status	Advant Tablets 32mg of Getz Pharma,,
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
888.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cansartan plus 16mg+12.5mg Tablet
	Composition	Each Tablet Contains: Candesartan cilexitil…16mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 7744 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Angiotensin II receptor antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND HCT of USFDA approved
	Me-too status	Kandex -H Tablet 16mg/12.5mg of AGP
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

889.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cansartan plus 32.5mg+12.5mg Tablet
	Composition	Each Tablet Contains: Candesartan cilexitil…32mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 7745 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Angiotensin II receptor antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND of USFDA approved
	Me-too status	Advantec Tablet of Getz Pharma,,
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
890.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Etox Tablet 60mg
	Composition	Each film coat Tablet Contains: Etoricoxib …60mg
	Diary No. Date of R& I & fee	Dy.No 7725 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	10's : As per SRO
	Approval status of product in Reference Regulatory Authorities	ARCOXIA 60 MG of (MHRA approved)
	Me-too status	Oraxib 60mg Table M/s. Atco Lab
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification	
891.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Indamide 2.5mg Tablet
	Composition	Each Tablet Contains: Indapamide…2.5mg
	Diary No. Date of R& I & fee	Dy.No 7722 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Natrilix 2.5 mg Tablets of (MHRA approved)
	Me-too status	Indamid Tablets 2.5mg. M/s Ferozsons Laboratories
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
892.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Indopril 2mg Tablet

	Composition	Each Tablet Contains: Perindopril Erbumine…2mg
	Diary No. Date of R& I & fee	Dy.No 7734 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Perindopril Erbumine 2 mg tablets of (MHRA approved)
	Me-too status	Dopril Tablets 2mg of M/s Novamed Pharmaceuticals,
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
893.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Indopril 4mg Tablet
	Composition	Each Tablet Contains: Perindopril Erbumine…4mg
	Diary No. Date of R& I & fee	Dy.No 7735 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Perindopril Erbumine 4 mg tablets of (MHRA approved)
	Me-too status	Dopril Tablets 2mg. M/s Novamed Pharmaceuticals,
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
894.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Indopril 8mg Tablet
	Composition	Each Tablet Contains: Perindopril Erbumine…8mg
	Diary No. Date of R& I & fee	Dy.No 7736 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Perindopril Erbumine 4 mg tablets of (MHRA approved)
	Me-too status	Hartace Tablets 8mg. M/s CSH, Pharmaceuticals
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
895.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Repanide 0.5mg Tablet
	Composition	Each Tablet Contains: Repaglinide…0.5mg
	Diary No. Date of R& I & fee	Dy.No 7731 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019

	Pharmacological Group	Diuretic Blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Repaglinide of (MHRA approved)
	Me-too status	Repascot Tablets 0.5mg. M/s Scotmann Pharmaceuticals
	GMP status	Last GMP inspection conducted on 04-09-2018 and the report concludes that the on the day of inspection the firm has Good compliance of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
896.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Repanide 1mg Tablet
	Composition	Each Tablet Contains: Repaglinide…..1mg
	Diary No. Date of R& I & fee	Dy.No 7732 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Diuretic Blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Repaglinide of (MHRA approved)
	Me-too status	Repascot Tablets 1mg. M/s Scotmann Pharmaceuticals
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
897.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Repanide 2mg Tablet
	Composition	Each Tablet Contains: Repaglinide…..2mg
	Diary No. Date of R& I & fee	Dy.No 7733 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Diuretic Blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Repaglinide of (MHRA approved)
	Me-too status	Repascot Tablets 2mg. M/s Scotmann Pharmaceuticals
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
898.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sparox 200mg Tablet
	Composition	Each film coated Tablet Contains: Sparfloxacin …200mg
	Diary No. Date of R& I & fee	Dy.No 7724 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5

	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Unispar Tablets M/s Universal Pharmaceuticals
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	Zagam Tablets of (USFDA) Discontinued
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
899.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Monoflex C 37.5mg/325mg Tablet
	Composition	Each Tablet Contains: Tramadol HCL…37.5mg Paracetamol…325mg
	Diary No. Date of R& I & fee	Dy.No 7721 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramacet tablet of (MHRA approved)
	Me-too status	Radol-P tablet of M/s Regal Pharmaceuticals
	GMP status	Last GMP inspection conducted on 04-09-2018 and the report concludes that the on the day of inspection the firm has Good compliance of GMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
900.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Iron Pros Plus 400/2.5 mg Tablet
	Composition	Each Tablet Contains: Iron Protein Succinylate……400mg (Eq to 20mg elemental iron) Folic Acid……2.5mg
	Diary No. Date of R& I & fee	Dy.No. 36295 dated 01-11-2018 Rs.20,000/- 31-10-2018
	Pharmacological Group	Antianemic preparations
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2 x 7's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Eisen Tablets of Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 31-07-2018.and report concludes firm has GOOD level of GMP compliance
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
901.	Name and address of manufacturer / Applicant	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Glitamit 50/850mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Vildagliptin…50mg Metformin HCl…850mg
	Diary No. Date of R& I & fee	Dy.No. 41991 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+850mg Tablet M/s Getz
	GMP status	Last GMP inspection conducted on 20-12-2017 and report concludes that The panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest."
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
902.	Name and address of manufacturer / Applicant	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Glitamit 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……50mg Metformin……1000mg
	Diary No. Date of R& I & fee	Dy.No. 41990 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	Last GMP inspection conducted on 20-12-2017 and report concludes that The panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest."
	Remarks of the Evaluator[IV]	• Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
903.	Name and address of manufacturer / Applicant	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Silsin 50mg Tablts
	Composition	Each Film Coated Tablet Contains: Sertraline as Hydrochloride…50mg
	Diary No. Date of R& I & fee	Dy.No. 41992 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti depressant
	Type of Form	Form 5
	Finished product Specification	USP

	Pack size & Demanded Price	2 x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zoloft Tablet Of (USFDA Approved)
	Me-too status	Ertalin 50 mg Tablets M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 20-12-2017 and report concludes that The panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest."
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
904.	Name and address of manufacturer / Applicant	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Silsin 100mg Tablts
	Composition	Each Film Coated Tablet Contains: Sertraline as Hydrochloride……100mg
	Diary No. Date of R& I & fee	Dy.No. 41993 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti depressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zoloft Tablet Of (USFDA Approved)
	Me-too status	Ertalin 100 mg Tablets M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 20-12-2017 and report concludes that The panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest."
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
905.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Teldipine 40mg/5mg Tablet
	Composition	Each Bi-layered Uncoated tablet contains: Amlodipine Besylate eq to Amlodpine…… 5mg Telmisartan ……..… 40mg
	Diary No. Date of R& I & fee	Dy.No 41840 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Ezitab-AM 5/40mg TABLET by Werrick Pharma (Reg no. 082041)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	Evidence of bilayered compression machine not provided
	Decision:Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.	
906.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Teldipine 40mg/10mg Tablet

	Composition	Each Bi-layered Uncoated tablet contains: Amlodipine Besylate eq to Amlodpine…… 10mg Telmisartan ……..… 40mg
	Diary No. Date of R& I & fee	Dy.No 41841 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Ezitab-AM 10/40mg TABLET Werrick Pharmaceuticals (Reg no. 082045)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	Evidence of bilayered compression machine not provided
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.	
907.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Teldipine 80mg/5mg Tablet
	Composition	Each Bi-layered Uncoated tablet contains: Amlodipine Besylate eq to Amlodpine…… 5mg Telmisartan ……..… 80mg
	Diary No. Date of R& I & fee	Dy.No 41842 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Ezitab-AM 5/80mg TABLET by Werrick Pharma (Reg no. 082044)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	Evidence of bilayered compression machine not provided
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.	
908.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Teldipine 80mg/10mg Tablet
	Composition	Each Bi-layered Uncoated tablet contains: Amlodipine Besylate eq to Amlodpine…… 10mg Telmisartan ……..… 80mg
	Diary No. Date of R& I & fee	Dy.No 41843 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta of USFDA Approved
	Me-too status	Telam 80mg/10mg Tablet of M/s Macter
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	Evidence of bilayered compression machine not provided
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet biayered	

	machine by area FID.	
909.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Betawin 24m Tablet
	osition	Each Uncoated Tablet Contains: Betahistine Dihydrochloride …….24mg
	Diary No. Date of R& I & fee	Dy.No 41818 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti-Vertigo
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Betahistine of MHRA Approved
	Me-too status	Enier 24mg Tablet of Sami Pharmaceutical
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
910.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Betawin 48m Tablet
	osition	Each Uncoated Tablet Contains: Betahistine Dihydrochloride …….48mg
	Diary No. Date of R& I & fee	Dy.No 41879 dated 07-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Vertigo
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Statobex 48mg Tablet by Atco Laboratories (058433)
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator[IV]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which weredeclared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
911.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Linocell 600mg Tablets
	Composition	Each Film Coated Tablet Contains: Linezolid……600mg
	Diary No. Date of R& I & fee	Dy.No 6195 dated 12-02-2019 Rs.20,000/- 12-02-2019
	Pharmacological Group	Oxazoldone Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	10's, 5's, 12's ;As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 400 mg tablet of (USFDA approved)
	Me-too status	Ecasil 600mg tablet by M/s Sami (Reg#066904)
	GMP status	Last GMP inspection conducted on 11-01-2019and report concludes that panel recommend the renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

912.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Combo Pack (Osmolar ORS Zincat-OD Syrup)
	Composition	Each Sachet Contains: Sodium Chloride…1.3g Tri Sodium Citrate Dihydrate…1.45gm Potassium Chloride…0.75gm Anhydrous Glucose…6.75gm Each 5ml Contains: Elemental Zinc as Zinc Sulphate Monohydrate…20mg
	Diary No. Date of R& I & fee	Dy.No 1679 dated 14-01-2019 Rs.20,000/- 14-01-2019
	Pharmacological Group	Anti diaarheal (Oral electrolyter replacer)
	Type of Form	Form 5
	Finished product Specifications	International Pharmacopoeia Zinc: USP
	Pack size & Demanded Price	4 sachet, 1 x 60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Me-too status is not available as combo pack
	GMP status	Last GMP inspection of conducted on 09-07-2019, and the report concludes that the Overall GMP of the firm is rated as good, based on the area inspected, the people met and the documents reviewed
	Remarks of the Evaluator[IV]	
	Decision: Deferred for following: • **Confirmation of WHO approval status of relevant dosage form** • **Submission of application on Form 5D since the applied combo pack is not registered in Pakistan** • **Submission of balance fee 30,000/-**	
913.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Combo Pack (Osmolar ORS Zincat 20mg Tablet)
	Composition	Each Sachet Contains: Sodium Chloride…1.3g Tri Sodium Citrate Dihydrate…1.45gm Potassium Chloride…0.75gm Anhydrous Glucose…6.75gm Each Dispersible Tablet Contains: Elemental Zinc as Zinc Sulphate Monohydrate…20mg
	Diary No. Date of R& I & fee	Dy.No 1680 dated 14-01-2019 Rs.20,000/- 14-01-2019
	Pharmacological Group	Anti diaarheal(Oral electrolyter replacer)
	Type of Form	Form 5
	Finished product Specifications	International Pharmacopoeia Zinc : USP
	Pack size & Demanded Price	4 sachet, 1 x 10'sl: As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Me-too status is not available as combo pack
	GMP status	Last GMP inspection of conducted on 09-07-2019, and the report concludes that the Overall GMP of the firm is rated as good, based on the area inspected, the people met and the documents reviewed
	Remarks of the Evaluator[IV]	

	Decision: Deferred for following: • **Confirmation of WHO approval status of relevant dosage form** • **Submission of application on Form 5D since the applied combo pack is not registered in Pakistan** • **Submission of balance fee 30,000/-**	
914.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Misso Tablet 100mcg
	Composition	Each Tablet Contains: Misoprostol (As 1 %HPMC dispersion)… …100mcg
	Diary No. Date of R& I & fee	Dy.No 4646 dated 01-02-2019 Rs.20,000/- 01-02-2019
	Pharmacological Group	Prostaglandin
	Type of Form	Form 5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec of (FDA approved)
	Me-too status	Tecmiso 100mcg tablet M/s NabiQasim,
	GMP status	Last GMP inspection conducted on 20-07-2019 and report concludes that as per findings of the inspection recorded on cGMP audit proforma and keeping in view the overall cGMP compliance staus of the firm in terms of plant, premises, manufacturing, quality control, environmental facilities provided, documentation, qualified staff employed, validation and caliberation record evaluation, the panel unanimously recommended the grant of cGMP certificate to the firm.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
915.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Misso Tablet 200mcg
	Composition	Each Tablet Contains: Misoprostol (As 1 %HPMC dispersion)…200mcg
	Diary No. Date of R& I & fee	Dy.No 4647 dated 01-02-2019 Rs.20,000/- 01-02-2019
	Pharmacological Group	Prostaglandin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec of (USFDA approved)
	Me-too status	Miso 200mcg tablet M/s Global Pharmaceuticals,
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
916.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Ator Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate eq to Atorvastatin…10mg
	Diary No. Date of R& I & fee	Dy.No 5870 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Hypolipidamic(Statin)
	Type of Form	Form 5
	Finished product Specifications	JP
	Pack size & Demanded Price	2 x 10's: As Per SRO
	Approval status of product in Reference	Lipitor tablets by Pfizer (MHRA Approved)

	Regulatory Authorities	
	Me-too status	Lipitor of M/s Pfizer
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
917.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Ator Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate eq to Atorvastatin…20mg
	Diary No. Date of R& I & fee	Dy.No 5869 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Hypolipidamic(Statin)
	Type of Form	Form 5
	Finished product Specifications	JP
	Pack size & Demanded Price	2 x 10's: As Per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor tablets by Pfizer (MHRA Approved)
	Me-too status	Lipitor of M/s parke-davis
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
918.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Ateze Tablet 10/10mg
	Composition	Each film coated Tablet Contains: Atorvastatin as calcium trihydrate…10mg Ezetimibe…10mg
	Diary No. Date of R& I & fee	Dy.No 4638 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Lipid lowering Agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Liptruzet of USFDA approved
	Me-too status	Iril 10/10 Tablet of M/S Genix Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	Firm change formulation from uncoated tablet to film coated Tablet with submission of fee of Rs. 5000/- (deposit slip # 1984265) dated 02-06-2020.
	Decision: Approved with innovator's specification.	
919.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Ateze Tablet 20/10mg
	Composition	Each film coated Tablet Contains: Atorvastatin as calcium trihydrate…20mg Ezetimibe…10mg
	Diary No. Date of R& I & fee	Dy.No 4639 dated 01-02-2019 Rs.20,000/- 01-02-2019
	Pharmacological Group	Lipid lowering Agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Liptruzet of USFDA approved
	Me-too status	Lipiget EZ 20mg+10mg Tablet of M/S Getz Pharma
	GMP status	As above

	Remarks of the Evaluator[IV]	Firm change formulation from uncoated tablet to film coated Tablet with submission of fee of Rs. 5000/- (deposit slip # 1984266) dated 02-06-2020.
	Decision: Approved with innovator's specification.	
920.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Topmate Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Topiramate…25mg
	Diary No. Date of R& I & fee	Dy.No 5857 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic agent
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax Of (USFDA Approved)
	Me-too status	Lowseiz 25mg Tablets of M/S Helix Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
921.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Topmate Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Topiramate…50mg
	Diary No. Date of R& I & fee	Dy.No 5858 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic agent
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax Of (USFDA Approved)
	Me-too status	Lowseiz 50mg Tablets of M/S Helix Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
922.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Topmate Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Topiramate…100mg
	Diary No. Date of R& I & fee	Dy.No 5876 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic agent
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax Of (USFDA Approved)
	Me-too status	Epilock 100 mg Tablets of M/S Welmark Pharmaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
923.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Telmi Tablet 40mg
	Composition	Each Tablet Contains:

		Telmisartan…..40mg
	Diary No. Date of R& I & fee	Dy.No 5859 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 40mg Tablets of M/S Highnoon Laboratories
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
924.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Telmi Tablet 80mg
	Composition	Each Tablet Contains: Telmisartan……80mg
	Diary No. Date of R& I & fee	Dy.No 5860 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 80mg Tablets of M/S Highnoon Laboratories
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
925.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Cotelmi Tablet 40/12.5mg
	Composition	Each Bilayer uncoated Tablet Tablet Contains: Telmisartan…12.5mg Hydrochlorothiazide…40mg
	Diary No. Date of R& I & fee	Dy.No 5878 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 40/12.5mg Tablet of M/S Tabros Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	Firm change formulation from uncoated tablet to Bilayer uncoated Tablet with submission of fee of Rs. 5000/- (deposit slip # 1984279) dated 02-06-2020..
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.	
926.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Cotelmi Tablet 80/12.5mg
	Composition	Each Bilayer uncoated Tablet Contains: Telmisartan…12.5mg Hydrochlorothiazide…80mg
	Diary No. Date of R& I & fee	Dy.No 5877 dated 11-02-2019 Rs.20,000/- 11-02-2019

	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 80/12.5mg Tablet of M/S Tabros Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	Firm change formulation from uncoated tablet to Bilayer uncoated Tablet with submission of fee of Rs. 5000/- (deposit slip # 1984272) dated 02-06-2020..
	Decision: Deferred for confirmation of required manufacturing equipment i.e. tablet biayered machine by area FID.	
927.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Cefodox 40mg Suspension
	Composition	Each 5ml reconstituted suspension contains: Cefpodoxime Proxetil eq to Cefpodoxime…40mg
	Diary No. Date of R& I & fee	Dy.No 5882 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ml ; As per PRC
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime 40mg / 5 ml powder for oral suspension of MHRA approved
	Me-too status	Podomax Dry Suspension of M/s Hicon Pharmaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	Dry powder suspension (Cephalosporin) section available.
	Decision: Approved.	
928.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Clomix Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Clomipramine HCL…25mg
	Diary No. Date of R& I & fee	Dy.No 5885 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PLACIL of TGA; Australia Approved
	Me-too status	Clomipril Tablets of M/s Libra
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
929.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Epivon Tablet 250mg
	Composition	Each enteric coated tablet contains: Divalproex Sodium eq. to Valproic acid …250mg
	Diary No. Date of R& I & fee	Dy.No 5871 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic & Anticonvulsant
	Type of Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Depakote tablet USFDA Approved
	Me-too status	Valrox Tablet 250mg of M/s Polyfine Chemical
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
930.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Epivon Tablet 500mg
	Composition	Each enteric coated tablet contains: Divalproex Sodium eq. to Valproic acid …500mg
	Diary No. Date of R& I & fee	Dy.No 5872 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic & Anticonvulsant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Depakote tablet USFDA Approved
	Me-too status	Valrox Tablet of M/s Polyfine Chemical
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
931.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Epivon Syrup 250mg
	Composition	Each 5ml contains: Sodium Valproate eq to valproic acid …250mg
	Diary No. Date of R& I & fee	Dy.No 5873 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic & Anticonvulsant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Gen- Valproic 250mg/5ml of canada
	Me-too status	Valrox Tablet 250mg/5ml of M/s Polyfine Chemical
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
932.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Fludezan Injection 25mg
	Composition	Each 1ml ampoule contains: Fluphenazine Decanoate…25mg
	Diary No. Date of R& I & fee	Dy.No 5883 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fluphenazine of Fresenius Kabi of (USFDA)
	Me-too status	Xzine Injection of Global Pharmaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	vehicle used is sesame oil as was used in MHRA product
	Decision: Approved.	

933.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	G-Met Tablet 1/500mg
	Composition	Each Film Coated Tablet Contains: Glimepride…1mg Metformin as HCL…500mg
	Diary No. Date of R& I & fee	Dy.No 4640 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Anti-Diabetic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Diabold Plus Tablet M/s Barret Hodgson ,
	GMP status	As above
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
934.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	G-Met Tablet 2/500mg
	Composition	Each Film Coated Tablet Contains: Glimepride…2mg Metformin as HCL…500mg
	Diary No. Date of R& I & fee	Dy.No 4641 dated 01-02-2019 Rs.20,000/- 01-02-2019
	Pharmacological Group	Anti-Diabetic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Gpride-M SR Tablet M/s Sami pharamaceuticals
	GMP status	As above
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
935.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Lacost Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Dy.No 5879 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Nurosa 50mg Table M/s Helix Pharma

	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
936.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Lacost Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Dy.No 5880 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Nurosa 100mg Table M/s Helix Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
937.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Lacost Tablet 150mg
	Composition	Each Film Coated Tablet Contains: Lacosamide…150mg
	Diary No. Date of R& I & fee	Dy.No 5881 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat tablet of (USFDA approved)
	Me-too status	Atcomid 150mg Tablet M/s Atco Lab
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
938.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Levrace Tablet 250mg
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Dy.No 5868 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levetiracetam of (MHRA Approved)
	Me-too status	Letrawin Tablets 250mg of M/s Opal Laboratory
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
939.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Levrace Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg

	Diary No. Date of R& I & fee	Dy.No 5867 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levetiracetam of (MHRA Approved)
	Me-too status	Letrawin Tablets 500mg of M/s Opal Laboratory
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
940.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Levrace Tablet 750mg
	Composition	Each Film Coated Tablet Contains: Levetiracetam…750mg
	Diary No. Date of R& I & fee	Dy.No 5866 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA of (USFDA approved)
	Me-too status	Fitzloc 750mg Tablet by M/s OBS Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
941.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Levrace Oral Solution 100mg
	Composition	Each ml contains: Levetiracetam…100mg
	Diary No. Date of R& I & fee	Dy.No 5864 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA 100mg/ml oral solution of USFDA approved
	Me-too status	Tamlev 100mg/ml oral Solution M/s Medisure Lab
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
942.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Levrace Injection 500mg
	Composition	Each 5ml Ampoule contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy.No 5864 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA 500mg/5ml oral solution of USFDA approved

	Me-too status	Lumark Injection M/s Searle Pak
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
943.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Levon Tablet 0.75mg
	Composition	Each Tablet Contains: Levonorgestrel…0.75mg
	Diary No. Date of R& I & fee	Dy.No 5884 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Hormonal contraceptives for systemic use
	Type of Form	Form -5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Morning Pill Tablet by M/s OBS
	GMP status	As above
	Remarks of the Evaluator[IV]	The firm change formulation from film coated tablet to uncoated tablet with submission of fee of Rs. 5000/- (deposit slip # 1984264). Tablet Hormone section available but not clear Steriodal Hormonal Tablet Section or non Steriodal Hormonal Tablet Section
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
944.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Nebol Tablet 2.5mg
	Composition	Each Tablet Contains: Nebivolol HCL eq to Nebivolol…2.5mg
	Diary No. Date of R& I & fee	Dy.No 5887 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Beta-1 receptor blocker
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic Tablet Of (USFDA Approved)
	Me-too status	Nibovo Tablets 2.5mgM/s. Dyson Research Laboratories
	GMP status	As above
	Remarks of the Evaluator[IV]	Firm change formulation from film coated tablet to uncoated Tablet with submission of fee of Rs. 5000/- (deposit slip # 1984268) dated 02-06-2020.
	Decision: Approved with innovator's specification.	
945.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Nebol Tablet 5mg
	Composition	Each Tablet Contains: Nebivolol HCL eq to Nebivolol…5mg
	Diary No. Date of R& I & fee	Dy.No 5888 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Beta-1 receptor blocker
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic Tablet Of (USFDA Approved)

	Me-too status	Nebilol 5mg Tablet M/s Genix Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	Firm change formulation from film coated tablet to uncoated Tablet with submission of fee of Rs. 5000/- (deposit slip # 1984269) dated 02-06-2020.
	Decision: Approved with innovator's specification.	
946.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Nebol Tablet 10mg
	Composition	Each Tablet Contains: Nebivolol HCL eq to Nebivolol…10mg
	Diary No. Date of R& I & fee	Dy.No 5886 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Beta-1 receptor blocker
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic Of (USFDA Approved)
	Me-too status	Nabilox 10mg Tablet M/s Nabiqasim
	GMP status	As above
	Remarks of the Evaluator[IV]	Firm change formulation from film coated tablet to uncoated Tablet with submission of fee of Rs. 5000/- (deposit slip # 1984270) dated 02-06-2020.
	Decision: Approved with innovator's specification.	
947.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Quetin Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate…25mg
	Diary No. Date of R& I & fee	Dy.No 5863 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Quit 25mg Tablets of M/s Navegal Labs, (Reg.# 068244)
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
948.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Quetin Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate…100mg
	Diary No. Date of R& I & fee	Dy.No 5862 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine Approved by MHRA of UK
	Me-too status	Qusel tablet 100mg of M/s Hilton Pharma
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

949.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Quetin Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate…200mg
	Diary No. Date of R& I & fee	Dy.No 5861 dated 11-02-2019 Rs.20,000/- 11-02-2019
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SEROQUEL (of USFDA approved)
	Me-too status	Quit 200mg Tablets of M/s Navegal Labs, (Reg.# 068241)
	GMP status	As above
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
950.	Name and address of manufacturer / Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk BY M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial
	Brand Name +Dosage Form + Strength	Pleom Injection 40mg
	Composition	Each amber glass vial contains: Omeprazole as sodium …40mg
	Diary No. Date of R& I & fee	Dy.No 8265 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacture's specification
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazol 40mg injection of (MHRA approved)
	Me-too status	Fymezole Dry Powder Injection IV of M/s Fynk Pharmaceuticals
	GMP status	Last GMP inspection of Perk Pharma conducted on 10-01-2019 and the report concludes that the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their compliance. The firm may be considerd operating in satisfactory level of cGMp compliance. & Last GMP inspection of Mediate Pharmaceuticals conducted on 04-03-2020 and the report concludes that the firm was considered to be operating at an acceptable level of compliance.
	Remarks of the Evaluator[IV]	• Firm revised salt form "Omeprazole as sodium" without submission of fee. • Copy of Contract manufacturing agreement attached • Number of sections of applicant approved by Licensing Board: 04 • Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Deferred for submission of fee for revision of formulation.	
951.	Name and address of manufacturer / Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk BY M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial

	Brand Name +Dosage Form + Strength	Ketoper 30mg Injection
	Composition	Each ampoule contains: Ketorolac Tromethane…30mg/ml
	Diary No. Date of R& I & fee	Dy.No 8264 dated 25-02-2019 Rs.50,000/- 25-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1ml x 5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Toradol 30mg/ml of TGA approved
	Me-too status	Ketopan Injection 30mg by M/s Welwrd Pharmaceuticals,
	GMP status	Last GMP inspection of Perk Pharma conducted on 10-01-2019 and the report concludes that the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their compliance. The firm may be considerd operating in satisfactory level of cGMp compliance. & Last GMP inspection of Mediate Pharmaceuticals conducted on 04-03-2020 and the report concludes that the firm was considered to be operating at an acceptable level of compliance.
	Remarks of the Evaluator[IV]	• Copy of Contract manufacturing agreement attached • Number of sections of applicant approved by Licensing Board: 04 • Number of products already registered/approved on contract manufacturing in the name of applicant: Nil
	Decision: Approved.	
952.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Atomin 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Atenolol…25mg
	Diary No. Date of R& I & fee	Dy.No. 40503 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antihypertensive/Beta Blocker
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Atenolol 25mg of (MHRA Approved)
	Me-too status	Atenoscot Tablets 25mg of M/S Scotmann Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
953.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Atomin 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Atenolol…50mg
	Diary No. Date of R& I & fee	Dy.No. 40504 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antihypertensive/Beta Blocker
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 100's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Atenolol 50mg of (MHRA Approved)
	Me-too status	Atenoscot Tablets 50mg of M/S Scotmann Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
954.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Atomin 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Atenolol…100mg
	Diary No. Date of R& I & fee	Dy.No. 40505 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antihypertensive/Beta Blocker
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 100's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Atenolol 100mg of (MHRA Approved)
	Me-too status	Atenoscot Tablets 100mg of M/S Scotmann Pharma
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved	
955.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tarcit 5mg/5ml Syrup
	Composition	Each 5ml contains: Cetirizine Dihydrochloride…5mg
	Diary No. Date of R& I & fee	Dy.No. 40502 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	30, 60ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Piriteze Allergy 1mg/ml Syrup of (MHRA approved)
	Me-too status	Rizox 5mg/5ml Syrup of M/s Espoir
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved	
956.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Miso 200mcg Tablet
	Composition	Each Tablet Contains: Misoprostol…..200mcg
	Diary No. Date of R& I & fee	Dy.No. 41494 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Prostaglandin

	Type of Form	Form 5
	Finished product Specification	IP
	Pack size & Demanded Price	5's, 10's, 20's As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec of (FDA approved)
	Me-too status	Miso 200mcg tablet M/s Global Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	Availability of Misoprostol as 1 % HPMC could not be verified.
	Decision: Deferred for confirmation of physical form of Misoprostol used in the composition whether in dispersion form or otherwise.	
957.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tramax 50mg Capsule
	Composition	Each Capsule Contains: Tramadol Hcl……50mg
	Diary No. Date of R& I & fee	Dy.No. 41496 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Narcotic analgesic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYDOL 50mg Capsules of (MHRA approved)
	Me-too status	Magadol 50mg Capsule of M/s Safe Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
958.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Laxolax 5mg/5ml Syrup
	Composition	Each 5ml contains: Sodium picosulfate …5mg
	Diary No. Date of R& I & fee	Dy.No. 40500 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Laxative
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Dulcolax Pico Liquid of (MHRA approved)
	Me-too status	Laxacos of M/s Bio-Labs Reg # 056766
	GMP status	Last GMP inspection conducted on 10-04-18**,** and report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
959.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Laxolax 5mg Tablet
	Composition	Each Tablet Contains:

		Sodium picosulfate…5mg
	Diary No. Date of R& I & fee	Dy.No. 40499 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Laxative
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, 60's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Laxoberal laxative tablets of Sanofi Aventis Germany
	Me-too status	U-Salax of M/s Usawa (Reg. 075548)
	GMP status	Last GMP inspection conducted on 10-04-18**,** and the report concludes that the firm was considered to be operating at an acceptable level of compliance with good manufacturing practices
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
960.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Laboratories Private Limited. 149-Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Podcure 40mg/5ml Dry Suspension
	Composition	Each 5ml contains: Cefpodoxime as Proxetil…40mg
	Diary No. Date of R& I & fee	Dy.No 7991 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ml ; As per PRC
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime 40mg / 5 ml powder for oral suspension of MHRA approved
	Me-too status	Podomax Dry Suspension of M/s Hicon Pharmaceuticals
	GMP status	Last GMP inspection of Fedro Pharmaceuticals conducted on 30-01-2019 and report concludes the firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their CGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
961.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Amodip P 5mg/4mg Tablet
	Composition	Each Tablet Contains: Amlodipine as besylate…5mg Perindopril Erbumine…4mg
	Diary No. Date of R& I & fee	Dy.No 7737 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Calcium Channel Blocker + ACE Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, / As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065962)
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

962.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Amodip P 5mg/8mg Tablet
	Composition	Each Tablet Contains: Amlodipine as besylate…5mg Perindopril Erbumine…8mg
	Diary No. Date of R& I & fee	Dy.No 7738 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Calcium Channel Blocker + ACE Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, / As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharma (R.No.065961)
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
963.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Amodip P 10mg/4mg Tablet
	Composition	Each Tablet Contains: Amlodipine as besylate…10mg Perindopril Erbumine…4mg
	Diary No. Date of R& I & fee	Dy.No 7739 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Calcium Channel Blocker + ACE Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, / As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065959)
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
964.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Amodip P 10mg/8mg Tablet
	Composition	Each Tablet Contains: Amlodipine as besylate…10mg Perindopril Erbumine…8mg
	Diary No. Date of R& I & fee	Dy.No 7740 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Calcium Channel Blocker + ACE Inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, / As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065960)
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

965.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Calcitrol B Ointment
	Composition	Each gram contains: Calciterol as Monohydrate…50mcg Betamethasone as Dipropionate…0.5mg
	Diary No. Date of R& I & fee	Dy.No 7723 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Anti-psoriatic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	15gm / As per SRO
	Approval status of product in Reference Regulatory Authorities	Dovobet 50 microgram/g + 0.5 mg/g ointment of MHRA Approved
	Me-too status	Daivobet of Zam Zam corporation (Reg # 031379
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	• Ointment section available
	Decision: Approved with innovator's specification.	
966.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Bactrocin 2% w/w Ointment
	Composition	Each gram contains: Mupirocin free base…2% w/w
	Diary No. Date of R& I & fee	Dy.No 7726 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Topical antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	15gm x 1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Bactroban 2% Ointment of (MHRA approved)
	Me-too status	Mupiderm Ointment of M/s Tabros Pharma
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	Firm change formulation from Mupirocin as calcium to Mupirocin(free base) with submission of fee of Rs: 5000/- Deposit slip no #1979080, Dated: 01-06-2020
	Decision: Approved.	
967.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Bactrocin 2% w/w cream 15gm
	Composition	Each gram contains: Mupirocin as calcium…15gm
	Diary No. Date of R& I & fee	Dy.No 7727 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Topical antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	15gm x 1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Bactroban 2% cream of (MHRA approved)
	Me-too status	Tryderm 2% CreamM/s Ciba Pharmaceuticals
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	

968.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ropinson 0.25mg Tablet
	Composition	Each film coated Tablet Contains: Ropinirole as Hcl…0.25mg
	Diary No. Date of R& I & fee	Dy.No 7728 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Anti-Parkinson/ Dopamine agonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	REQUIP of USFDA approved
	Me-too status	Ronirol 0.25mg Tablets of M/s Hilton Pharma
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
969.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ropinson 1mg Tablet
	Composition	Each film coate tablet Contains: Ropinirole as Hcl……1mg
	Diary No. Date of R& I & fee	Dy.No 7729 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Anti-Parkinson/ Dopamine agonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	REQUIP of USFDA approved
	Me-too status	Ronirol 1mg Tablets of M/s Hilton Pharma
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator	
	Decision:Approved.	
970.	Name and address of manufacturer / Applicant	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ropinson 2mg Tablet
	Composition	Each film coated Tablet Contains: Ropinirole as Hcl……2mg
	Diary No. Date of R& I & fee	Dy.No 7730 dated 21-02-2019 Rs.20,000/- 21-02-2019
	Pharmacological Group	Anti-Parkinson/ Dopamine agonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	REQUIP of USFDA approved
	Me-too status	Ronirol 2mg Tablets of M/s Hilton Pharma
	GMP status	Certificate of cGMP based on the inspection conducted on 20-05-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
971.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Acit 25mg Capsule
	Composition	Each Capsule Contains: Acitretin……25mg

	Diary No. Date of R& I & fee	Dy.No 7066 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Second –Generation Retinoid
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Soriatane Approved by USFDA approved
	Me-too status	Acetin Capsules 25mg of M/s Genome Pharmaceuticals (Reg.# 064013)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
972.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Adelen 250mg/ml Injection
	Composition	Each ml Contains: Citicoline as Sodium…250mg
	Diary No. Date of R& I & fee	Dy.No 7065 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Psychostimulants, Agents Used For ADHD And Nootropics (Other psychostimulants and nootropics)
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	1ml x 5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	CITICOLINA FERRER 1000 mg/4ml solution for injection of Spain approved
	Me-too status	Neurolin Injection of M/s Global Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	Fill volume 1ml while in reference and metoo 4ml
	Decision: Deferred for evidence of approval of applied fill volume i.e Citicoline (as Sodium) 250mg/1ml in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
973.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Retan 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Eletriptan as Hydrobromide…20mg
	Diary No. Date of R& I & fee	Dy.No 7071 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Anti-Migraine
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	2's, 6's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	RELPAX 20mg tablet of USADA approved
	Me-too status	Elle Tablets 20mg of M/s Wilshire Laboratories
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
974.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Retan 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Eletriptan as Hydrobromide…40mg
	Diary No. Date of R& I & fee	Dy.No 7889 dated 22-02-2019 Rs.20,000/- 22-02-2019

	Pharmacological Group	Anti-Migraine
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	2's, 6's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	RELPAX 20mg tablet of USADA approved
	Me-too status	Relpax 40mg Tablets of Pfizer Laboratories Ltd.
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
975.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Melzin 800mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Mesalamine…800mg
	Diary No. Date of R& I & fee	Dy.No 7901 dated 22-02-2019 Rs.20,000/- 22-02-2019 (Duplicate)
	Pharmacological Group	Aminosalicylate anti-inflammatory
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Asacol HD delayed-release tablet of USFDA approved
	Me-too status	MASACOL 800mg Tablet of GETZ Pharma (Reg#061348)
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
976.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Adkast 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Montelukast as sodium…10mg
	Diary No. Date of R& I & fee	Dy.No 8687 dated 27-02-2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 7's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair Of (MHRA Approved)
	Me-too status	Mecost 10mg Tablet M/s Sigma
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
977.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Amelox 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Norfloxacin…400mg
	Diary No. Date of R& I & fee	Dy.No 7890 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP

	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Noroxin of USFDA approved
	Me-too status	Bacnor Tablets 400mg of M/s Dyson Research Laboratories
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	On Challan form generic name of another product was mentioned with cutting Brand name Amelox written.
	Decision: Deferred for submission of fee for instant product.	
978.	Name and address of manufacturer / Applicant	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Virbi 400mg Tablet
	Composition	Each film coated Tablet Contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	Dy.No 7067 dated 19-02-2019 Rs.20,000/- 19-02-2019
	Pharmacological Group	Anti viral
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Barovir 400mg Tablet of M/s BarrettHodgson Reg # 056000
	GMP status	Last GMP inspection conducted on 05-01-2018 and report concludes that firm had maintained conformance to cGMP.
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

b. Deferred cases

979.	Name and address of manufacturer / Applicant	Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad Manufactured by Bio Labs (Pvt) Ltd, Plot #, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	EPI 40mg Injection
	Composition	Each vial contain: Esomeprazole (as Sodium).....40mg
	Diary No. Date of R& I & fee	Dy. No. 5781 Date:29-08-2016 Rs. 50,000/-
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer spec
	Pack size & Demanded Price	1's : As per PRC
	Approval status of product in Reference Regulatory Authorities	Nexium I.V. 40mg of (MHRA approved)
	Me-too status (with strength and dosage form)	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP status	Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance
	Previous Remarks of the Evaluator [IV]	Contract agreement attached Number of already registred contract manufactured products: Nil
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products **(M-282)**
	Evaluation by PEC	Registration Board discussed the inspection report in details. Deliberations were made on used and available capacity keeping in view registered product, currently applied products and future products. After thorough deliberation, the Board decided to allow contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Plot No.145 Industrial Triangle, Kahuta Road, Islamabad for following sections: • Dry Suspension (Cephalosporin) • Capsule (Cephalosporin) • Dry vial injectable (Cephalosporin) • Lyophilized vial injectable (General)
	Decision: Registration Board deferred the case for confirmation of dry powder vial filling facility	
980.	Name and address of manufacturer / Applicant	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura
	Brand Name +Dosage Form + Strength	Piram 20mg/ml Injection
	Composition	Each ml Contains: Piroxicam……20mg
	Diary No. Date of R& I & fee	Dy.No. 33689 dated 10-10-2018 Rs.20,000/- 10-10-2018
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form -5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	1ml x 5's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France

	Me-too status (with strength and dosage form)	Salden 20mg Injection of M/s Danas Pharmaceutical (Reg.#080373)
	GMP status	Last GMP inspection conducted on 21-02-2018 and report concludes Overall hygienic condition of firm was satisfactory at time of Inspection. They were advised to improve further their documentation as mentioned above. They agreed.
	Previous Remarks of the Evaluator[IV]	Alternative brands Picam Injection B.Cam • Injection Section available • Terminal sterilization not done.
	Previous decision(s)	**Deferred for following reasons:** Deferred for justification/clarification on scientific grounds of not performing Terminal sterilization. **(M-293)**
	Evaluation by PEC	Firm submitted revised method of manufacturing with terminal sterilization.
	Decision: Approved with innovator's specification.	
981.	Name and address of manufacturer / Applicant	Legacy Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Pirozin 20mg Tablets
	Composition	Each tablet contains:- Piroxicam-beta-cyclodextrin equivalent to Piroxicam….20mg
	Diary No. Date of R& I & fee	Rs.8000/- dated 21-1-2011 Rs.12000/- dated 4-8-2015
	Pharmacological Group	Antirheumatic
	Type of Form	Form -5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	20's: Rs.175.00
	Approval status of product in Reference Regulatory Authorities	Cycladol tablet (ANSM approved)
	Me-too status (with strength and dosage form)	Pirujin Tablet M/s Jupiter Pharma
	GMP status	Last Inspection conducted on 30-03-2017 for grant of additional 3 section , panel recommend grant of additional section and overall evaluation of the inspection report is good
	Previous Remarks of the Evaluator[IV]	Latest GMP inspection report (conducted within the period of last one year). In some documents piroxin is mentioned as brand name while in other documents pirozin is mentioned as brand name .Firm replied Piroxin is correct brand name On challan from of Rs; 12000/- pirozin is mentioned while in other challan of Rs; 8000/- piroxin is mentioned.
	Previous decision(s)	**Deferred for following reasons:** Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-283)**
	Evaluation by PEC	Firm submitted GMP certificate on the basis of inspection conducted on 18-07-2019 More over firm now submitted that our brand name is Pirozin.
	Decision: Approved with innovator's specification.	
982.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Drifen 100mg/16.7ml Injection
	Composition	Each 16.7ml Vial Contains: Paclitaxel……100mg
	Diary No. Date of R& I & fee	Dy.No. 5601 dated 07-02-2019 Rs.20,000/- 07-02-2019

	Pharmacological Group	Antineoplastic Agents(Taxanes) ATC Code: L01CD01
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Hospira Anzatax (Paclitaxel) Injection 100 Mg/16.7ml Of TGA Approved
	Me-too status (with strength and dosage form)	Ebetaxel 100mg/16.7ml Of M/S Bio Pharma, Multan
	GMP status	Last GMP inspection conducted on 19 -09-2018 and report concludes that panel unanimously recommends the approval of above 16, new/additional sections " Overall evaluation of the Inspection report is rated as Good".
	Previous Remarks of the Evaluator[IV]	Liquid Vial SVP (Oncology) Section available. Firm change formulation from 100mg/17ml to 100mg/16.7ml with submission of fee of Rs:5000/- Deposit slip No# 1929149 dated: 28-11-2019
	Previous decision(s)	**Deferred for following reasons:** Deferred for submission of Balance fee for revision of formulation. **(M-293)**
	Evaluation by PEC	Firm submitted balance fee of RS: 15000/- through deposit slip no: 2017892 Dated: 06-03-2020
	Decision: Approved.	
983.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Reclast 4mg/5ml Injection
	Composition	Each 5ml Ampoule Contains: Zoledronic Acid Monohydrate Eq. to Zoledronic Acid…4mg
	Diary No. Date of R& I & fee	Dy.No. 36361 dated 01-11-2018 Rs.20,000/- Dated 01-11-2018
	Pharmacological Group	Drugs for treatment of bone diseases, biphosphonates
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	5ml x 1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zometa 4mg/5 mL single-dose vials of US-FDA approved
	Me-too status (with strength and dosage form)	Macdronic Injection 4mg/5ml Of M/S Macter
	GMP status	Last GMP inspection conducted on 26-01-2018.and report concludes that firm was considered to be operating at good level of GMP compliance.
	Previous Remarks of the Evaluator[IV]	Alternatvie brand names Zeclast Zoldro Zobone • Terminal sterilization not performed.
	Previous decision(s)	**Deferred for following reasons:** Deferred for justification/clarification on scientific grounds of not performing Terminal sterilization**. (M-293)**
	Evaluation by PEC	Firm submitted revised method of manufacturing with terminal sterilization.
	Decision: Approved with innovator's specification.	
984.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Reclast 4mg/100ml Infusion

	Composition	Each 100ml Vial Contains: Zoledronic Acid Monohydrate Eq. to Zoledronic Acid…….4mg
	Diary No. Date of R& I & fee	Dy.No. 36362 dated 01-11-2018 Rs.20,000/- 01-11-2018
	Pharmacological Group	Drugs for treatment of bone diseases, biphosphonates
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	100ml x 1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zometa 4mg/100 mL of US-FDA approved
	Me-too status (with strength and dosage form)	Zoleron 4mg/100ml Infusion Of M/S Genix Pharma
	GMP status	Last GMP inspection conducted on 26-01-2018.and report concludes that firm was considered to be operating at good level of GMP compliance.
	Previous Remarks of the Evaluator[IV]	• Terminal sterilization not performed.
	Previous decision(s)	**Deferred for following reasons:** Deferred for justification/clarification on scientific grounds of not performing Terminal sterilization**. (M-293)**
	Evaluation by PEC	Firm submitted revised method of manufacturing with terminal sterilization.
	Decision: Approved with innovator's specification.	
985.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Reclast 5mg/100ml Infusion
	Composition	Each 100ml Vial Contains: Zoledronic Acid Monohydrate Eq. to Zoledronic Acid……5mg
	Diary No. Date of R& I & fee	Dy.No. 36363 dated 01-11-2018 Rs.20,000/- 01-11-2018
	Pharmacological Group	Drugs for treatment of bone diseases, biphosphonates
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	100ml x 1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Reclast 5mg/100 mL of US-FDA approved
	Me-too status (with strength and dosage form)	Macdronic Infusion Of M/S Macter
	GMP status	Last GMP inspection conducted on 26-01-2018.and report concludes that firm was considered to be operating at good level of GMP compliance.
	Previous Remarks of the Evaluator[IV]	Alternatvie brand names Zeclast Zoldro Zobone • Terminal sterilization not performed.
	Previous decision(s)	**Deferred for following reasons:** Deferred for justification/clarification on scientific grounds of not performing Terminal sterilization**. (M-293)**
	Evaluation by PEC	Firm submitted revised method of manufacturing with terminal sterilization.
	Decision: Approved with innovator's specification.	
986.	Name and address of manufacturer / Applicant	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan By: Mediate Pharma (pvt)Ltd., Plot No.150-151, Sector 24 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Latezol/L ZOL Tablet 2.5mg

	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 1217 dated 10-01-2019 Rs.20,000/- 09-01-2019
	Pharmacological Group	Non Steroidal aromatase inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1's, 10's, 14's ,30's; As per DPC
	Approval status of product in Reference Regulatory Authorities	FEMARA letrozole 2.5mg coated tablet by Novartis Pharmaceuticals Australia Pty Ltd (TGA Approved)
	Me-too status (with strength and dosage form)	Femara 2.5mg Tablet by Novartis (Reg. No. 021129)
	GMP status	Last GMP inspection of Helix Pharma conducted on 24-09-2018 and report concludes that Keeping in view the areas inspected, documents reviewed and people met, it is concluded that the firm is operating at satisfactory level of compliance with GMP. & Last GMP inspection of Mediate Pharma conducted on 02-04-2019 and report concludes that firm considered to be operating at an acceptable level of good compliance with GMP guidelines
	Previous Remarks of the Evaluator[IV]	• Firm submitted Remaining Fee of Rs: 30000/- for contract manufacturing Deposit Slip No# 0809489; Dated: 15-03-2019 • Copy of Valid Contract manufacturing agreement submitted. • Number of sections of applicant approved by • Licensing Board: 08 • Number of products already registered/approved on contract manufacturing in the name of applicant:09
	Previous decision(s)	**Deferred for following reasons:** Registeration Board Deferred the case for clarification /justification from the firm "M/s Helix Pharma"regarding manufacturing of applied formulation on contract despite of having their own approved manufacturing facility i.e Tablet Section**. (M-293)**
	Evaluation by PEC	Firm submitted reply Please note that Helix Pharma (Pvt), Ltd has initiated a major renovation & upgrade project of OSD area and embarked upon to invest several million of Rs. For the cGMP compliance as per Drugs Act1 1976 & DRAP Act 2012 requirement,(DRAP approval letter of Revised Layout plan dated july 22, 2019 attached) Considering that the current renovation/upgraded project which is already underway, we like to avail the Tablet manufacturing facility of M/s Mediate Pharma (Pvt)., Ltd. For manufacturing of said product, the application for contract manufacturing agreement between Helix Pharma, Karachi & Mediate Pharma, Karachi has been submitted which would been submitted which would be an interim arrangement for 03years
	Decision: Deferred for confirmation of status of other tablet products.	
987.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Zibix 200mg Tablet
	Composition	Each film coated Tablet Contains:

		Celecoxib……200mg
	Diary No. Date of R& I & fee	Dy.No.16179 dated 02-05-2018 Rs.20,000/- 02-05-2018
	Pharmacological Group	Anti- inflammatory
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, & 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status (with strength and dosage form)	Coxia 200 mg Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 28-09-2017 and the report concludes that firm was found at good level of GMP.
	Previous Remarks of the Evaluator[IV]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Previous decision(s)	**Deferred for following reasons:** Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting**.. (M-291)**
	Evaluation by PEC	Firm submitted evidence Celecoxib 200mg uncoated tablet PMDA Japan approved while applied formulation is film coated tablet
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
988.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Apriset 80mg & 125mg Capsule
	Composition	One Capsule Contains: Aprepitant……125mg Two Capsule Contains: Aprepitant……80mg
	Diary No. Date of R& I & fee	Dy.No. 36360 dated 01-11-2018 Rs.20,000/- 01-11-2018
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Emend capsule 80mg of USFDA approved Emend capsule 125mg of USFDA approved
	Me-too status (with strength and dosage form)	Apritus 80mg Capsule of M/s S.J&G Apritus 125mg Capsule of M/s S.J&G
	GMP status	Last GMP inspection conducted on 26-01-2018.and report concludes that firm was considered to be operating at good level of GMP compliance.
	Previous Remarks of the Evaluator[IV]	Two strength are applied in same dossier and on one challan form both strengths are mentioned.
	Previous decision(s)	**Deferred for following reasons:** Deferred for review of formulation and packing as per innovator product and relevant packaging facilities **(M-293)**
	Evaluation by PEC	Firm in reply submitted that they applied for Combo Pack of 3 capsules (one capsule of 125mg & two capsules of 80mg also provided SRA reference and metoo. Approval status of product in Reference Regulatory: EMEND® 125 mg hard capsules, EMEND® 80 mg hard capsules. Aluminium

		Authorities	blister containing one 125mg capsule and two 80mg capsules
		Me-too status (with strength and dosage form)	Apreon Combo Pack Capsules of M/S Ferozesons Labs,. Reg. No. 68204
		Pack size & Demanded Price	2 + 1(8mg +125mg): As per SRO
	Decision: Deferred for confirmation of relevant packaging facilities.		
989.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi	
	Brand Name +Dosage Form + Strength	Welcame-B 20mg Tablet	
	Composition	Each Tablet Contains: Piroxicam Beta Cyclodextrin as Piroxicam…..20mg	
	Diary No. Date of R& I & fee	Dy.No. 33472 dated 09-10-2018 Rs.20,000/- Dated 14-09-2018	
	Pharmacological Group	NSAID	
	Type of Form	Form 5	
	Finished product Specifications	Manufacturer Specs	
	Pack size & Demanded Price	2 x 10's As per SRO	
	Approval status of product in Reference Regulatory Authorities	Cycladol tablet (ANSM approved)	
	Me-too status (with strength and dosage form)	Pirujin Tablet M/s Jupiter Pharma	
	GMP status	Last GMP inspection conducted on 12-12-2018 and report concludes the firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance.	
	Previous Remarks of the Evaluator[IV]	Firm revise formulation from coated to uncoated tablet without submission of fee.	
	Previous decision(s)	**Deferred for following reasons:** Deferred for submission of fee for revision of formulation **(M-293)**	
	Evaluation by PEC	Firm submitted fee for revision of formulation of RS: 5000/- through deposit slip no: 2044404 Dated: 03-03-2020	
	Decision: Approved with innovator's specification.		
990.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi	
	Brand Name +Dosage Form + Strength	Lorsafe 8mg/2ml Injection	
	Composition	Each 2ml Contains: Lornoxicam……8mg	
	Diary No. Date of R& I & fee	Dy.No. 36293 dated 01-11-2018 Rs.20,000/- Dated 31-10-2018	
	Pharmacological Group	NSAID	
	Type of Form	Form-5	
	Finished product Specifications	Manufacturer specifications	
	Pack size & Demanded Price	2ml x 1's Vial / As per SRO	
	Approval status of product in Reference Regulatory Authorities	Xefo 8mg powder for solution for injection Of EMA approved	
	Me-too status (with strength and dosage form)	Viltaz Injection 8mg/2ml by Wilshire (Reg. No. 077112)	
	GMP status	Last GMP inspection conducted on 31-07-2018.and report	

		concludes firm has GOOD level of GMP compliance
	Previous Remarks of the Evaluator[IV]	Firm revise formulation from coated to uncoated tablet without submission of fee.
	Previous decision(s)	**Deferred for following reasons:** Deferred for clarification whether lyophilized / dry powder or liquid injection and requisite facility **(M-293)**
	Evaluation by PEC	Firm submitted that their formulation is dry powder
	Decision: Deferred for evidence of availability of required manufacturing facility i.e., Lyophilizer.	

Case no. 02 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

991.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Phosvit Injection 10ml
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No. 26449 dated 01-08-2018 Rs.20,000/- Dated 01-08-2018
	Pharmacological Group	Phosphorus/Supplement/Vitamis
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10ml,:Decontrolled
	Me-too status	Not found in 10ml
	GMP status	Last GMP inspection conducted on 02-01-2018, 16-01-2018 & 23-01-2018 and report concludes that firm was considered to be operating at a good level of GMP compliance."
	Remarks of the Evaluator[IV]	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision:Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
992.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Fospho-AV Injection 10ml
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin...0.05mg Taurine…37.3mg Nicotinamide…23.0mg DL-Methionine…18.7mg
	Diary No. Date of R& I & fee	Dy.No. 26447 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Phosphorus/Supplement6/Vitamis/Aminoacids
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10ml,:Decontrolled
	Me-too status	Not found in 10ml
	GMP status	Last GMP inspection conducted on 02-01-2018, 16-01-2018 & 23-01-2018 and report concludes that firm was considered to be operating at a good level of GMP compliance."
	Remarks of the Evaluator[IV]	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision:Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

993.	Name and address of manufacturer / Applicant	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	Mentafarm Powder
	Composition	Each 1000gm contains: Amantadine HCL…98%
	Diary No. Date of R& I & fee	Dy.No. 43998 dated 27-12-2018 Rs.20,000/- 20-12-2018
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500g, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg : Decontrolled
	Me-too status	Emanta-98 Oral Powder Of M/S. Evergreen
	GMP status	Last GMP inspection conducted on 03-10-2018 report concludes that firm was considered to be maintaining satisfactory level of the cGMP
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
994.	Name and address of manufacturer / Applicant	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	Aspo C Powder
	Composition	Each kg contains: Acetylsalicylic acid…67gm Ascorbic acid…200gm
	Diary No. Date of R& I & fee	Dy.No. 44455 dated 31-12-2018 Rs.20,000/- Dated 27-12-2018
	Pharmacological Group	Antioxidant, Analgesic, Antipyretic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500g, 1kg, 5kg, 10kg,: Decontrolled
	Me-too status	Acetyle-C 20 Oral Powder Of M/S kohinoor Industries
	GMP status	Last GMP inspection conducted on 03-10-2018 report concludes that firm was considered to be maintaining satisfactory level of the cGMP
	Remarks of the Evaluator[IV]	
	Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs.	
995.	Name and address of manufacturer / Applicant	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	CB DOX Powder
	Composition	Each 1000gm contains: Doxycycline HCL…200gm Tylosin Tartrate…100gm Colistin Sulphate…480MIU Bromhexine HCL…5gm
	Diary No. Date of R& I & fee	Dy.No. 44454 dated 31-12-2018 Rs.20,000/- 27-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500g, 1kg, 5kg, 10kg,: Decontrolled
	Me-too status	Emeria Shell Powder Of M/S Inshal Pharmaceutical
	GMP status	Last GMP inspection conducted on 03-10-2018 report concludes that firm was considered to be maintaining satisfactory level of the cGMP
	Remarks of the Evaluator[IV]	
	Decision: Deferred for confirmation of conversion of Colistin Sulphate MIU to grams	

996.	Name and address of manufacturer / Applicant	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	U Mox Powder
	Composition	Each gm contains: Amoxicillin Trihydrate…200mg Colistin Sulphate…60,000,000 IU
	Diary No. Date of R& I & fee	Dy.No. 44453 dated 31-12-2018 Rs.20,000/- Dated 27-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500g, 1kg, 5kg, 10kg,: Decontrolled
	Me-too status	Almoxin-C Water Soluble Powder Of M/S Breeze Pharma
	GMP status	Last GMP inspection conducted on 03-10-2018 report concludes that firm was considered to be maintaining satisfactory level of the cGMP
	Remarks of the Evaluator	Colistine Sulphate 60,000,000 in applied formulation while in submitted generic reference contain Colistine Sulphate 60,00,000. Clarify.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and confirmation of conversion of Colistin Sulphate MIU to grams.	
997.	Name and address of manufacturer / Applicant	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	EC-Liquid
	Composition	Each 100ml contains: Enrofloxacin…10g Colistin as sulphate…5,000,000 IU
	Diary No. Date of R& I & fee	Dy.No. 44456 dated 31-12-2018 Rs.20,000/- 27-12-2018
	Pharmacological Group	Antibacterial, Anti-infective
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter, ,: Decontrolled
	Me-too status	Enroten Liquid Of M/S Kailgon Agro
	GMP status	Last GMP inspection conducted on 03-10-2018 report concludes that firm was considered to be maintaining satisfactory level of the cGMP
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
998.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd.Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	LS- COMI Powder
	Composition	Each 150gm contains: Lincomycin…33.3gm Spectinomycin…66.7gm
	Diary No. Date of R& I & fee	Dy.No. 39860 dated 04-12-2018 Rs.50,000/- 03-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	1Kg, 2.5Kg ;Decontrolled
	Me-too status	Lincotin Powder Of M/S Selmore
	GMP status	Last GMP inspection conducted on 16-01-2020 report concludes that a fair level of compliance was noted in veterinary sections.

	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
999.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Metho-Drain Powder
	Composition	Each kg powder contains: Methenamine…900gm Riboflaven…10gm Calcium pentothenate…5gm Nicotinamide…25gm
	Diary No. Date of R& I & fee	Dy.No. 40364 dated 05-12-2018 Rs.20,000/- Dated 30-11-2018
	Pharmacological Group	Anti-Toxic, Diuretic ,Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,150gm, 250gm, 500gm, 1kg, 2.5kg, 5kg, 10kg, :Decontrolled..
	Me-too status	Sancure Powder Of M/S Sanna Labs Reg.# 021499
	GMP status	According to the panel inspection report dated 16-07-2019 the firm at the time of inspection was found fit/suitable for manufacturing and testing of pharmaceutical products in all sections.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1000.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Floro Fin Powder 500mg
	Composition	Each gram powder contains: Florfenicol…500mg
	Diary No. Date of R& I & fee	Dy.No. 40960 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Biotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,150gm, 250gm, 500gm, 1kg, 2.5kg, 5kg, 10kg, :Decontrolled..
	Me-too status	Naflor Powder.Of M/S Nawan Laboratories Reg.# 049513
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1001.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Klora Zine Powder
	Composition	Each 100gm powder contains: Sulphachlorpyridazine…30%
	Diary No. Date of R& I & fee	Dy.No. 42058 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Anti-Biotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,150gm, 250gm, 500gm, 1kg, 2.5kg, 5kg, 10kg, :Decontrolled..

	Me-too status	Nobi Esb3 Powder Of M/S Noble Pharma Reg.# 058734
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1002.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Min-Flush Powder
	Composition	Each 100gm powder contains: Methenamine …85g Vitamin B1…700mg Vitamin C…100mg Sorbitol…5g
	Diary No. Date of R& I & fee	Dy.No. 40361 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Anti-Toxic. Diuretic, Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,150gm, 250gm, 500gm, 1kg, 2.5kg, 5kg, 10kg, :Decontrolled..
	Me-too status	Uritox Powder Of M/S Attabak Pharmaceuticals, Reg.# 075722
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1003.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Met-Flush Powder
	Composition	Each 100gm powder contains: Methenamine mandelate…90g Vitamin B1…700mg Vitamin C…100mg Sorbitol…5g
	Diary No. Date of R& I & fee	Dy.No. 40362 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Anti-Toxic. Diuretic, Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm,150gm, 250gm, 500gm, 1kg, 2.5kg, 5kg, 10kg, :Decontrolled..
	Me-too status	Vety-Flush Powder Of M/S Vety-Care Reg.# 019938
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1004.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Zee-Dox Powder

	Composition	Each gm powder contains: Tylosin tartrate…100mg Doxycycline HCl.…200g Bromhexine…10mg Colistin sulphate…500,000 IU
	Diary No. Date of R& I & fee	Dy.No. 40360 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Anti-Biotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	100gm,150gm, 250gm, 500gm, 1kg, 2.5kg, 5kg, 10kg, :Decontrolled..
	Me-too status	Montydox Powder Of M/S Westmont Pharmaceutical Reg.# 071008
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator’s specification.	
1005.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Octin- B Water soluble powder
	Composition	Each kg powder contains: Tylosin tartrate…200g Doxycycline…400g Bromhexine…10g Colistin sulphate…1000 MIU
	Diary No. Date of R& I & fee	Dy.No. 40363 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Anti-Biotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	100gm,150gm, 250gm, 500gm, 1kg, 2.5kg, 5kg, 10kg, :Decontrolled..
	Me-too status	Mexin Plus Water Soluble Powder Of M/S Medicure Laboratories Reg.# 058956
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator’s specification.	
1006.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Inflor Liquid
	Composition	Each 100ml contains: Colistin Sulphate…50 MIU Florfenicol…11gm
	Diary No. Date of R& I & fee	Dy.No. 40356 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Anti-Biotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications

	Pack size & Demanded Price	100 ml,150ml, 250 ml, 500 ml,1Lit, 2.5 Lit,5 Lit, 10 Lit ; Decontrolled
	Me-too status	Flo Raft Oral Liquid Of M/S. Nawal Pharmaceuticals, Reg.# 078252
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1007.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Co- Fenicol Liquid
	Composition	Each 100ml contains: Florfenicol…10gm Colistin Sulphate…2.5gm
	Diary No. Date of R& I & fee	Dy.No. 40961 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Biotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100 ml,150ml, 250 ml, 500 ml,1Lit, 2.5 Lit,5 Lit, 10 Lit ; Decontrolled
	Me-too status	Co-Flor Liquid Of M/S. Wimits Pharma, Reg.#078326
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1008.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Endo Shell Liquid
	Composition	Each ml contains: Triclabendazole…120mg Levamisole HCL…75mg
	Diary No. Date of R& I & fee	Dy.No. 40959 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anthlmentic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100 ml,150ml, 250 ml, 500 ml,1Lit, 2.5 Lit,5 Lit, 10 Lit ; Decontrolled
	Me-too status	Endoex 19.5% Liquid of M/S.Hawk Bio Pharma, R# 079119
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1009.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Metha Prim Liquid

	Composition	Each 100 ml liquid contains: Tylosin tartrate…5gm Sulphamethoxypridazine…5gm Trimethoprim…4gm Bromhexine…0.5gm
	Diary No. Date of R& I & fee	Dy.No. 40357 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100 ml,150ml, 250 ml, 500 ml,1Lit, 2.5 Lit,5 Lit, 10 Lit ; Decontrolled
	Me-too status	Tetra Star Liquid Of M/S Biogen Pharma., Reg.# 075621
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1010.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	DC-Tyle Liquid`
	Composition	Each 1000ml liquid contains: Tylosin tartrate…200gm Doxycycline HCL…250gm Bromhexine hcl…12gm Colistin sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No. 40359 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antibacterial, Mucolytic Agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100 ml,150ml, 250 ml, 500 ml,1Lit, 2.5 Lit,5 Lit, 10 Lit ; Decontrolled
	Me-too status	Tylotar Forte Solution.Of M/S Evergreen Pharmaceuticals, Reg.# 078288
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1011.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Vitonic Liquid
	Composition	Each ml contains: Vitamin E…200mg Sorbitol…50mg Choline Chloride…50mg Selenium…2.3mg Zinc…4mg
	Diary No. Date of R& I & fee	Dy.No. 40358 dated 05-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antibacterial, Mucolytic Agent
	Type of Form	Form 5

	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	100 ml,150ml, 250 ml, 500 ml,1Lit, 2.5 Lit,5 Lit, 10 Lit ; Decontrolled
	Me-too status	Eg Supertonic Solution Of M/S Evergreen Pharmaceuticals, Reg.# 074071
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator’s specification.	
1012.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Nitro Shell Injection 340mg/ml
	Composition	Each ml contains: Nitroxynl…340mg
	Diary No. Date of R& I & fee	Dy.No. 40958 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anthlmentic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	100 ml ; Decontrolled
	Me-too status	Nitronil 34% Injection Of M/S Manhattan Pharma, Reg.# 052366
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator’s specification.	
1013.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries.Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Imido P Injection
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No. 40957 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Anti-Protozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	100 ml ; Decontrolled
	Me-too status	Imipro Injection.Of M/S Selmore, Reg.# 029610
	GMP status	Last inspection conducted on dated 16-07-2019 the firm has rectified majority of the observations from the previous inspection in the firm was found fit/suitable for manufacturing and testing of pharmaceuticals products in all sections
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator’s specification.	
1014.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited.18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Calcifas Injection
	Composition	Each ml Contains: Calcium Gluconate…266mg Boric Acid…54mg

	Diary No. Date of R& I & fee	Dy.No. 4220 dated 30-01-2019 Rs.20,000/- 30-01-2019
	Pharmacological Group	Mineral supplements
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	300ml ; Decontrolled
	Me-too status	Calpho-P Injection of M/S Selmore Pharmaceuticals Reg # 034575
	GMP status	Last GMP inspection conducted on 28-05-2019, and the report concludes that the panel recommend the grant of renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator’s specification.	
1015.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited.18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Liverfas Injection
	Composition	Each ml Contains: Phenoxy-2-Methyl-2-Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No. 4217 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Liver tonic
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	50ml ; Decontrolled
	Me-too status	Hepasel Injection of M/S Selmore Pharmaceuticals Reg # 046518
	GMP status	Last GMP inspection conducted on 28-05-2019, and the report concludes that the panel recommend the grant of renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator’s specification.	
1016.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited.18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Doxyfas 50% Water Soluble Powder
	Composition	Each Gm Contains: Doxycycline Hyclate…500mg
	Diary No. Date of R& I & fee	Dy.No. 4216 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer‘s specifications
	Pack size & Demanded Price	100 gm, 500gm, 1000gm ; Decontrolled
	Me-too status	Doxyveto- 50 S Soluble Powder Of M/S Vmd Pakistan Reg # 023470
	GMP status	Last GMP inspection conducted on 28-05-2019, and the report concludes that the panel recommend the grant of renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator’s specification.	
1017.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited.18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Ketafas Injection
	Composition	Each ml Contains: Ketamine Hcl Eq. to Ketamine Base…100mg
	Diary No. Date of R& I & fee	Dy.No. 4218 dated 30-01-2019 Rs.20,000/- 30-01-2019

	Pharmacological Group	General anesthetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml ; Decontrolled
	Approval status of product in Reference Regulatory Authorities	Ketaset injection of Boehngar ingelheim Animal Health (USFDA approved)
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 28-05-2019, and the report concludes that the panel recommend the grant of renewal of DML.
	Remarks of the Evaluator[IV]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for confirmation of generic status.	
1018.	Name and address of manufacturer / Applicant	M/s Intervac Pvt. Limited. 18-Km, Lahore Sheikhupura Road, Sheikhupura,
	Brand Name +Dosage Form + Strength	Colifas 60-Injection
	Composition	Each 100ml Contains: Colistin Sulphate…60 MIU
	Diary No. Date of R& I & fee	Dy.No. 4219 dated 30-01-2019 Rs.20,000/- 30-01-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml ; Decontrolled
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 28-05-2019, and the report concludes that the panel recommend the grant of renewal of DML.
	Remarks of the Evaluator[IV]	• COLIRAN-60 INJECTION of M/S ZAKFAS PHARMACEUTICAL Reg #057073 Provided metoo is available in 10ml and 30ml
	Decision: Deferred for evidence of applied formulation/drug in same filled volume already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1019.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Radek Oral Liquid
	Composition	Each ml Contains: Vitamin A…10,000 IU Vitamin D3…2,000 IU Vitamin E…4mg Vitamin K3…2mg
	Diary No. Date of R& I & fee	Dy.No. 4920 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml,500ml, 1Liter, 2.5Liter, 5Liter, 5Liter, Decontrolled
	Me-too status	Adek Excel Oral Solution of M/S Nawan Laboratories Reg# 058985
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly

	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1020.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	E-Sel Oral Liquid
	Composition	Each ml Contains: Vitamin E (Alpha Tocopherol Acetate)…100mg Sodium Selenite…2mg
	Diary No. Date of R& I & fee	Dy.No. 4921 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml,500ml, 1Liter, 2.5Liter, 5Liter, 5Liter; Decontrolled
	Me-too status	Vim-Sel Oral Soulution of M/S Nawan Laboratories Reg# 053999
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1021.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Broment oral powder 20/4mg
	Composition	Each g contains: Bromhexine HCl…20mg Menthol…4mg
	Diary No. Date of R& I & fee	Dy.No. 9919 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Mucolytic, Antitussive/Expectorant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm,15gm, 25gm, 50gm,100 gm, 250gm, 500gm, 1Kg, 5Kg, ; Decontrolled
	Me-too status	TUSNIL 2% POWDER of M/S UNIVET PHARMACEUTICALS,Reg# 075627
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

Case no. 03 Registration applications of newly granted DML or New section (Veterinary)

a. Deferred Cases

<table>
<tr><td>1022.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Grand Pharma Plot# 5-A, St.# N-5, National Industrial zone, RCCI Estate Rawat- Islamabad</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>G- Pen 2.5gm Powder for Injection</td></tr>
<tr><td></td><td>Composition</td><td>Each dry powder vial Contains:
Benzyl Penicillin..(USP)…500,000IU
Procaine Penicillin(USP)…1,500,000IU
Steptomycin Sulphate (USP)…..2.5gm</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy.No. 21131 dated 18-10-2019 Rs.20,000/- Dated 18-10-2019</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Antibiotic/Penicillin</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished product Specifications</td><td>Manufacturer specifications</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>1’s : Decontrolled</td></tr>
<tr><td></td><td>Me-too status (with strength and dosage form)</td><td>Biopen 2.5gm Injection Of M/S Selmore Pharmaceutical (Reg# 081717)</td></tr>
<tr><td></td><td>GMP status</td><td>Grant of six additional section via letter Dated:26th September,2019</td></tr>
<tr><td></td><td colspan="2">Previous Remarks of the Evaluator[IV]
<table>
<tr><th>Remarks</th><th>Response</th></tr>
<tr><td>Procaine G Penicillin in USP while applied as Procaine Penicillin. Clarify</td><td>Firm submitted that they will use Penicilline G Procaine in applied formulation</td></tr>
<tr><td>Applied pack size 2.5gm/vial while applied formulation contain
Steptomycin Sulphate (USP)…..2.5gm & also
Benzyl Penicillin..(USP)…500,000IU
Procaine Penicillin(USP)…1,500,000IU
Clarify</td><td>Firm reply that their fill weight is 4.3gm/vial and 2.5gm is used with brand name only, so , it is part of brand name.</td></tr>
</table></td></tr>
<tr><td></td><td>Previous decision(s)</td><td>Deferred for following reasons:
Deferred for submission of fee for revision of form 5 and label claim. (M-293)</td></tr>
<tr><td></td><td>Evaluation by PEC</td><td>Firm submitted fee of RS: 5000/- through deposit slip no: 2024947 Dated: 10-03-2020</td></tr>
<tr><td></td><td colspan="2">Decision: Approved with innovator’s specification.</td></tr>
<tr><td>1023.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Grand Pharma Plot# 5-A, St.# N-5, National Industrial zone, RCCI Estate Rawat- Islamabad</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>G- Pen 5gm Powder for Injection</td></tr>
<tr><td></td><td>Composition</td><td>Each dry powder vial Contains:
Benzyl Penicillin..(USP)…500,000IU
Procaine Penicillin(USP)…1,500,000IU
Steptomycin Sulphate (USP)…..5gm</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy.No. 21132 dated 18-10-2019 Rs.20,000/- 18-10-2019</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Antibiotic/Penicillin</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished product Specifications</td><td>Manufacturer specifications</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>1’s : Decontrolled</td></tr>
<tr><td></td><td>Me-too status (with strength and dosage form)</td><td>Biopen 5gm Injection Of M/S Selmore Pharmaceutical(Reg# 081718)</td></tr>
<tr><td></td><td>GMP status</td><td>Grant of six additional section via letter Dated:26th September,2019</td></tr>
<tr><td></td><td colspan="2">Previous Remarks of the Evaluator[IV]
<table>
<tr><th>Remarks</th><th>Response</th></tr>
<tr><td>Procaine G Penicillin in USP while applied as Procaine Penicillin. Clarify</td><td>Firm submitted that they will use Penicilline G Procaine in applied formulation</td></tr>
<tr><td>Applied pack size 5gm/vial while applied</td><td>Firm reply that their fill weight is 6.8gm/vial</td></tr>
</table></td></tr>
</table>

	formulation contain Steptomycin Sulphate (USP)…..5gm & also Benzyl Penicillin..(USP)…500,000IU Procaine Penicillin(USP)…1,500,000IU Clarify	and 5gm is used with brand name only, so , it is part of brand name.
	Previous decision(s)	**Deferred for following reasons:** Deferred for submission of fee for revision of form 5 and label claim. **(M-293)**
	Evaluation by PEC	Firm submitted fee of RS: 5000/- through deposit slip no: 2024936 Dated: 10-03-2020
	Decision: Approved with innovator's specification.	
1024.	Name and address of manufacturer / Applicant	M/s Grand Pharma Plot# 5-A, St.# N-5, National Industrial zone, RCCI Estate Rawat- Islamabad
	Brand Name +Dosage Form + Strength	Benzipro 40 Injection
	Composition	Each dry powder vial contains: Benzyl Penicillin……...1,000,000 IU Procaine Penicillin……...3,000,000 IU
	Diary No. Date of R& I & fee	Dy.No. 21134 dated 18-10-2019 Rs.20,000/- Dated 18-10-2019
	Pharmacological Group	Antibiotic/Penicillin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	50ml / vial : Decontrolled
	Me-too status (with strength and dosage form)	Penisel-40 Dry Powder Injection Of M/S Selmore Pharma (Reg# 080956)
	GMP status	Grant of six additional section via letter Dated:26th September,2019
	Previous Remarks of the Evaluator[IV]	
	Remarks / **Response** Procaine G Penicillin in USP while applied as Procaine Penicillin. Clarify / Firm submitted that they will use Penicilline G Procaine in applied formulation	
	Previous decision(s)	**Deferred for following reasons:** Deferred for submission of fee for revision of form 5 and label claim. **(M-293)**
	Evaluation by PEC	Firm submitted fee of RS: 5000/- through deposit slip no: 2024935 Dated: 11-03-2020
	Decision: Approved with innovator's specification.	
1025.	Name and address of manufacturer / Applicant	M/s Grand Pharma Plot# 5-A, St.# N-5, National Industrial zone, RCCI Estate Rawat- Islamabad
	Brand Name +Dosage Form + Strength	G-Pro 40 Injection
	Composition	Each dry vial contains: Procaine Penicillin……..4,000,000 IU
	Diary No. Date of R& I & fee	Dy.No. 21135 dated 18-10-2019 Rs.20,000/- 18-10-2019
	Pharmacological Group	Antibiotic/Penicillin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	40 Lac units / vial : Decontrolled
	Me-too status (with strength and dosage form)	Provet 40 Lac Dry Injection of M/s Breeze Pharma (Reg# 059162)
	GMP status	Grant of six additional section via letter Dated:26th September,2019
	Previous Remarks of the Evaluator[IV]	
	Remarks / **Response** Procaine G Penicillin in USP while applied as Procaine Penicillin. Clarify / Firm submitted that they will use Penicilline G Procaine in applied formulation	
	Previous decision(s)	**Deferred for following reasons:**

		Deferred for submission of fee for revision of form 5 and label claim. **(M-293)**
	Evaluation by PEC	Firm submitted fee of RS: 5000/- through deposit slip no: 2024948 Dated: 10-03-2020
	Decision: Approved with innovator's specification.	

Case no. 04 Registration applications of categories to be considered on priority

a. Export facilitation (new cases)

Export Facilitation: Applications was received through letter No.F.1-6/2019-PR.I (EFD) dated 27th Dec, 2019 "M/s Hilton Pharma, Karachi have achieved benchmark OF USD 377992.72 as defined in the Board's decision during fiscal year 2018-2019. In this regard, please find the applications submitted by the firm."		
1026.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Flux 10mg Tablet
	Composition	Each Tablet Contains: Fluoxetine as HCL…10mg
	Diary No. Date of R& I & fee	Dy.No. 40784 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	SSRI
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's, 30's, & As per SRO
	Approval status of product in Reference Regulatory Authorities	SARAFEM of USFDA approved
	Me-too status	Futine 10 mg Tablet by M/s Wilshire Laboratories, ,
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
1027.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Flux 20mg Tablet
	Composition	Each Tablet Contains: Fluoxetine as HCL…20mg
	Diary No. Date of R& I & fee	Dy.No. 40786 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	SSRI
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's, 30's, & As per SRO
	Approval status of product in Reference Regulatory Authorities	SARAFEM of USFDA approved
	Me-too status	Futine 20 mg Tablet by M/s Wilshire Laboratories, ,
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
1028.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Flux 40mg Tablet
	Composition	Each film coated Tablet Contains: Fluoxetine as HCL…40mg

	Diary No. Date of R& I & fee	Dy.No. 40787 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	SSRI
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's, 30's, & As per SRO
	Approval status of product in Reference Regulatory Authorities	Mutan 40 mg film-coated tablets of AGES Austria approved.
	Me-too status	Futine 10 mg Tablet by M/s Wilshire Laboratories, ,
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	Firm change formulation from uncoated to film coated with submission of fee of RS: 5000/- Deposit Slip No: 1995450 Dated:20-02-2020
	Decision: Approved.	
1029.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Flux 40mg Capsule
	Composition	Each Capsule Contains: Fluoxetine as HCL…40mg
	Diary No. Date of R& I & fee	Dy.No. 407791 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	SSRI
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's,28's & As per SRO
	Approval status of product in Reference Regulatory Authorities	PROZAC capsule of USFDA approved
	Me-too status	Not found
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1030.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Nebihil 2.5mg Tablets
	Composition	Each Tablet Contains: Nebivolol HCl eq to Nebivolol…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 43238 dated 19-12-2018 Rs.20,000/- 10-12-2018
	Pharmacological Group	Beta-1 receptor blocker
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic Tablet Of (USFDA Approved)
	Me-too status	Nibovo Tablets 2.5mgM/s. Dyson Research Laboratories
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	

1031.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Nebihil 5mg Tablets
	Composition	Each Tablet Contains: Nebivolol HCl eq to Nebivolol…..5mg
	Diary No. Date of R& I & fee	Dy.No. 43237 dated 19-12-2018 Rs.20,000/- Dated 10-12-2018
	Pharmacological Group	Beta-1 receptor blocker
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic Tablet Of (USFDA Approved)
	Me-too status	Nibovo Tablets 2.5mgM/s. Dyson Research Laboratories
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1032.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Nebihil 10mg Tablets
	Composition	Each Tablet Contains: Nebivolol HCl eq to Nebivolol…..10mg
	Diary No. Date of R& I & fee	Dy.No. 43239 dated 19-12-2018 Rs.20,000/- Dated 10-12-2018
	Pharmacological Group	Beta-1 receptor blocker
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic Tablet Of (USFDA Approved)
	Me-too status	Nibovo Tablets 2.5mgM/s. Dyson Research Laboratories
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
Veterinary		
1033.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Encohil Plus Oral Liquid
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin sulphate…3.5gm Amantadine Hcl…4gm
	Diary No. Date of R& I & fee	Dy.No. 7204 dated 27-05-2019 Rs20,000/- Dated 24-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	250ml, 500ml, 100ml, 5000ml : Decontrolled
	Approval status of product in Reference Regulatory Authorities	……

	Me-too status	Amantacol Oral Liquid Of M/S. Prix Pharmaceutica
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Registeration board deferred the case for consideration of expert Working group sicnce applied formulation conatains combination of antiviral and antibacterial.	
1034.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Encohil Oral Liquid
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No. 7203 dated 27-05-2019 Rs20,000/- Dated 24-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	250ml, 500ml, 100ml, 5000ml : Decontrolled
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Enco Tin Liquid Of M/S Inshal Pharmaceutical
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1035.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Himido 120mg/ml Injection (10ml)
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No. 27479 dated 18-12-2019 Rs20,000/- Dated 18-12-2019
	Pharmacological Group	Anti-Protozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10ml : Decontrolled
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Durazol Injection Of M/S Mylab
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1036.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Himido 120mg/ml Injection (50ml)
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No. 27480 dated 18-12-2019 Rs20,000/- Dated 18-12-2019
	Pharmacological Group	Anti-Protozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification

	Pack size & Demanded Price	50ml : Decontrolled
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Durazol Injection Of M/S Mylab
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1037.	Name and address of manufacturer / Applicant	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Himido 120mg/ml Injection (100ml)
	Composition	Each ml Contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No. 27481 dated 18-12-2019 Rs20,000/- Dated 18-12-2019
	Pharmacological Group	Anti-Protozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	100ml : Decontrolled
	Approval status of product in Reference Regulatory Authorities	……
	Me-too status	Durazol Injection Of M/S Mylab
	GMP status	Last GMP inspection conducted on 10-07-2019 and report concludes firm was considered to be operating at Good level on Compliance with GMP."
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
Export Facilitation: Applications was received through letter No.F.1-6/2019-PR.I (EFD) dated 27th Dec, 2019 "M/s Medisure Laboratories, Karachi have achieved benchmark OF USD 551443.75 as defined in the Board's decision during fiscal year 2018-2019. In this regard, please find the applications submitted by the firm."		
1038.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Febuxa 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat…….40mg
	Diary No. Date of R& I & fee	Dy.No. 44518 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antigout preparation(Non-purine xanthine oxidase Inhibitor)
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 40mg Tablet of (USFDA approved)
	Me-too status	Febuxin 40mg Tablet of M/s AGP
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1039.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Febuxa 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat…….80mg

	Diary No. Date of R& I & fee	Dy.No. 44519 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antigout preparation(Non-purine xanthine oxidase Inhibitor)
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 80mg Tablet of (USFDA approved)
	Me-too status	Febuxin 80mg Tablet of M/s AGP
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1040.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Duava 20mg Capsule
	Composition	Each Capsule Contains: Duloxetine HCL Enteric Coated Pellets Eq. to Duloxetine……20mg
	Diary No. Date of R& I & fee	Dy.No. 44524 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 20mg Capsule by M/s Martin Dow
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	Source of pellets: Surge Laboratories
	Decision: Approved.	
1041.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Duava 60mg Capsule
	Composition	Each Capsule Contains: Duloxetine HCL Enteric Coated Pellets Eq. to Duloxetine……60mg
	Diary No. Date of R& I & fee	Dy.No. 44525 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Serotonin and Noradrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta of (USFDA approved)
	Me-too status	Swenta 60mg Capsule by M/s Martin Dow
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	Source of pellets: Surge Laboratories
	Decision: Approved.	
1042.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Densoaid 2mg/ml Injection (4ml)
	Composition	Each Ampoule Contains: Ondansetron as hydrochloride dihydrate ……8mg

	Diary No. Date of R& I & fee	Dy.No. 3169 dated 23-01-2019 Rs. 20,000 Dated 22-01-2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form -5
	Finished product Specification	USP
	Pack size & Demanded Price	4ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 2 mg/ml Injection of (MHRA approved)
	Me-too status	Doston 8mg Injection by M/s Vision Pharmaceuticals
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
1043.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Densoaid 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron hydrochloride dihydrate …4mg
	Diary No. Date of R& I & fee	Dy.No. 3170 dated 23-01-2019 Rs. 20,000 Dated 22-01-2019
	Pharmacological Group	Selective serotonin 5-HT3 receptor antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's,50's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRAN Of (USFDA Approved)
	Me-too status	Ondonix 4mg Tablet M/s Genix Pharma
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
1044.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cefsure 2gm IM Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…2gm
	Diary No. Date of R& I & fee	Dy.No. 8527 dated 26-02-2019 Rs. 20,000 Dated 25-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 2g powder of MHRA approved
	Me-too status	Triax 2gm Injection of M/s.Wilshire Laboratories
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	In generic IM or IV can not be differentiated.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1045.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Onyfine 250mg Tablet
	Composition	Each Tablet Contains: Terbinafine Hcl Eq. to Terbinafine…250mg
	Diary No. Date of R& I & fee	Dy.No. 9200 dated 28-02-2019 Rs. 20,000 Dated 28-02-2019
	Pharmacological Group	Antifungal

	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 250mg Tablet Genus Pharmaceuticals Limited, MHRA Approved
	Me-too status	Lamisil Tablet by M/s Sandoz
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
1046.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Namadol P Tablet 37.5mg/325mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCL…37.5mg Paracetamol…325mg
	Diary No. Date of R& I & fee	Dy.No.16307 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramacet tablet of (MHRA approved)
	Me-too status	Radol-P tablet of M/s Regal Pharmaceuticals
	GMP status	Certificate of GMP based on inspection conducted on 30-09-2019
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
1047.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone**,** Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Emestin 250/250mg Injection I.V
	Composition	Each vial contains: Imipenem as Monohydrate…250mg Cilastatin as Sodium…250mg (Sterile mixture also contains sodium bicarbonate as buffer)
	Diary No. Date of R& I & fee	Dy.No. 16316 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	PRIMAXIN® (imipenem and cilastatin) for Injection, for intravenous use. USFDA approved
	Me-too status	Cilapen 250mg Injections of M/s Bosch Pharmaceuticals,
	GMP status	Certificate of GMP Issued on 02-10-2019 & Last GMP inspection conducted on 03-08-18and report concludes firm was considered to be operating in compliance with the acceptable level of cGMP Standards.
	Remarks of the Evaluator[IV]	• Number of sections of applicant approved by Licensing Board : 13 • Number of products already registered/approved on

		contract manufacturing in the name of applicant. Nil • Dry powder Injectable Section(Carbapenems) of M/S Nicholas Pharmaceuticals available.
	Decision: Approved.	
1048.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan By M/s Nicholas Pharmaceuticals.Plot # 34, St. # SS-02, National Industrial Zone**,** Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Emestin 500/500mg Injection I.V
	Composition	Each vial contains: Imipenem as Monohydrate…500mg Cilastatin as Sodium…500mg (Sterile mixture also contains sodium bicarbonate as buffer)
	Diary No. Date of R& I & fee	Dy.No. 16301 dated 07-03-2019 Rs.50,000/- 06-03-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	PRIMAXIN® (imipenem and cilastatin) for Injection, for intravenous use. USFDA approved
	Me-too status	Cilapen 500mg Injections of M/s Bosch Pharmaceuticals,
	GMP status	Certificate of GMP Issued on 02-10-2019 & Last GMP inspection conducted on 03-08-18and report concludes firm was considered to be operating in compliance with the acceptable level of cGMP Standards.
	Remarks of the Evaluator[IV]	• Number of sections of applicant approved by Licensing Board : 13 • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil • Dry powder Injectable Section(Carbapenems) of M/S Nicholas Pharmaceuticals available.
	Decision: Approved.	
1049.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan By M/s Nicholas Pharmaceuticals.Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Morpen 500mg Injection I.V
	Composition	Each vial contains: Meropenem as trihydrate (with anhydrous Sodium Carbonate)…500mg
	Diary No. Date of R& I & fee	Dy.No. 16302 dated 07-03-2019 Rs50,000/- 06-03-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MERREM® IV (meropenem for injection) 500mg, for intravenous use. US-FDA approved
	Me-too status	Olver Injection of M/s Genix
	GMP status	Certificate of GMP Issued on 02-10-2019 & Last GMP inspection conducted on 03-08-18and report

		concludes firm was considered to be operating in compliance with the acceptable level of cGMP Standards.
	Remarks of the Evaluator[IV]	• Number of sections of applicant approved by Licensing Board : 13 • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil • Dry powder Injectable Section(Carbapenems) of M/S Nicholas Pharmaceuticals available.
	Decision: Approved.	
1050.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Morpen 1g Injection I.V
	Composition	Each vial contains: Meropenem as trihydrate (with anhydrous Sodium Carbonate)…1g
	Diary No. Date of R& I & fee	Dy.No. 16303 dated 07-03-2019 Rs50,000/- Dated 06-03-2019
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MERREM® IV (meropenem for injection) 1g, for intravenous use. US-FDA approved
	Me-too status	Olver Injection of M/s Genix
	GMP status	Certificate of GMP Issued on 02-10-2019 & Last GMP inspection conducted on 03-08-18and report concludes firm was considered to be operating in compliance with the acceptable level of cGMP Standards.
	Remarks of the Evaluator[IV]	• Number of sections of applicant approved by Licensing Board : 13 • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil • Dry powder Injectable Section(Carbapenems) of M/S Nicholas Pharmaceuticals available.
	Decision: Approved.	
Export Facilitation: Applications was received through letter No.F.1-6/2019-PR.I (EFD) dated 27th Dec, 2019 "M/s Star Laboratories, Lahore have achieved benchmark OF USD 1,969,464.41 as defined in the Board's decision during fiscal year 2018-2019. In this regard, please find the applications submitted by the firm."		
1051.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd. 23-km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Neuro Plus 500mg Tablet
	Composition	Each Tablet Contains: Citicoline as Sodium…500mg
	Diary No. Date of R& I & fee	Dy.No. 7402 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Nootropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	3 x 10's; As per SRO

	Approval status of product in Reference Regulatory Authorities	Cognizine Germany but not traceable.
	Me-too status	Cercolin Tablets of M/s Schazoo Laboratories
	GMP status	Last GMP inspection conducted on 05-10-2018 & 12-11-2018 and report concludes firm was considered to be operating at satisfactory level on Compliance with GMP."
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
Export Facilitation: Applications was received through letter No.F.1-6/2019-PR.I (EFD) dated 27th Dec, 2019 "M/s Focus & Rulz Pharmaceuticals, Islamabad have achieved benchmark OF USD 222074.19 as defined in the Board's decision during fiscal year 2018-2019. In this regard, please find the applications submitted by the firm."		
1052.	Name and address of manufacturer / Applicant	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bontan 62.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bosentan Monohydrate Eq. to Bosentan…62.5mg
	Diary No. Date of R& I & fee	Dy.No. 13736 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 Duplicate File bearing Dy No. 29644 dated 09-01-2020
	Pharmacological Group	Endothelin Receptor Antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	14's, 28's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tracleer of USFDA approved
	Me-too status	Bozpah 62.5mg Tablet of M/s Nabiqasim
	GMP status	Last GMP inspection conducted on 15-01-2019 & 17-01-2019 and report concludes that "Keeping in view of the above facts on record, the panel unanimously recommends a- renewal of DML by way of formulation to M/s Focus and Rulz Pharma Islamabad. b- Grant of additional sections and regularization of following sections. i- Sachet section (gen) new ii- Cephalosporin section extension iii- Changes of ground floor and first floor layout plan.
	Remarks of the Evaluator[IV]	
	Decision: Approved. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1053.	Name and address of manufacturer / Applicant	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bontan 125mg Tablet
	Composition	Each Film Coated Tablet Contains: Bosentan Monohydrate Eq. to Bosentan…125mg
	Diary No. Date of R& I & fee	Dy.No. 13738 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (Duplicate challan)
	Pharmacological Group	Endothelin Receptor Antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	14's, 28's ; As per SRO

	Approval status of product in Reference Regulatory Authorities	Tracleer of USFDA approved
	Me-too status	Bozpah 125mg Tablet of M/s Nabiqasim
	GMP status	Last GMP inspection conducted on 15-01-2019 & 17-01-2019 and report concludes that "Keeping in view of the above facts on record, the panel unanimously recommends a- renewal of DML by way of formulation to M/s Focus and Rulz Pharma Islamabad. b- Grant of additional sections and regularization of following sections. i- Sachet section (gen) new ii- Cephalosporin section extension iii- Changes of ground floor and first floor layout plan.
	Remarks of the Evaluator[IV]	
	Decision: Approved. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1054.	Name and address of manufacturer / Applicant	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tramalgia-P 37.5/325 mg Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol HCL…37.5mg Paracetamol…325mg
	Diary No. Date of R& I & fee	Dy.No. 13734 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramacet tablet of (MHRA approved)
	Me-too status	Radol-P tablet of M/s Regal Pharmaceuticals
	GMP status	Last GMP inspection conducted on 15-01-2019 & 17-01-2019 and report concludes that "Keeping in view of the above facts on record, the panel unanimously recommends a- renewal of DML by way of formulation to M/s Focus and Rulz Pharma Islamabad. b- Grant of additional sections and regularization of following sections. i- Sachet section (gen) new ii- Cephalosporin section extension iii- Changes of ground floor and first floor layout plan.
	Remarks of the Evaluator[IV]	
	Decision: Approved.	
1055.	Name and address of manufacturer / Applicant	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mornexx 10/10 mg tablet
	Composition	Each Enteric Coated Tablet Contains: Doxylamine Succinate…10mg Pyridoxine Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No. 13737 dated 07-03-2019 Rs.20,000/- 07-03-2019 Duplicate File bearing Dy No. 29644 dated 09-01-2020
	Pharmacological Group	Anti-Histamine + Vitamin B6
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, 30's ; As per SRO

	Approval status of product in Reference Regulatory Authorities	Diclegis of (USFDA approved)
	Me-too status	Xyquil DR Tablet of M/s Sami
	GMP status	Last GMP inspection conducted on 15-01-2019 & 17-01-2019 and report concludes that "Keeping in view of the above facts on record, the panel unanimously recommends a- renewal of DML by way of formulation to M/s Focus and Rulz Pharma Islamabad. b- Grant of additional sections and regularization of following sections. i- Sachet section (gen) new ii- Cephalosporin section extension iii- Changes of ground floor and first floor layout plan.
	Remarks of the Evaluator[IV]	In refrence agency delayed release film coated tablet
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities	
1056.	Name and address of manufacturer / Applicant	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Raftine Suspension
	Composition	Each 10ml Suspension Contains: Sodium Alginate…1000mg Potassium bicarbonate…200mg
	Diary No. Date of R& I & fee	Dy.No. 13737 dated 07-03-2019 Rs.20,000/- 07-03-2019 Duplicate File bearing Dy No. 29644 dated 09-01-2020
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	12ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Gaviscon Advance of (MHRA approved)
	Me-too status	Gesecon Advance syrup of M/s Winthrox
	GMP status	Last GMP inspection conducted on 15-01-2019 & 17-01-2019 and report concludes that "Keeping in view of the above facts on record, the panel unanimously recommends a- renewal of DML by way of formulation to M/s Focus and Rulz Pharma Islamabad. b- Grant of additional sections and regularization of following sections. i- Sachet section (gen) new ii- Cephalosporin section extension iii- Changes of ground floor and first floor layout plan.
	Remarks of the Evaluator[IV]	In reference Aniseed(fennel) and peppermint flavor while applied formulation contains orange flavor
	Decision: Deferred for confirmation of flavor due to variation from reference product.	
Export Facilitation: Applications was received through letter No.F.1-6/2019-PR.I (EFD) dated 27th Dec, 2019 "M/s Medipak, Lahore have achieved benchmark OF USD 286714 as defined in the Board's decision during fiscal year 2018-2019. In this regard, please find the applications submitted by the firm."		
1057.	Name and address of manufacturer / Applicant	M/s Medipak Limited 132, Industrial Estate, Kot Lakhpat Lahore
	Brand Name +Dosage Form + Strength	Medimox Tablet 400mg
	Composition	Each film coated tablet contains: Moxifloxacin as Hydrochloride …400mg
	Diary No. Date of R& I & fee	Dy.No. 12570 dated 06-03-2019 Rs.20,000/- Dated 05-03-

		2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	1x5's : As per SRO
	Approval status of product in Reference Regulatory Authorities	AVELOX of USFDA approved
	Me-too status	Moxox 400mg of M/s Wellborne Pharmachem and Biologicals
	GMP status	Last GMP inspection conducted on 11-07-2019 and report concludes that " The panel observed that the firm had rectified most of the deficiency pointed out in the inspection dated 13-04-2016. Further improvements suggested would be verified in the next inspection due for renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1058.	Name and address of manufacturer / Applicant	M/s Medipak Limited 132, Industrial Estate, Kot Lakhpat Lahore
	Brand Name +Dosage Form + Strength	Lotenol Opthalmic Suspension 5/3mg/ml
	Composition	Each ml contains: Loteprednol Etabone…….5mg Tobramycin ……3mg
	Diary No. Date of R& I & fee	Dy.No. 12573 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Corticosteroid+Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	5ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	Zylet ophthalmic suspension of (USFDA approved)
	Me-too status	Lotepred-T of M/s Elko
	GMP status	Last GMP inspection conducted on 11-07-2019 and report concludes that " The panel observed that the firm had rectified most of the deficiency pointed out in the inspection dated 13-04-2016. Further improvements suggested would be verified in the next inspection due for renewal of DML.
	Remarks of the Evaluator[IV]	Firm change formulation from Tobramycin as Sulphate to Tobramycin with submission of fee of Rs: 5000/-through deposit slip No# 1980764 Dated: 11-03-2020
	Decision: Approved with innovator's specification.	
1059.	Name and address of manufacturer / Applicant	M/s Medipak Limited 132, Industrial Estate, Kot Lakhpat Lahore
	Brand Name +Dosage Form + Strength	Prednilot Opthalmic suspension 5mg/ml
	Composition	Each ml contains: Loteprednol Etabone…5mg
	Diary No. Date of R& I & fee	Dy.No. 12572 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	5ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	Lotemax ophthalmic suspension of (USFDA approved)
	Me-too status	Loton Ophthalmic Suspension of M/s Medicaids
	GMP status	Last GMP inspection conducted on 11-07-2019 and report concludes that " The panel observed that the firm had

		rectified most of the deficiency pointed out in the inspection dated 13-04-2016. Further improvements suggested would be verified in the next inspection due for renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1060.	Name and address of manufacturer / Applicant	M/s Medipak Limited 132, Industrial Estate, Kot Lakhpat Lahore
	Brand Name +Dosage Form + Strength	Latoprost Eye Drops 0.05mg/ml
	Composition	Each ml contains: Latanoprost…….0.05mg
	Diary No. Date of R& I & fee	Dy.No. 12574 dated 06-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Prostaglandin
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	2.5ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	Latanoprost 50 micrograms / ml Eye Drops, Solution. of (MHRA approved)
	Me-too status	Latim Eye Drops of M/s Macquin's
	GMP status	Last GMP inspection conducted on 11-07-2019 and report concludes that " The panel observed that the firm had rectified most of the deficiency pointed out in the inspection dated 13-04-2016. Further improvements suggested would be verified in the next inspection due for renewal of DML.
	Remarks of the Evaluator[IV]	
	Decision: Approved with innovator's specification.	
1061.	Name and address of manufacturer / Applicant	M/s Medipak Limited 132, Industrial Estate, Kot Lakhpat Lahore
	Brand Name +Dosage Form + Strength	Floxipred Opthalmic suspension
	Composition	Each ml contains: Prenisolone acetate……10mg Ofloxacin ……3mg
	Diary No. Date of R& I & fee	Dy.No. 12564 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Corticosteroid + Ant-infective
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	5ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Oflopred Ophthalmic Suspension of BarretHodgson, (Reg# 061205)
	GMP status	Last GMP inspection conducted on 11-07-2019 and report concludes that " The panel observed that the firm had rectified most of the deficiency pointed out in the inspection dated 13-04-2016. Further improvements suggested would be verified in the next inspection due for renewal of DML.
	Remarks of the Evaluator[IV]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

b. Export facilitation (Deferred cases)

1062.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700
	Brand Name +Dosage Form + Strength	Dobmine 250mg / 5ml Injection
	Composition	Each 5ml contains: Dobutamine HCl eq. to Dobutamine …….. 250mg
	Diary No. Date of R& I & fee	Dy.No. 8802 dated 27-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Cardiotonic
	Type of Form	Form-5
	Finished product Specifications	USP Specs.
	Pack size & Demanded Price	5mlx1's & 5mlx10's :As per PRC
	Approval status of product in Reference Regulatory Authorities	Not found.
	Me-too status (with strength and dosage form)	Botamin Injection by M/s Fynk Pharmaceuticals
	GMP status	Last GMP inspection conducted on 02/05/18and report concludes that The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process."
	Previous Remarks of the Evaluator[IV].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting
	Previous decision(s)	Deferred for following reasons: • Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.. **(M-290)**
	Evaluation by PEC	Firm submitted fee of Rs: 20000/- Deposit Slip No: 2005102 Dated: 10-01-2020 and revise formulation as follows Douro 250mg/20ml Injection Each 20ml Contains: Dobutamine Hcl Eq. to Dobutamine…250mg 20ml x1's: As per SRO DOBUTREX Dobutamine 250mg/20mL injection solutio of TGA Approved Dobutamine Injection 250mg of Haji medicine (Reg#027345)
	Decision: Approved.	

Case no. 05 Registration applications of import cases

a. New Cases (Human)

1063.	Name and address of Applicant	M/S Bristol Mayer Biotech Pakistan, 73-B Guldasht Town Lahore Cantt Pakistan
	Detail of Drug Sale License	Address : 73-B Guldasht Town, Zarar Shaheed road Lahore Validity : 07/04/2020 Status**:** to sell drugs in a whole sale distribution
	Name and address of manufacturer	VEM ILAC San.ve Tic. A.s. Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Faith Bulvari No: 38 Kapakli/ TEKIRDAĞ/TURKEY
	Name and address of marketing authorization holder	VEM ILAC San.ve Tic. A.s. Söğütözü Mahallesi 2177. Cadde No: 10B/49 Cankaya/Ankara/Turkey
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 33319 Dated : 08/10/2018
	Fee including differential fee	Rs : 50,000 Dated : 08/10/2018
	Brand Name +Dosage Form + Strength	Fericose 100mg/5ml I.V Solution for Injection
	Composition	Each 5ml ampoule Contains Iron as Iron Sucrose (Iron (III) Hydroxide Sucrose Complex) Eq to elemental Iron……100mg
	Finished Product Specification	USP
	Pharmacological Group	Iron Trivalent Parentral prepartions
	Shelf life	36 months
	Demanded Price	As per SRO
	Pack size	1 Vial/box
	International availability	Venofer 100mg/5ml Injection of MHRA approved
	Me-too status	Bisleri 100mg/5ml Injection of M/S Sami Pharma
	Detail of certificates attached	**Valid and Legalized CoPP** **Certificate No**: 2018/3541 **Certified by:** Turkish Medicines and Medical devices Agency Söğütözü Mahallesi 2176. Sokak No:5 06520 Cankaya/Ankara/Turkey Product license and date of issue : 252/21 -23 July.2013 **Valid until :** 03-10-2020 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP **GMP certificate** GMP certificate No : TR/GMP/2018/27 Date of Issue: 30-01-2018 Valid until : 05/2020 **GMP certificate and Free sale certificate** Certificate No : 2018/3635 Date of Issue: 03-10-2018 Valid until : 09-10/2020 **Sole Contract Agreement** 22-10-2018 Validity: 2 Years
	Remarks of the Evaluator[IV]	• Remaining fee of Rs:50000/- Submitted. Deposit slip No# 1957531 Dated: 02-12-2019 • Stability studies according to Zone IV-A not submitted.
	Decision: Deferred for submission of Stability studies according to Zone IV-A.	

b. New Cases (Veterinary)

1064.	Name and address of Applicant	M/S MUSTAFA BROTHERS 186-D, Peoples Colony No. 1, Faisalabad- PAKISTAN
	Detail of Drug Sale License	Address: P-186-D Peoples Colony No. 1 Faislabad Validity : 12/02/2019 Status**:** drug to sell drugs in a distributor
	Name and address of manufacturer	M/s Vetsintez LLC 30 Smolna St., Kharkiv- 61001 Ukraine. Production Site: 2 Liois Pasteur st 61075-Kharkiv City**.**
	Name and address of marketing authorization holder	M/s Vetsintez LLC 30 Smolna St., Kharkiv- 61001 Ukraine.
	Name of exporting country	Ukarine
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 7184 Dated : 26/02/2018
	Fee including differential fee	Rs : 1,00,000 Dated : 26/02/2018
	Brand Name +Dosage Form + Strength	CYANOPHOR Solution for Injection
	Composition	Each ml of contains Butaphosphane …….....100mg Cyanocobalamine (Vitamin B_{12})……..0.05mg (Horses, Cattle, Foals, Calvs, Sheeps, Goats,Lambs,Dogs, Cats, Fur bearing animals Laying Hens ,Chickens)
	Finished Product Specification	
	Pharmacological Group	Vitamins with minerals
	Shelf life	3 years
	Demanded Price	50ml - 1.70 USD 100ml – 3. 50 USD
	Pack size	20ml, 50ml, 100ml,250ml, 500ml
	International availability	
	Me-too status	CATOSAL 10% INJECTABLE SOLUTION OF M/S BAYER PAKISTAN (100ML)
	Detail of certificates attached	•Copy of Agreement M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad. & M/s Vetintez LLC 30 Smolna st. , kharkiv-61001, Ukraine Dated : 15-05-2015 Valid till: 15-05-2020
	Remarks of the Evaluator[IV]	• Submit Attested copy of valid Drug Sale License • Submit Original Ambassy attested legalized Free sale certificate • Submit Attested Valid GMP certificate of manufacture. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • For injectable only one pack size amongst 20ml, 50ml, 100ml, 250ml, 500ml can be applied. Applied dossier is for which pack size clarify. • Submit Accelerated Stability studies according to zone IV-A condition of applied formulation. Long term Stability studies performed at 18±2° /60% RH ± 5% RH condition at initial, 6th month, 12th month,24th month,30th month & 36th month. Please

		provide reference of these conditions. • Finished Product Specification are not provided.
	Decision:Deferred for following: • **Submit Attested copy of valid Drug Sale License** • **Submit Original Ambassy attested legalized Free sale certificate** • **Submit Attested Valid GMP certificate of manufacture.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **For injectable only one pack size amongst 20ml, 50ml, 100ml, 250ml, 500ml can be applied. Applied dossier is for which pack size clarify.** • **Submit Accelerated Stability studies according to zone IV-A condition of applied formulation.** • **Long term Stability studies performed at 18±2° /60% RH ± 5% RH condition at initial, 6th month, 12th month,24th month,30th month & 36th month. Please provide reference of these conditions.** • **Finished Product Specification are not provided**.	
1065.	Name and address of Applicant	M/S MUSTAFA BROTHERS 186-D, Peoples Colony No. 1, Faisalabad- PAKISTAN
	Detail of Drug Sale License	Address: P-186-D Peoples Colony No. 1 Faislabad Validity : 12/02/2019 Status: drug to sell drugs in a distributor
	Name and address of manufacturer	M/s Vetsintez LLc 30 Smolna St., Kharkiv- 61001 Ukraine. Production Site: 2 Liois Pasteur st 61075-Kharkiv City
	Name and address of marketing authorization holder	M/s Vetsintez LLc 30 Smolna St., Kharkiv- 61001 Ukraine.
	Name of exporting country	Ukarine
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 7185 Dated : 26/02/2018
	Fee including differential fee	Rs : 1,00,000 Dated : 26/02/2018
	Brand Name +Dosage Form + Strength	Tilmicovet 25% Oral Solution
	Composition	Each ml of contains Tilmicosin (as tilmicosin Phosphate).....250mg (Poultry {broilers, chickens and turkeys}, Calves)
	Finished Product Specification	
	Pharmacological Group	Antibacterial veterinary medicines
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml, 500ml, 1000ml, 5000ml
	International availability	
	Me-too status	MOTIL LIQUID OF M/S. BREEZE PHARMA
	Detail of certificates attached	•Copy of Agreement M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad. & M/s Vetintez LLC 30 Smolna st. , kharkiv-61001, Ukraine Dated : 15-05-2015
	Remarks of the Evaluator[IV]	• Submit Attested copy of valid Drug Sale License • Submit Original Ambassy attested legalized Free sale certificate • Submit Attested Valid GMP certificate of manufacture. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th

		meeting. • Submit Accelerated Stability studies according to zone IV-A condition of applied formulation. Long term Stability studies performed at 18±2° /60% RH ± 5% RH condition at initial, 6th month, 12th month, 24th month,30th month & 36th month. Please provide reference of these conditions. • Finished Product Specification are not provided.
	Decision:Deferred for following: • **Submit Attested copy of valid Drug Sale License** • **Submit Original Ambassy attested legalized Free sale certificate** • **Submit Attested Valid GMP certificate of manufacture.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submit Accelerated Stability studies according to zone IV-A condition of applied formulation.** • **Long term Stability studies performed at 18±2° /60% RH ± 5% RH condition at initial, 6th month, 12th month, 24th month,30th month & 36th month. Please provide reference of these conditions.** • **Finished Product Specification are not provided.**	
1066.	Name and address of Applicant	M/s Chakwal Pharma International.
	Detail of Drug Sale License	Address: OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore Validity : 13/11/2019 Status: to sell drugs as a distribution
	Name and address of manufacturer	Medivet sa, route de korbous km 58020 soliman, TUNISIA
	Name and address of marketing authorization holder	Medivet sa, route de korbous km 5 58020 soliman, TUNISIA
	Name of exporting country	Tunisia
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 6473 Dated 21-02-2018
	Fee including differential fee	Rs : 1,00,000 Dated 21-02-2018
	Brand Name +Dosage Form + Strength	TRICLAZOLE 10% Oral Suspension
	Composition	Each 100ml contains: Triclabendazole…..10g
	Finished Product Specification	Inhouse
	Pharmacological Group	Anthelmintic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml,500ml, 1000ml
	International availability	
	Me-too status	FASIVET 10% SUSPENSION of M/s REDEX PHARMACEUTICAL
	Detail of certificates attached	**CERTIFICATE OF PHARMACEUTICALPRODUCT** **Certified by:** Directorate of pharmacy and Medicine, 31 Khartoum road1002 Tunis- TUNISIA **Product License NO:** 147.1235.11 **Issued on :** 27/08/2011 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate: Yes confirms as recommended by WHO confirms from COPP **Contract Agreement** 03-02-2016

		Validity: 5 years
	Remarks of the Evaluator[IV]	• Applied formulation is suspension while in form 5A in strength of active ingredient per unit Oral solution mentioned. Clarify • On form 5A address of applicant not mentioned. • Validity of COPP could not be confirmed. • Real time stability studies according to zone IV-A of applied formulation not submitted • Shelf life in form 5A mentioned 36 years while stability studies submitted for 24 months. Justify • Submit Valid attested GMP certificate of manufacturer. • Submit Finished Product Specification. • Submit Label according to The Drugs (Labelling and Packing) Rules, 1986.
	Decision:Deferred for following: • **Applied formulation is suspension while in form 5A in strength of active ingredient per unit Oral solution mentioned. Clarify** • **On form 5A address of applicant not mentioned.** • **Validity of COPP could not be confirmed.** • **Real time stability studies according to zone IV-A of applied formulation not submitted** • **Shelf life in form 5A mentioned 36 years while stability studies submitted for 24 months. Justify** • **Submit Valid attested GMP certificate of manufacturer.** • **Submit Finished Product Specification.** • **Submit Label according to The Drugs (Labelling and Packing) Rules, 1986.**	

c. Deferred cases

i. Human

1067.	Name and address of Applicant	M/S Bristol Mayer Biotech Pakistan, 73-B Guldasht Town Lahore Cantt Pakistan
	Detail of Drug Sale License	Address : 73-B Guldasht Town, Zarar Shaheed road Lahore Validity : 07/04/2020 Status**:** to sell drugs in a whole sale distribution
	Name and address of manufacturer	Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Faith Bulvari No: 38 Kapakli/ TEKIRDAĞ/TURKEY
	Name and address of marketing authorization holder	VEM ILAC San.ve Tic. A.s. Söğütözü Mahallesi 2177. Cad No:10 B/49 Cankaya/ANKARA/TURKEY
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 18446 Dated : 21/05/2018
	Fee including differential fee	Rs : 50,000 Dated : 21/05/2018
	Brand Name +Dosage Form + Strength	Blumet 100mg/10ml Injection
	Composition	Each ml Contains Methylene blue ……10mg
	Finished Product Specification	USP
	Pharmacological Group	Antidote
	Shelf life	36 months
	Demanded Price	As per SRO
	Pack size	10ml Ampoule
	International availability	NA
	Me-too status	Not Available
	Detail of certificates attached	**Valid and Legalized CoPP** **Certificate No**: 2018/1595

		Certified by: Turkish Medicines and Medical devices Agency Söğütözü Mahallesi 2176. Sokak No:5 06520 Cankaya/Ankara/Turkey Product license and date of issue : 2014/442 _26.05.2014 **Valid until :** 25-04-2022 **Free sale:** Free sale of the product in exporting country.: Yes confirms from COPP **GMP certificate** GMP certificate No : 2018/1580 Date of Issue: 24-04-2018 Valid until : 24/04/2020 **Sole Contract Agreement** 07-06-2018
	Remarks of the Evaluator[IV]	• Long term Stability studies for only 06 months submitted. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Reference provided PROVAYBLUE 5mgml (50mg/10ml) USFDA is in different strength. And label provided of Akron, Inc. have disclaimer that this drug has not been found by FDA to be safe and effective, and this labelling has not been approved by FDA.
	Previous decision(s) (M-288) **Deferred for following:** • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm • Long term Stability studies data for claimed shelf life. **Evaluation by PEC:** Firm submitted long term stability studies for 36 month at 30°C ± 5°C & 75±5%RH	
	Decision:Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

ii. Veterinary

1068.	Name and address of Applicant	M/s SCHIWO PAKISTAN 11G, Shah Rukn e Alam Colony, Multan
	Detail of Drug Sale License	Address: 11G, Shah Rukn e Alam Colony, Multan Validity : 26/08/2021 Status**:** to sell drugs in a whole sale distribution
	Name and address of manufacturer	ASIFAC **Address:** 220 Pham The hien St.,Dist. 8, Ho Chi Minh city, Vietnam **Factory:** Road no 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Veit Nam
	Name and address of marketing authorization holder	ASIFAC **Address:** 220 Pham The hien St.,Dist. 8, Ho Chi Minh city, Vietnam **Factory:** Road no 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Veit Nam
	Name of exporting country	Vietnam

	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy No : 12374 Dated : 17-08-2017	
	Fee including differential fee	Rs : 1,00,000 Dated : 17-08-2017	
	Brand Name +Dosage Form + Strength	ASI-FLORFENICOL 10% Liquid	
	Composition	Each 1000ml contains: Florfenicol……..100gm	
	Finished Product Specification	Inhouse	
	Pharmacological Group	Antibiotic	
	Shelf life	2 Years	
	Demanded Price	10,500/-1liter,	
	Pack size	1 liter	
	International availability	----	
	Me-too status	PRI-FLORECOL 10 ORAL LIQUID of M/S. PRIX PHARMACEUTICA	
	Detail of certificates attached	**CERTIFICATE OF FREE SALES** **Certified by:** Department of Animal Health of Vietnam **Certificate No:** Ref.N^{o} : 1077/2019/QLT- CFS **Product Registration Name:** HCM-X11-93 **Issued on :** 26/09/2019 **Validity : 2 years** **Free sale:** freely sold in Viet Nam and overseas market **GMP certificate** **Issued by**: Department of Animal Health of Vietnam **Issued on**: 26, December 2016 **Validity**: 05 years **Contract Agreement** 14-06-2018	
	Previous Remarks of the Evaluator[IV]	On form 5A address of applicant is different than address on. Please clarify.	Firm reply that our previous Head office was **M/s SCHIWO PAKISTAN** Off. No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad , Multan, Punjab, Pakistan .Now our present Head office and drug sale address is **M/s SCHIWO PAKISTAN** 11G, Shah Rukn e Alam Colony, Multan
	Previous decision(s): Deferred for Submission of fee for revision of form 5A with refrence to change in address of Applicant (M-293) **Evaluation by PEC:** Firm submitted fee of Rs: 5000/- Deposit slip No# 0600968, Dated: 20-01-2020		
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.		
1069.	Name and address of Applicant	M/s SCHIWO PAKISTAN 11G, Shah Rukn e Alam Colony, Multan	
	Detail of Drug Sale License	Address: 11G, Shah Rukn e Alam Colony, Multan Validity : 26/08/2021 Status**:** to sell drugs in a whole sale distribution	
	Name and address of manufacturer	ASIFAC **Address:** 220 Pham The hien St.,Dist. 8, Ho Chi Minh city, Vietnam **Factory:** Road no 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Veit Nam	
	Name and address of marketing authorization holder	ASIFAC **Address:** 220 Pham The hien St.,Dist. 8, Ho Chi Minh city, Vietnam	

		Factory: Road no 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Veit Nam	
	Name of exporting country	Vietnam	
	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy No : 12375 Dated : 17-08-2017	
	Fee including differential fee	Rs : 1,00,000 Dated : 17-08-2017	
	Brand Name +Dosage Form + Strength	ASI-COLISTIN Powder	
	Composition	Each 1000g contains: Colistin sulphate……..4,800 MIU	
	Finished Product Specification	Inhouse	
	Pharmacological Group	Antibiotic	
	Shelf life	2 Years	
	Demanded Price	Rs: 12,500/-1kg,	
	Pack size	1kg	
	International availability	----	
	Me-too status	COLISTIN S POWDER of M/s ALINACOMBINE	
	Detail of certificates attached	**CERTIFICATE OF FREE SALES** **Certified by:** Department of Animal Health of Vietnam **Certificate No:** Ref.N^{o} : 1084/2019/QLT- CFS **Product Registeration Name:** HCM-X11-163 **Issued on :** 26/09/2019 **Validity : 2 years** **Free sale:** freely sold in Viet Nam and overseas market **GMP certificate** **Issued by**: Department of Animal Health of Vietnam **Issued on**: 26, December 2016 **Validity**: 05 years **Contract Agreement** 14-06-2018	
	Previous Remarks of the Evaluator[IV]	On form 5A address of applicant is different than address on. Please clarify.	Firm reply that our previous Head office was **M/s SCHIWO PAKISTAN** Off. No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad , Multan, Punjab, Pakistan .Now our present Head office and drug sale address is **M/s SCHIWO PAKISTAN** 11G, Shah Rukn e Alam Colony, Multan
	Previous decision(s): Deferred for Submission of fee for revision of form 5A with refrence to change in address of Applicant **(M-293)** **Evaluation by PEC:** Firm submitted fee of Rs: 5000/- Deposit slip No# 0600967, Dated: 20-01-2020		
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.		
1070.	Name and address of Applicant	M/s SCHIWO PAKISTAN 11G, Shah Rukn e Alam Colony, Multan	
	Detail of Drug Sale License	Address: 11G, Shah Rukn e Alam Colony, Multan Validity : 26/08/2021 Status**:** to sell drugs in a whole sale distribution	
	Name and address of manufacturer	ASIFAC **Address:** 220 Pham The hien St.,Dist. 8, Ho Chi Minh city, Vietnam **Factory:** Road no 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Veit Nam	
	Name and address of marketing	ASIFAC	

	authorization holder	**Address:** 220 Pham The hien St.,Dist. 8, Ho Chi Minh city, Vietnam **Factory:** Road no 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Veit Nam	
	Name of exporting country	Vietnam	
	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy No : 23257 Dated : 08-07-2018	
	Fee including differential fee	Rs : 1,00,000 Dated : 05-07-2018	
	Brand Name +Dosage Form + Strength	ASI-LINCO 4.4% (Oral Powder)	
	Composition	Each 1000G contains: LINCOMYCINE……..44gm	
	Finished Product Specification	Inhouse	
	Pharmacological Group	Antibiotic	
	Shelf life	2 Years	
	Demanded Price	3,150/-1kg, 1500/-5kg,	
	Pack size	1kg, 5kg	
	International availability	-----	
	Me-too status	LINCOS-P POWDER.of M/s A & K PHARMACEUTICAL,	
	Detail of certificates attached	**CERTIFICATE OF FREE SALES** **Certified by:** Department of Animal Health of Vietnam **Certificate No:** Ref.N^{o} : 1080/2019/QLT- CFS **Product Registeration Name:** HCM-X11-121 **Issued on :** 26/09/2019 **Validity : 2 years** **Free sale:** freely sold in Viet Nam and overseas market **GMP certificate** **Issued by**: Department of Animal Health of Vietnam **Issued on**: 26, December 2016 **Validity**: 05 years **Contract Agreement** 14-06-2018	
	Previous Remarks of the Evaluator[IV].	On form 5A address of applicant is different than address on. Please clarify.	Firm reply that our previous Head office was **M/s SCHIWO PAKISTAN** Off. No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad , Multan, Punjab, Pakistan .Now our present Head office and drug sale addresss is **M/s SCHIWO PAKISTAN** 11G, Shah Rukn e Alam Colony, Multan
	Previous decision(s): Deferred for Submission of fee for revision of form 5A with refrence to change in address of Applicant **(M-293)** **Evaluation by PEC:** Firm submitted fee of Rs: 5000/- Deposit slip No# 0600966, Dated: 20-01-2020		
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.		
1071.	Name and address of Applicant	M/s SCHIWO PAKISTAN 11G, Shah Rukn e Alam Colony, Multan	
	Detail of Drug Sale License	**Address:** 11G, Shah Rukn e Alam Colony, Multan **Validity :** 26/08/2021 **Status:** to sell drugs in a whole sale distribution	
	Name and address of manufacturer	ASIFAC **Address:** 220 Pham The hien St.,Dist. 8, Ho Chi Minh city, Vietnam	

		Factory: Road no 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Veit Nam	
	Name and address of marketing authorization holder	ASIFAC **Address:** 220 Pham The hien St.,Dist. 8, Ho Chi Minh city, Vietnam **Factory:** Road no 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Veit Nam	
	Name of exporting country	Vietnam	
	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy No :23259 Dated : 05-07-2018	
	Fee including differential fee	Rs : 1,00,000 Dated : 05-07-2018	
	Brand Name +Dosage Form + Strength	**ASI-ENROFLOXACIN 100** (Oral Solution)	
	Composition	Each 100ml contains: Enrofloxacin……..10 g	
	Finished Product Specification	Inhouse	
	Pharmacological Group	Quinolone antibiotic	
	Shelf life	2 years	
	Demanded Price	6,500/-1liter	
	Pack size	1 liter	
	International availability	------	
	Me-too status	CERIFLOX 10% ORAL SOLUTION of M/s STAR LABS	
	Detail of certificates attached	**CERTIFICATE OF FREE SALES** **Certified by:** Department of Animal Health of Vietnam **Certificate No:** Ref.N^{o} : 1075/2019/QLT- CFS **Product Registeration Name:** HCM-X11-139 **Issued on :** 26/09/2019 **Validity : 2 years** **Free sale:** freely sold in Viet Nam and overseas market **GMP certificate** **Issued by**: Department of Animal Health of Vietnam **Issued on**: 26, December 2016 **Validity**: 05 years **Contract Agreement** 14-06-2018	
	Previous Remarks of the Evaluator[IV]	On form 5A address of applicant is different than address on. Please clarify.	Firm reply that our previous Head office was **M/s SCHIWO PAKISTAN** Off. No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad , Multan, Punjab, Pakistan .Now our present Head office and drug sale addresss is **M/s SCHIWO PAKISTAN** 11G, Shah Rukn e Alam Colony, Multan
	Previous decision(s): Deferred for Submission of fee for revision of form 5A with refrence to change in address of Applicant **(M-293)** **Evaluation by PEC:** Firm submitted fee of Rs: 5000/- Deposit slip No# 0600965, Dated: 20-01-2020		
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.		

Case no. 06 Registration applications of drugs for which stability study data is submitted

a. New cases

b. Deferred cases

c. Verification of stability study data

Deferred case

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1072.	M/s. Vision Pharmaceuticals , Plot # 22-23, Industrial Triangle, Kahuta road, Islamabad	K-Fast 50mg Sachet Each Sachet contains:- Diclofenac Potassium....50mg NSAID Manufacturer's specification	Dy.No.2695; 21-01-2019; Rs.50,000/- 21-01-2019 30's As per SRO	CAMBIA (USFDA) approved. Last inspection conducted on 26-01-2018 and report concludes that firm was operating at Good level of GMP compliance.

STABILITY STUDY DATA

Drug	K-Fast 50mg Sachet		
Name of Manufacturer	M/s. Vision Pharmaceuticals , Plot # 22-23, Industrial Triangle, Kahuta road, Islamabad		
Manufacturer of API	Huixian Dongpu Chemicals co Ltd , China		
API Lot No.	20170520		
Description of Pack (Container closure system)	Paper coated aluminium sachet		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (month) Real Time: 0,1,2 3,4,5,6 (month)		
Batch No.	NPD801(T-01)	NPD801(T-02)	NPD801(T-03)
Batch Size	1000 Sachet	1000 Sachet	1000 Sachet
Manufacturing Date	16-05-2018	17-05-2018	21-05-2018
Date of Initiation	23-05- 2018	24-05- 2018	25-05- 2018
No. of Batches	3		
Date of Submission	21-01-2019 (Dy. No. 2695)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	Documents To Be Provided	Status
1.	COA of API	Copy of COA Shanghai Pharma group Changzhou kony Pharmaceuticals co., Ltd is submitted
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate No.HN20160178 issued by Cfda is attached but could not verified from CFDA database
3.	Protocols followed for conduction of stability study and details of tests.	Yes

4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of Assistant Director (I & E) DRAP (Karachi) attested dated: 21-06-2018 Commercial Invoice No WIS180048 Dated:05-06-2018 is submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Certificate No on GMP certificate in China FDA database is for another manufacturer
GMP certificate of API manufacturer issued by regulatory authority of country of origin could not be confirmed from China FDA database.

Initially firm submitted stability data containing API Diclofenac Potassium from Huixian Dongpu Chemicals co Ltd, China. GMP of Huixian Dongpu Chemicals co Ltd, China can not be verified from CFDA database. Thereafter, the firm submitted new stability data with API source i.e Henan Dongtai Pharma co Ltd , China.

NEW STABILITY DATA SUBMITTED BY THE FIRM

Drug	K-Fast 50mg Sachet		
Name of Manufacturer	M/s. Vision Pharmaceuticals , Plot # 22-23, Industrial Triangle, Kahuta road, Islamabad		
Manufacturer of API	Henan Dongtai Pharma co Ltd , China		
API Lot No.	303161222-6		
Description of Pack (Container closure system)	Paper coated aluminium sachet		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (month) Real Time: 0,1,2 3,4,5,6 (month)		
Batch No.	NPD801 A (T-01)	NPD801 A (T-02)	NPD801 A (T-03)
Batch Size	1000 Sachet	1000 Sachet	1000 Sachet
Manufacturing Date	10-08-2018	11-08-2018	14-08-2018
Date of Initiation	27-08- 2018	27-08- 2018	27-08- 2018
No. of Batches	3		
Date of Submission	20-03-2019 (Dy. No. 1288)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	Documents To Be Provided	Status
1.	COA of API	Copy of COA Henan Dongtai Pharma co Ltd , China is submitted
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate No.HA20170001 issued by CFDA is attached. Valid till 22-01-2022

3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of Assistant Director (I & E) DRAP (islamabad) attested dated: 09-01-2017 Commercial Invoice No DT1612132Y Dated: 11-01-2017 is submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The panel may be requested to verify and report about following point in addition to authenticity of stability data and associated documents,

Whether stability studies from both API sources performed. Initially firm submitted stability data containing API Diclofenac Potassium from Huixian Dongpu Chemicals co Ltd , China. GMP of Huixian Dongpu Chemicals co Ltd , China can not be verified from CFDA database. Thereafter, the firm submitted new stability data with API source i.e Henan Dongtai Pharma co Ltd , China .

Report on Inspection for verification of Authenticity/Genuineness of data submitted by M/s. Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23, Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad for registration of K-fast 50mg (Diclofenac potassium) sachet

Inspection Date and Time: 17, 18 and 19 December, 2019

Inspection Site: M/s. Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23 Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad.

Background:

M/s. Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22-23, Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad applied for registration of K-fast 50mg (Diclofenac potassium) sachet with following composition:

K-fast sachet 50mg

Each sachet contains:-

Diclofenac potassium……50mg

Chairman Registration Board constituted a three member panel for on-site investigation to confirm the genuineness/authenticity of submitted stability data and associated documents, import of API, quality, specification, test analysis, facilities etc. Panel was requested to conduct inspection of the firm to verify the data submitted by the firm and to submit a report on approved format for further consideration of case by the Registration Board. The Chairman Registration Board further advised the panel to verify and report about following point:

Initially, the firm has submitted stability studies data containing API Diclofenac potassium imported from Huixian Dongpu Chemicals Co. Ltd, China. GMP of Huixian Dongpu Chemicals Co. Ltd, China cannot be verified from the official database of SFDA. Thereafter, the firm submitted new stability data with new API source Henan Dongtai Pharma Co. Ltd., China.

The Panel was requested to confirm whether the firm has conducted stability studies with each API from two different sources. It was clarified during audit that the firm conducted stability studies with API imported from M/s Henan Dongtai Pharm Co. Ltd., East Changhong Tangyin Henan, China only. The firm did not continue the studies with API imported from source M/s Huixian Dongpu Chemicals Co. Ltd, China and submitted the destruction record (Report no. 1725/NCR dated 22 March, 2019) of stability batches manufactured from this earlier source.

Composition of Panel:
Dr. Qurban Ali, (Member Registration Board).
Mr. Babar Khan, Area FID, DRAP, Islamabad.
Mr. Hanifullah, Assistant Director (PEC) DRAP, Islambad.

Scope of Inspection:
On-site investigation to confirm the genuineness/authenticity of submitted stability data and associated documents like import of API, quality specification and test analysis facilities etc.

Tools for Inspection:
The Inspection was conducted by using a structured questionnaire approved by DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data integrity and security of data in respective databases were also audited. The detail of inspection is summarized as under:
(Some of the observations have been highlighted as bold with bullet point against the respective question).

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API including approval from DRAP?	DICLOFENAC POTASSIUM Invoice Number: DT1612132Y Assistant Director (I & E) DRAP attestation date: 09.02.17 Exporter: M/s Henan Dongtai Pharm CO LTD, EAST CHANGHONG TANGYIN HENAN, CHINA Manufacturer: as above Batch No. 303161222-6 Mfg. Date: 22-12-2016 Exp. Date: 21-12-2020 Quantity: 300Kg
2.	What was the rationale behind selecting the particular manufacturer of API?	The firms provide the rational that Since Diclofenac Potassium is already being used at VISION PHARMACEUTICALS PVT. LTD. in the product Diclofenac Potassium 32% pellets since quite long, therefore, based on the track record of HENAN DONGTAI PHARM CO. LTD. the API source is validated and use of same source is preferred rather than going for an unknown source. The documents of source, HENAN DONGTAI PHARM CO. LTD., are more authentic. The firm has submitted a document comparing the parameters between two sources namely M/s Henan Dongtai Pharm Co. Ltd. China and M/s Huxian Doungpu Chemicals Co. Ltd. China. The document shows the concluding remarks that M/s Henan Dongtai Pharm Co. Ltd. China will be the preferred source with date of 28th August, 2018. While the firm mentioned the manufacturing date of 10th August 2018, 11th August 2018 and 14th August 2018 in the stability studies for the batch # NPD801 (T-01), NPD801 (T-02) and NPD801 (T-03) respectively. This means that the source was qualified after the API has been used in the manufacturing of Finished product batches.
3.	Do you have documents confirming the import of Diclofenac potassium reference standard and impurity standards?	The firm imported following reference standard and impurity standard: Diclofenac potassium primary reference standard from the USP (Lot No. R034L0) Order placing date: 08 June, 2018 Shipment date:11.06.2018 Commercial Invoice no. 31068571(Dated 11 June, 2018) AD attestation date 11.07.2018 Firm has also imported impurity (Diclofenac related compound A USP RS) for identification/quantification of specified impurities from Pharmaffiliates: Invoice no. EXP/2019-20/121 dated 21.06.2019 Lot no. PA/ACE/01109 AD attestation date 11.07.2018
4.	Do you have	The firm has submitted COAs of API, reference standards and impurity

<table>
<tr><td></td><td>certificate of Analysis of the API, reference standards and impurity standards?</td><td>standards as per details below:
Diclofenac potassium API from Henan Dongtai Pharm CO.LTD
(for Batch No.303161222-6)
Diclofenac potassium primary reference standard USP (Lot No. R034L0)
Diclofenac potassium Impurity A RS USP from Pharmaffiliates (Lot no. PA/ACE/01109).</td></tr>
<tr><td>5.</td><td>Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?</td><td>The firm has submitted copy of GMP certificate No:HA20170001 in the name of Manufacturer that is “M/s Henan Dongtai Pharm Co. Ltd, East Changhong Road, Tangyin County, Anyang City, China” for API Diclofenac Potassium USP issued by HeNan Province Food and Drug Administration.
Issuing date: 23-01-2017
Valid till: 22-01-2022
The name of city “Anyang” is mentioned on GMP while it is not mentioned on COA.</td></tr>
<tr><td>6.</td><td>Do you use API manufacturer method of testing for testing API?</td><td>The firm stated that they have used pharmacopoeial (USP) method for testing of API as per statement of API source.</td></tr>
<tr><td>7.</td><td>Do you have stability studies reports on API?</td><td>Firm has submitted data of long term stability studies of three batches 131118-5 (Mfg: 18th Nov, 2013), 131118-6 (Mfg: 18th Nov, 2013) & 131119-5 (Mfg: 18th Nov, 2013) conducted by the API manufacturer M/s Henan Dongtai Pharm Co Ltd, East Changhong Tangyin Henan, China, under conditions of Zone-IV A that is 30 Co + 2 Co & 65 % RH + 5 % (for real time studies) up to 48 months and 40 Co + 2 Co & 75 % RH + 5 % (for accelerated studies) up to 6 months for API namely Diclofenac potassium. The data submitted by the API manufacturer lies within the limits for the Assay & related impurities.

Parameter like pH, viscosity etc. have not been tested by API manufacture in its studies for stability.
Typo-mistake in limit of impurity A has been noticed that is “NMT 0.15 %” has been mentioned instead of “NMT 0.1 %” in stability studies of batch no. 131119-6 in real time studies.</td></tr>
<tr><td>8.</td><td>If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?</td><td>Since the manufacturer has conducted the stability studies using USP compendia in which they have quantified the impurities as per pharmacopoeia, which gives sense that the studies have been conducted as per SIM method.</td></tr>
<tr><td>9.</td><td>Do you have method for quantifying the impurities in the API?</td><td>Yes, they have used USP method for quantifying the impurities in the API.</td></tr>
<tr><td>10.</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>Yes, they have remaining quantities of the API, reference standard and impurities standards as per details given in the following table which have been verified by the panel during the visit:
<table>
<tr><th>Raw Material</th><th>Lot No.</th><th>Place of Consumption</th><th>Quantity</th></tr>
<tr><td rowspan="6">Diclofenac Potassium</td><td rowspan="3">303161222-6</td><td>NPD801(T-01)</td><td>50 gram</td></tr>
<tr><td>NPD801(T-02)</td><td>50 gram</td></tr>
<tr><td>NPD801(T-03)</td><td>50 gram</td></tr>
<tr><td>Total Quantity</td><td colspan="2">300kg</td></tr>
<tr><td>Quantity Consumed</td><td colspan="2">150grams</td></tr>
<tr><td>Remaining Quantity</td><td colspan="2">299.85kg (Rest used in commercial manufacturing)</td></tr>
</table></td></tr>
</table>

		<table><tr><th>Item Type</th><th>Lot No.</th><th>Total Quantity</th><th>Remaining Quantity</th></tr><tr><td>Diclofenac Potassium Reference Standard</td><td>R034LO</td><td>200mg</td><td>125mg</td></tr><tr><th>Item Type</th><th>Lot No.</th><th>Total Quantity</th><th>Remaining Quantity</th></tr><tr><td>Diclofenac Potassium Related Compound A</td><td>PA/ACE/01109</td><td>25mg</td><td>10mg</td></tr></table>
11.	Have you used pharmaceutical grade excipients?	The firm has used following excipients of pharmaceutical grade except flavors Anise and Mint: <table><tr><th>S. No.</th><th>Excipients</th><th>Pharma grade</th></tr><tr><td>1</td><td>Sucralose</td><td>BP</td></tr><tr><td>2</td><td>Mannitol</td><td>BP/USP/EP</td></tr><tr><td>3</td><td>Aspartame</td><td>BP</td></tr><tr><td>4</td><td>Potassium Hydrogen Carbonate</td><td>BP</td></tr><tr><td>5</td><td>Anise Flavour</td><td>Manufacturer's Specification</td></tr><tr><td>6</td><td>Mint Flavour</td><td>Manufacturer's Specification</td></tr></table> The firm has used flavors Anise and Mint which were of manufacturer's specifications.
12.	Do you have documents confirming the import of the used excipients?	The firm has imported only one excipient MANNITOL for the applied formulation through exporter M/s HANGZHOU STARSHINE PHARMACEUTICAL CO LTD (Room B2, 10F, Tianyuan Building, No.508 Wensan Road, Hangzhou, China) from the manufacturer M/s SHANDONG TIANLI PHARMACEUTICAL CO LTD (South of Anshun Street and West of Xingyuanxi Road, Gucheng subdistrict office, Shouguang, Shandong, China) with Batch No. 301802314, manufacturing date:15th Feb, 2018 Expiry Date: 14th Feb, 2020. The firm acquired following other raw material excipients from local suppliers as per details below: <table><tr><th>S.No</th><th>Excipient</th><th>Supplier</th><th>Batch No.</th></tr><tr><td>1.</td><td>Sucralose</td><td>Global</td><td>A17071614</td></tr><tr><td>2.</td><td>Aspartame</td><td>National</td><td>W 16121510</td></tr><tr><td>3.</td><td>Potassium Hydrogen Carbonate</td><td>Musaji Adam & Sons</td><td>PO201PD1</td></tr><tr><td>4.</td><td>Anise</td><td>Hamza</td><td>24151</td></tr><tr><td>5.</td><td>Mint</td><td>Hamza</td><td>24152</td></tr></table> The firm procured the excipient from local supplies. The firm has developed an SOP for vendor qualification but above listed suppliers are not included in the approved list of vendor suppliers.

<table>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has performed tests on the excipients as per details below:
<table>
<tr><th>S. No.</th><th>Excipients</th><th>Report No.</th><th>Release Date</th></tr>
<tr><td>1</td><td>Sucralose</td><td>0916/RM/17</td><td>15.12.2017</td></tr>
<tr><td>2</td><td>Mannitol</td><td>0414/RM/18</td><td>30.05.2018</td></tr>
<tr><td>3</td><td>Aspartame</td><td>0264/RM/17</td><td>10.04.2017</td></tr>
<tr><td>4</td><td>Potassium Hydrogen Carbonate</td><td>0417/RM/18</td><td>31.05.2018</td></tr>
<tr><td>5</td><td>Anise Flavour</td><td>0409/RM/18</td><td>29.05.2018</td></tr>
<tr><td>6</td><td>Mint Flavour</td><td>0410/RM/18</td><td>29.05.2018</td></tr>
</table>
The firm did not acquire COAs of above excipient before purchase or during vendor qualifications. However, the firm provided COA of all excipients during audit.
The QC report for Sucralose have no signature of QA Manager for release of excipient.
Some tests done by source like tests for microorganism for Sucralose (artificial sweetner) but not performed by firm.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of K-FAST 50mg Sachet (Diclofenac Potassium)?</td><td>The firm has written and authorized protocols No.RD/PD/001 for the development of K-FAST 50mg Sachet (Diclofenac Potassium) in accordance with ICH Q-8 Pharmaceutical Development guidelines.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipients compatibility studies?</td><td>The firm has not performed Drug-Excipients compatibility studies. They have submitted the reason/logic for this that as their formulation (API & Excipients) is similar/comparable to that of Voltfast sachet of Novartis Pharma, Switzerland approved by Swissmedics. The quantities of sweetening agents that is Sucralose and Aspartame were within safe limits as per USFDA inactive ingredient database.

The firm referred the product approved by the Swiss Medic which contains Aspartame and saccharine sodium. Hence, the firm should perform compatibility studies.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The comparative dissolution studies have not been performed by the firm. However, the firm has performed comparative assay, LOD and pH studies in comparison with Voltfast to which firm is referring as reference product. This so-called reference product seemed approved by UAE drug agency as it contains UAE: NDC 4924-6116-01-03 & NAFDAC Reg. No. 04-9014. Though it is mentioned on box that it is manufactured by M/s Miphar S.p.A., Milan, Italy for M/s Novartis Pharma AG, Basle, Switzerland.

It was advised to the firm to perform comparative dissolution profile according to WHO guidelines in at least 3 different media of pH 1.2, 4.5 & 6.8 (to simulate the in vivo absorption site) in comparison with the reference product approved by reference drug agency.
The firm has been using sucralose and aspartame in the formulation while the product to which they are referring as reference product namely Voltfast contains aspartame and saccharine sodium.</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>The firm possesses a Research & Development (R&D) section for product development studies.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product</td><td>Yes, the firm has following necessary equipment in R & D section though for the development of K-fast sachet. Following is the list of equipments.
<table>
<tr><th>Sr.</th><th>Equipment Name</th><th>Equipment</th><th>Qualification</th></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td>development section for development of K-fast?</td><td>
<table>
<tr><td>No.</td><td></td><td>ID</td><td>Date</td></tr>
<tr><td>1</td><td>Multi Functional Pharmaceutical R&D Machinery</td><td>VP/RD/001</td><td>20 July 2016</td></tr>
<tr><td>2</td><td>Bag Forming Filling Sealing Machine</td><td>DXDK80CH</td><td>04 Feb 2016</td></tr>
</table>
</td></tr>
<tr><td>19.</td><td>Are the equipments in product development section qualified?</td><td>The following equipments used in production and analysis of trial batches are qualified.
<table>
<tr><td>S. No.</td><td>Equipment Name</td><td>Equipment ID</td><td>Qualification Date</td></tr>
<tr><td>1</td><td>Multi Functional Pharmaceutical R&D Machinery</td><td>VP/RD/001</td><td>20 July 2016</td></tr>
<tr><td>2</td><td>Bag Forming Filling Sealing Machine</td><td>DXDK80CH</td><td>04 Feb 2016</td></tr>
</table>
</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance/calibration/re-qualification program for the equipment used in PD section?</td><td>The firm has maintenance/calibration program for the equipment used in R & D as per following details.
<table>
<tr><td>S. No.</td><td>Equipment Name</td><td>Equipment ID</td><td>Last Maintenance Date</td></tr>
<tr><td>1</td><td>Multi Functional Pharmaceutical R&D Machinery</td><td>VP/RD/001</td><td>October 2019</td></tr>
<tr><td>2</td><td>Bag Forming Filling Sealing Machine</td><td>DXDK80CH</td><td>October 2019</td></tr>
</table>
</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has provided the details of their technical personnel involved in the development of K-fast Sachet.
<table>
<tr><th>S.No</th><th>Name</th><th>Designation</th><th>Qualification</th><th>Experience</th></tr>
<tr><td>1</td><td>Dr. Zia</td><td>Chief</td><td>B Pham</td><td>27 Years</td></tr>
<tr><td>2</td><td>Aatikah</td><td>Manager</td><td>Pharm-D</td><td>9 Years</td></tr>
<tr><td>3</td><td>Humera</td><td>Manager QC</td><td>M.Sc</td><td>21 Years</td></tr>
<tr><td>4</td><td>Saima</td><td>Assistant</td><td>Pharm-D</td><td>9 Years</td></tr>
<tr><td>5</td><td>Altaf</td><td>Deputy</td><td>M.Sc</td><td>13 Years</td></tr>
<tr><td>6</td><td>Muhamm</td><td>Assistant</td><td>Pharm-D</td><td>5 Years</td></tr>
<tr><td>7</td><td>Laila Tul</td><td>R&D Officer</td><td>Pharm-D</td><td>3 Years</td></tr>
</table>
The above technical persons were involved in the development of product and however persons at S.No.1, 2, 4, 6 & 7 have now left the firm.
Dr. Zia ud Din, Chief Operating Officer/TD (Technical Director) also meet the panel on last day of inspection to detail about the formulation development.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of K-FAST Sachet as required?</td><td>The firm has manufactured following three stability batches for the stability studies of K-fast Sachet:
<table>
<tr><th>S. No.</th><th>Stability Batches</th><th>Batch Sizes</th></tr>
<tr><td></td><td>NPD801(T-01)</td><td>3kg</td></tr>
<tr><td></td><td>NPD801(T-02)</td><td>3kg</td></tr>
<tr><td></td><td>NPD801(T-03)</td><td>3kg</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The firm has set the criteria for fixing the batch size of stability batches based on the quantity sufficient for testing during the studies both for accelerated and real time studies to cover all testing time points.
<table>
<tr><th>Trial No.</th><th>Batch Size</th><th>Theoretical Quantity</th><th>Actual Packs Yield</th><th>Packs for Real Time</th><th>Packs for Accelerated</th><th>Total Packs Required</th></tr>
<tr><td>Trial No 1</td><td>3 Kg</td><td>1000 Sachets</td><td>30 Packs</td><td>8 Packs</td><td>7 Packs</td><td>15 Packs</td></tr>
<tr><td>Trial No 2</td><td>3 Kg</td><td>1000 Sachets</td><td>30 Packs</td><td>8 Packs</td><td>7 Packs</td><td>15 Packs</td></tr>
<tr><td>Trial No 3</td><td>3 Kg</td><td>1000 Sachets</td><td>30 Packs</td><td>8 Packs</td><td>7 Packs</td><td>15 Packs</td></tr>
</table></td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record of production of stability batches. The firm has shown the BMR of all three batches showing the complete history of manufacturing and testing of batches step by step:
<table>
<tr><td>NPD801 (T-01)</td><td>3 Kg</td></tr>
<tr><td>NPD801 (T-02)</td><td>3 Kg</td></tr>
<tr><td>NPD801 (T-03)</td><td>3 Kg</td></tr>
</table></td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has controlled protocol no. SOR 03544 for testing the stability batches of applied formulation at 30 Co + 2 Co & 65 % RH + 5 % for real time studies and at 40 Co + 2 Co & 75 % RH + 5 % for accelerated studies with them.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has used pharmacopoeia (USP) method of Diclofenc potassium tablets for testing of Diclofenac potassium sachet and validate this method through their method validation protocol No: MVP/032/2018 for batch No: NPD801. The firm has also submitted a report No: MVR/032/2018 for batch No: NPD801 T01 verifying the validation studies of the analytical method covering following parameters of validation as defined in compendia:
Specificity
Precision
Repeatability
Accuracy and recovery
Ruggedness
Robustness
Linearity and range</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>The firm has not conducted method transfer studies. The firm submitted that since they have developed the method from pharmacopoeia (Pharmacopoeial method of tablets) in their own laboratory and they have validated it so there is no need to do such studies.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming qualification of equipment/ instruments being used in the test and analysis of APIs and finished drugs.</td><td>The firm showed documents like Report No.2477 dated 16.05.2019 by Kamstec International authorized by Waters (the firm showed the evidence from the website for this authorization), confirming the qualification of HPLC (Waters e 2695) being used in the test and analysis of APIs and the finished drug.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm has performed SIM studies on the product and covering aspects like Photolytic degradation, peroxide degradation, thermal degradation, acid degradation, and base degradation studies for 72 hours.
The number of theoretical plates and tailing factor are missing in the chromatograms.</td></tr>
</table>

<table>
<tr><td>30.</td><td>Do your HPLC software is 21CFR compliant?</td><td>Complete product development as well as stability studies have been performed on 21CFR complaint HPLC (Waters e 2695) with software version Empower 3 Software database version 7.40.00.00 Waters 2002-2017.</td></tr>
<tr><td>31.</td><td>Can you show Audit Trail reports on K-fast sachet?</td><td>Yes, the firm has showed the audit trail record. Moreover, record and chromatograms are attached with stability record. It has a limited/controlled access as well.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm has remaining quantities of stability batches as per following details:<table><tr><td>NPD801 (T-01)</td><td>6 packs</td></tr><tr><td>NPD801 (T-02)</td><td>6 Packs</td></tr><tr><td>NPD801 (T-03)</td><td>6 Packs</td></tr></table></td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>The firm has completed the accelerated stability testing on the three stability batches of K-fast Sachet. Also the firm has completed the real time stability testing up to 12 months on all three batches with satisfactory results.</td></tr>
<tr><td>34.</td><td>Do you have valid calibration status for the equipments used in production in analysis?</td><td>The firm has valid calibration status for the equipment used in K-fast Sachet production and analysis as detailed in following table.<table><tr><td>S. No.</td><td>Equipment Name</td><td>Equipment ID</td><td>Last calibration date</td><td>Last calibration date</td></tr><tr><td>1</td><td>Multi Functional Pharmaceutical R&D Machinery</td><td>VP/RD/001</td><td>October 2019</td><td>October 2019</td></tr><tr><td>2</td><td>Bag Forming Filling Sealing Machine</td><td>DXDK80CH</td><td>October 2019</td><td>October 2019</td></tr></table></td></tr>
<tr><td>35.</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>Continuous power supply and monitoring with back up of 1 kv generator is available for stability chamber to address the problem of load shedding and for continuous/uninterrupted power supply. Portable digital data loggers are available for continuous monitoring of temperature and humidity conditions of stability chamber. The firm submitted date-wise data of temperature and humidity conditions of stability chambers used for accelerated and real time studies for every next hour.</td></tr>
<tr><td>36.</td><td>Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?</td><td>The related manufacturing area, equipment, personnel and utilities are rated as GMP compliant.
The firm was advised to increase the capacity of the R&D in terms of facilities, technical staff and training thereof.</td></tr>
</table>

Conclusions & Recommendations:

It was clarified during audit that the firm conducted stability studies with API imported from M/s Henan Dongtai Pharm Co. Ltd., East Changhong Tangyin Henan, China only. The firm did not continue the studies with API imported from source M/s Huixian Dongpu Chemicals Co. Ltd, China and submitted the destruction record (Report no. 1725/NCR dated 22 March, 2019) of stability batches manufactured from this earlier source.

On the basis of risk based approach, the genuineness/authenticity of stability data submitted by the firm for registration of K-Fast Sachet is verifiable to an acceptable/satisfactory level. However, during audit it was revealed that the firm is not clear regarding reference product compare to which they would have to establish the formulation and perform pharmaceutical development studies. Earlier, they referred the brand "Cambia" of Assertio as their reference product whose formulation was found as different (e.g., mannitol has been used with specific particle size) from the applied one by the panel. It is hence, recommended that the assessment related to formulation and manufacturing technology may be carried out again by PEC so as to ascertain/ensure the similarity/comparability of same in the light of approval by reference agency(ies) before grant of registration by the Registration Board.

The related manufacturing area, equipment, personnel and utilities are GMP compliant and suitable for the manufacturing of K-fast 50mg (Diclofenac potassium) sachet therefore, the panel recommends the registration of K-fast 50mg (Diclofenac potassium) sachet in the name of the manufacturer.

Evaluation by PEC:

Firm submitted an undertaking that their reference product was Voltfast Sachet 50mg of Swissmedic.
The assessment related to formulation and manufacturing technology may be carried out again by PEC and it is revealed that firm follow manufacturing process of Voltfast of Swissmedic
Firm submitted dissolution and compare it with Voltfast Sachet 50mg of Swissmedic. Valaue of Q is greater than 90% in 5 minutes.
Excipients are different from Voltfast Sachet 50mg but they did not perform compatibility studies.

Previous Decision: Registration Board after thorough deliberation decided to defer the case for re evaluation of the firm's applied formulation and the USFDA as well as Swissmedic approved reference product by Pharmaceutical Evaluation Cell.**(M-294)**

Evaluation by PEC

S. No	**Parameters**	**Cambia USFDA**		**Voltfast Swissmedic**	**Vision(Applied product)**
1.	Date of approval	17 June 2009		15 July 2005	Nil
2.	Excipient	2009 label (Chemistry review)	2017 label	1. Aspartame 2. Saccharinum natricum 3. Mannitol 4. Aromatica(Mint, Peppermint, Anise) 5. Potassium hydrogencarbon 6. Glycerrol dibehenate	1. Aspartame 2. Mannitol 3. Sucralose 4. Potassium bicarbonate 5. Flavour Anise 6. Flavour Mint
		1. Flavoring agents (anise and mint) 2. Aspartame 3. Glycerol behenate 4. Mannitol, 5. Potassium bicarbonate 6. saccharin sodium	1. Flavoring agents (anise and mint) 2. Glycerol behenate 3. Mannitol 4. Potassium bicarbonate 5. Sucralose		
3.	Indications	For the acute treatment of migraine attacks with or without aura in adults 18 years of age or older		Short-term treatment (maximum 3 days) of the following acute conditions: • Postoperative inflammation and pain, e.g. after dental and orthopedic surgery. • Painful post-traumatic inflammatory conditions, e.g. due to distortion. • Painful and / or inflammatory conditions in gynecology, e.g. primary dysmenorrhea or adnexitis. • Migraine attacks with or without aura . • As an adjuvant for severe painful, inflammatory infections of the throat, nose or ears, e.g. Pharyngotonsillitis, otitis. • Painful spine syndromes. • Extra-articular rheumatism.	For short term treatment of the following conditions: • Sprains, strains or other injuries. • Pain & swelling after surgery. • Painful menstrual periods • Migraine attacks • Back pain, frozen shoulder, tennis elbow, and other forms of soft tissue rheumatism. • Infection of the ear nose or throat.
4.	Dosage	Once daily Single 50 mg dose; mix single packet contents with 1 to 2 ounces or 2 to 4 tablespoons (30 to 60 mL) of water prior to administration		• As a general recommendation, the dose should be adjusted individually. Adverse effects can be reduced by administering the lowest effective dose over the shortest possible period of time to control the symptoms	• Dose to be individually adjusted, lowest effective dose to be given for the shortest duration • Adults: The recommended initially daily dose is 100 to 150 mg.

			• Adults: As a rule, the daily dose is 2-3 bags of Voltfast (100-150 mg / d). In lighter cases and for children over 14 years, 2 sachets of Voltfast per day (50-100 mg) are usually sufficient. The daily dose should generally be taken in 2-3 divided doses. • In primary dysmenorrhea, the daily dose has to be adjusted individually and is usually 1-3 bags. As a starting dose, 1-2 sachets should be prescribed. • Migraines: It is recommended to take an initial dose of 50 mg at the first sign of an impending migraine attack. If pain relief is not sufficient approx. 2 hours after taking the first dose, another dose of 50 mg can be taken. If necessary, further doses of 50 mg can be taken at intervals of 6-8 h, whereby the maximum dose of 150 mg must not be exceeded within 24 h. • Pediatrics (under 18 years) • Due to the dosage strength of Voltfast, use in children under 14 years of age is not recommended. There is currently no data available on the use of Voltfast in migraines in children. • Elderly patients (65 years and older): Basically, no adjustment of the initial dose is necessary in older patients. However, due to basic medical considerations, caution is required in the elderly. Particularly in the case of frail elderly patients or those with low body weight • Existing cardiovascular disease or major cardiovascular risk factors: Voltfast treatment is generally not recommended in patients with pre-existing cardiovascular disease or uncontrolled hypertension. If necessary, patients with existing cardiovascular disease, uncontrolled	The daily dose should generally be divided in up to 3 separate doses. • In primary dysmenorrhea, the daily dose should be individually adjusted and is generally 50 to 150mg. • In migraine, an initial dose of 50mg should be taken at the first signs of an impending attack. • Adolescents aged 14 and over: 50 to 100mg daily are usually sufficient, given as 1 to 2 divided doses. • Children and adolescents below 14 year of age: no recommended • Geriatrics. Renal impairment and hepatic impairment : No adjustment of the starting dose is required

			hypertension or significant risk factors for cardiovascular disease should only be treated with Voltfast after careful consideration and, if administered for more than 4 weeks, only with doses of up to 100 mg per day (see «Warnings and precautions »).Patients with kidney disease • Voltfast is contraindicated in patients with renal insufficiency (GFR <15 ml / min / 1.73 m^2) No specific studies have been performed in patients with renal impairment, and therefore no specific recommendations for dose adjustment can be made. Caution should be exercised when administering Voltfast to patients with renal impairment • Patients with liver disease: Voltfast is contraindicated in patients with hepatic insufficiency No specific studies have been performed in patients with hepatic impairment and therefore no specific recommendations for dose adjustment can be made. Caution should be exercised when administering Voltfast to patients with mild to moderate hepatic impairment	
5.	Manufacturing control (if available)	The firm has controlled the particle size of mannitol & performed multiple mixing	Not found	The firm has not controlled the particle size of mannitol & did not performed multiple mixing
6.	Quality control (if available)	Dissolution testing conducted	Not found	Comparative dissolution with Voltfast Sachet submitted.

The firm has submitted clinical data and reviews of Cambia. Which depicts that they have used the same as innovator product. However, the applied formulation varies in terms of the following:

- The firm has not controlled the particle size of mannitol as specified for CAMBIA Sachet.
- The firm has not performed multiple mixing as specified for CAMBIA Sachet.
- The firm has not used glyceryle behenate as mentioned in the CAMBIA Sachet. Moreover, the firm has used aspartame, which is not present in the CAMBIA Sachet.
- The firm has claimed clinical indications and dosage thereof, other than specified for CAMBIA Sachet.
- However, the firm has performed comparative assay, LOD and pH studies in comparison with Voltfast to which firm is referring as reference product. This so-called reference product seemed approved by UAE

drug agency as it contains UAE: NDC 4924-6116-01-03 & NAFDAC Reg. No. 04-9014. Though it is mentioned on box that it is manufactured by M/s Mipharm S.p.A., Milan, Italy for M/s Novartis Pharma AG, Basle, Switzerland.

2. The firm submitted an undertaking that they have not referred "Cambia of Assertio" as our reference product for the development of K- Fast Sachet. Instead we have referred "Voltfast (approved from Swissmedic) and performed all studies according to it. However, the firm has manufactured the batch of the product in May to August, 2018 and have subsequently submitted the application in January, 2019, wherein all the documents of CAMBIA Sachet have been attached.

3. To the best my knowledge, more data is available regarding the manufacturing and quality attributes of the product and regulatory information for CAMBIA in USFDA than the other brands.

Decision: Registration Board decided to approve registration of K-Fast 50mg Sachet with Innovator's specifications(Voltfast Sachet of Novartis Pharma Swissmedic) by M/s. Vision Pharmaceuticals,. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

c. Exemption from onsite verification of stability data

i. cases

1073.	Name and address of manufacturer / Applicant	M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi
	Brand Name +Dosage Form + Strength	Fludip 5 mg
	Composition	Each film coated tablet contains: Dapagliflozin propanediol monohydrate eq. to Dapagliflozin……....5mg
	Diary No. Date of R& I & fee	Dy.No 218 dated 09-09-2014 Rs. 50,000/- 08-09-2014
	Pharmacological Group	Sodium Glucose Co-transporter 2 Inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	10's, 20's, & 30's:As per SRO
	Approval status of product in Reference Regulator Authorities	Farxiga 5mg tablet of USFDA approved
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator[IV]	

STABILITY STUDY DATA

Drug	Fludip 5 mg
Name of Manufacturer	M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi
Manufacturer of API	M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China
API Lot No.	DPG-201803001
Description of Pack (Container closure system)	Alu-Alu blister
Stability Storage Condition	Real time : 30°C ± 2° C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH
Time Period	Real time: 9 months Accelerated:6 months
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6, 9 (month)

Batch No.	19SB-201-01	19SB-202-02	19SB-203-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	21-01-2019	21-01-2019	21-01-2019
No. of Batches	03		
Date of Submission	16-01-2020 (30567)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# DPG-201803001) from M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Wymly 25mg Tablet in its 281st Meeting. • Date of Inspection: 09-04-2018 • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm have submitted letter from an indentor Neon chemicals and supplier is M/S Jiangsu Yongan pharmaceuticals Co., Ltd, China</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference
standards and impurity standards</td><td>The firm has submitted
COA of API: Batch No. DPG-201803001
COA of Reference Standard: Batch No. DPG-201804001</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients
used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of all the excipients used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for manufacturing & stabilities studies</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table><tr><td colspan="3">Fludip 5 mg</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>19SB-201-01</td><td>1500 tablets</td><td>01-2019</td></tr><tr><td>19SB-202-02</td><td>1500 tablets</td><td>01-2019</td></tr><tr><td>19SB-203-03</td><td>1500 tablets</td><td>01-2019</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches.
The detail is as under:
<table><tr><td>Batch No.</td><td>Stability samples</td><td>Qty used</td><td>Remaining Qty in Chamber</td></tr><tr><td>19SB-201-01</td><td>440</td><td>320</td><td>120</td></tr><tr><td>19SB-202-02</td><td>440</td><td>320</td><td>120</td></tr><tr><td>19SB-203-03</td><td>440</td><td>320</td><td>120</td></tr></table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature
and humidity monitoring of stability chambers
(real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for Accelerated stability chamber from 01-01-2019 to 31-10-2019 and for Real Time stability chamber starting from 01-01-2019 to 31-10-2019</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with
COA.</td><td>The firm has submitted photocopy of method used for analysis of APIs along with COA. Analysis date:11-05-2018</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete
record of testing of stability batches (i.e.</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data</td></tr>
</table>

	chromatograms, lab reports, raw data sheets etc.)	sheets etc.) are submitted with 06 & 09 months stability data Accelerated & Real Time respectively.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) & **long term, 06 Months** (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.
16.	Analysis reports for excipients used.	The firm has submitted copy of COAs for the excipients used in the applied formulation.
17.	Drug-excipients compatibility studies.	The firm has stated that we manufactured lab scale batches of our applied products "Flucid 5mg" by using same formulation (excipients) of Innovator's Product.
18.	Record of comparative dissolution data.	Firm has submitted Comparative dissolution study of their product (Flucid Tablets) with Innovator's Brand "Forxiga Tablets" The details are as follows: Feature / Reference. Product / Product Genix Brand Name / Forxiga 5mg Tablet / Flucid 5mg Batch No. / NJ535 / 19SB-201-01 Mfg. Date / 03/2017 / 01-2019 Exp. Date / 02/2020 / 01-2021 Comparative dissolution studies have been performed in following mediums: 1. Ph 1.2 HCl buffer 2. Ph 4.5 Acetate buffer 3. Ph 6.8 Phosphate buffer Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches

Remarks of Evaluator:

S.No	Shortcoming communicated	Reply of Firm
1.	The firm has claimed that they manufactured lab scale batches of their applied product "Flucid 5mg" by using same formulation (excipients) of Innovator's Product however yellow colour added in core. Clarify.	Firm reply that they are adding colour in very minute quantity in core formulation for segregation of product to avoid mixing as they have different products on same tooling in order to comply GMP.
2.	Innovator used dry granulation method while applied product is manufactured by direct compression . Justify.	Direct compression and dry granulation methods are almost same processes except unit operation that is compaction involve in dry granulation, while in both processes, formulation developed without using any solvent or liquid solution
3.	Submit Real time Stability of API according to zone IV -A	Stability studies of 3batches according to Zone IV-A submitted.
4.	Chromatograms for Content uniformity and dissolution testing at initial testing for Batch No: 19SB-201-01and chromatograms at initial dissolution testing Batch no: 19SB-201-03 not submitted	Submitted.
5.	Evidence of procurement of reference product	submitted
6.	Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements for Q at 15 minutes	• Firm reply that they are following FDA dissolution method. Dissolution time is 30 minutes mentioned. • On the basis of CDP data, the results were

		found above the 85% in 15 minutes • The dissolution test were conducted again at 15 minutes. The results were found above 80%(Q) = 85% • The dissolution results of all 3 batches are attached for the reference. • The specifications are revised for 15 minutes of dissolution testing.

Decision: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications as per that of the innovator product at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

1074.	Name and address of manufacturer / Applicant	M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi
	Brand Name +Dosage Form + Strength	Fludip 10 mg
	Composition	Each film coated tablet contains: Dapagliflozin propanediol monohydrate eq. Dapagliflozin……....10mg
	Diary No. Date of R& I & fee	Dy.No 219 dated 09-09-2014 Rs. 50,000/- 08-09-2014
	Pharmacological Group	Sodium Glucose Co-transporter 2 Inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	10's, 20's, & 30's:As per SRO
	Approval status of product in Reference Regulator Authorities	Farxiga 10mg tablet of USFDA approved
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator[IV]	

STABILITY STUDY DATA

Drug	Fludip 10 mg		
Name of Manufacturer	M/s. Genix Pharma Private Limited 44, 45-B, Korangi Creek road, Karachi		
Manufacturer of API	M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China		
API Lot No.	DPG-201803001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2° C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6, 9 (month)		
Batch No.	19SB-204-01	19SB-205-02	19SB-206-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	24-01-2019	24-01-2019	24-01-2019
No. of Batches	03		

Date of Submission	16-01-2020 (30567)

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# DPG-201803001) from M/S Jiangsu Yogan Pharmaceutical Co., Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Wymly 25mg Tablet in its 281st Meeting. • Date of Inspection: 09-04-2018 • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice No ZY18031601G/W Dated: 16-03-2018 from Suzhou ZhiYu Biotechnology Co., Ltd is submitted & attested by ADC (Karachi) dated ;09-04-2018.
3.	Documents for the procurement of reference standard and impurity standards.	Firm have submitted letter from an indentor Neon chemicals and supplier is M/S Jiangsu Yongan pharmaceuticals Co., Ltd, China
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate No. JS20160548 issued to M/s Jiangsu Yongan pharmaceuticals Co., Ltd, China, Address: No.18, 237 Provincial highway, Jiangsu HUai an economic Development Zone Issued by China Food and drug administration. Valid up to 03-03-2021.

<table>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference
standards and impurity standards</td><td>The firm has submitted
COA of API: Batch No. DPG-201803001
COA of Reference Standard: Batch No. DPG-201804001</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients
used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of all the excipients used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for manufacturing & stabilities studies</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Fludip 5 mg</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>19SB-204-01</td><td>1500 tablets</td><td>01-2019</td></tr>
<tr><td>19SB-205-02</td><td>1500 tablets</td><td>01-2019</td></tr>
<tr><td>19SB-206-03</td><td>1500 tablets</td><td>01-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches.
The detail is as under:
<table>
<tr><td>Batch No.</td><td>Stability samples</td><td>Qty used</td><td>Remaining Qty in Chamber</td></tr>
<tr><td>19SB-204-01</td><td>440</td><td>320</td><td>120</td></tr>
<tr><td>19SB-205-02</td><td>440</td><td>320</td><td>120</td></tr>
<tr><td>19SB-206-03</td><td>440</td><td>320</td><td>120</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for Accelerated stability chamber from 01-01-2019 to 31-10-2019 and for Real Time stability chamber starting from 01-01-2019 to 31-10-2019</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of method used for analysis of APIs along with COA. Analysis date:11-05-2018</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 & 09 months stability data Accelerated & Real Time respectively.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has stated that we manufactured lab scale batches of our applied products “Flucid 5mg” by using same formulation (excipients) of Innovator’s Product.</td></tr>
</table>

<table>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product (Flucid Tablets) with Innovator's Brand "Forxiga Tablets" The details are as follows:
<table>
<tr><th>Feature</th><th>Reference. Product</th><th>Product Genix</th></tr>
<tr><td>Brand Name</td><td>Forxiga 10mg Tablet</td><td>Flucid 10mg</td></tr>
<tr><td>Batch No.</td><td>AAP0252</td><td>19SB-204-01</td></tr>
<tr><td>Mfg. Date</td><td>10/2016</td><td>01-2019</td></tr>
<tr><td>Exp. Date</td><td>09/2019</td><td>01-2021</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
1. Ph 1.2 HCl buffer
2. Ph 4.5 Acetate buffer
3. Ph 6.8 Phosphate buffer
Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for complete stability studies analysis of three batches</td></tr>
</table>

Remarks of Evaluator:

S.No	Shortcoming communicated	Reply of firm
1.	The firm has claimed that they manufactured lab scale batches of their applied product "Flucid 10mg" by using same formulation (excipients) of Innovator's Product however yellow color added in core. Clarify.	Firm reply that they are adding color in very minute quantity in core formulation for segregation of product to avoid mixing as they have different products on same tooling in order to comply GMP.
2.	Innovator used dry granulation method while applied product is manufactured by direct compression . Justify.	Direct compression and dry granulation methods are almost same processes except unit operation that is compaction involve in dry granulation, while in both processes, formulation developed without using any solvent or liquid solution
3.	Submit Real time Stability of API according to zone IV -A	Stability studies of 3batches according to Zone IV-A submitted.
4.	Evidence of procurement of reference product	submitted
5.	Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements for Q at 15 minutes.	• Firm reply that they are following FDA dissolution method. Dissolution time is 30 minutes mentioned. • On the basis of CDP data, the results were found above the 85% in 15 minutes • The dissolution test were conducted again at 15 minutes. The results were found above 80%(Q) = 85% • The dissolution results of all 3 batches are attached for the reference. • The specifications are revised for 15 minutes of dissolution testing.

Decision: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications as per that of the innovator product at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

ii. Deferred case

1075.	Name and address of manufacturer / Applicant	M/s. High-Q Pharmaceuticals, Plot 224/23 Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Agranil 60 mg
	Composition	Each film coated tablet contains: Ticagrelor… 60 mg
	Diary No. Date of R& I & fee	Dy.No 8185 dated 12-06-2098 Rs. 50,000/- Duplicate Dossier
	Pharmacological Group	Anti-coagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	BRILINTA of Astrazenica USFDA Approved.
	GMP status	Last inspection was conducted on 12-09-2018 for renewal/ grant of GMP Certificate and the report concludes Good compliance of GMP.
	Remarks of the Evaluator[IV]	

STABILITY STUDY DATA

Drug	Agranil 60 mg tablet		
Name of Manufacturer	M/s. High-Q Pharmaceuticals, Plot 224/23 Korangi Industrial Area, Karachi		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Ro ad, Yangkou chemical industrial park, Rudong coastal economic developme nt zone, Nantong Jiangsu province 226407, PR china		
API Lot No.	RD-TG-201712111/RD-TG-201806261		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30°C ± 2° C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6,9 (month)		
Batch No.	PD01/18	PD02/18	PD03/18
Batch Size	2252 Tablets	2252 Tablets	2252 Tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	16-05-2018	16-05-2018	16-05-2018
No. of Batches	03		
Date of Submission	01-04-2019 (2311)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# RD-TG-201712111) from M/S Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued to M/s Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china. Issued by Nantong Food and drug administration. Valid up to 7-9-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice (invoice No. CY118070, dated: 08-03-2018) has been submitted, manufacturer is Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province china attested by ADC DRAP Karachi dated 20-03-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Basovir 400mg tablet and Vesoft 400/100mg Tablets in its 279 & 284 Meeting. • Date of Inspection: 16-02-2018 & 12-07-2018. • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 20-03-2018, Copy of commercial invoice (invoice No. CY118070, dated: 08-03-2018) has been submitted, manufacturer is Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province china attested by ADC DRAP Karachi dated 20-03-2018.
3.	Documents for the procurement of reference standard and impurity standards.	Firm have certificate of analysis of API, working standard, and Impurities, all provided by Nantong Chanyoo, China. The firm has clarified that the reference standard and impurity standards are provided free of cost along with the APIs' consignment and not separately by Nantong Chanyoo.

<table>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The firm has submitted GMP of M/s Nantong Chanyoo Pharmatech Co, Ltd China issued by Nantong food and Drug Adminstration. This certificate is valid until 07- 09, 2020.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has submitted
COA of API: Batch No. RD-TG-201712111
COA of Reference Standard: Batch No. WTG01-1409901
COA of Impurities:
TGE: Batch No. WTG02-140901
TGD1: Batch No. WTG03-140901
TGD2: Batch No. WTG04-140901
TG-16: Batch No. WTG05-140901
De-ethoxyl of TG: Batch No. WTG06-1409901
Acetyl TG: Batch No. WTG07-1409901</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for manufacturing</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Agranil 60 mg Tablet</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>PD01/18</td><td>2252 tablets</td><td>05-2018</td></tr>
<tr><td>PD02/18</td><td>2252 tablets</td><td>05-2018</td></tr>
<tr><td>PD03/18</td><td>2252 tablets</td><td>05-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches. The detail is as under:
<table>
<tr><td>Batch No.</td><td>Batch yeild</td><td>Stability samples</td><td>Qty used</td><td>Remaining Qty in Chamber</td><td>Retain sample</td></tr>
<tr><td>PD01/18</td><td>2100 Tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>1400</td></tr>
<tr><td>PD02/18</td><td>2150 Tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>1450</td></tr>
<tr><td>PD03/18</td><td>2000 tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>1300</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for Accelerated stability chamber from 16-05-2018 to 16-11-2018 and for Real Time stability chamber starting from 16-05-2018 to 16-05-2018</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of method used for analysis of APIs along with COA.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete</td><td>The firm has submitted photocopy of Finished Product</td></tr>
</table>

<table>
<tr><td></td><td>record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 & 09 months stability data Accelerated & Real Time respectively.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Ticagrelor: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 60±5%RH) stability study reports of 03 batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Drug-excipients compatibility studies.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “ Brilinta”.
The details are as follows:
<table><tr><th>Feature</th><th>Reference product</th><th>Product of High-Q</th></tr><tr><td>Brand name</td><td>Brilinta 60mg tablet</td><td>Agranil 60mg tablet</td></tr><tr><td>Batch No.</td><td>PS06489</td><td>PD01/18</td></tr></table>Comparative dissolution studies have been performed in following mediums:
1. Ph 1.2 HCl buffer
2. Ph 4.5 Acetate buffer
3. Ph 6.8 Phosphate buffer</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted Audi trail could not be verified.</td></tr>
<tr><td colspan="3">Remarks of Evaluator:</td></tr>
<tr><td colspan="3"><table>
<tr><th>S. no</th><th>Deficiencies/Shortcomings</th><th>Reply by Firm</th></tr>
<tr><td>1.</td><td>Which polymorphic form of ticagrelor is used in stability batches.</td><td>The product manufactured by us according to the synthetic route presented in the dossier is characterized as crystalline form II</td></tr>
<tr><td>2.</td><td>Submitt Commercial invoices for excipients</td><td>Submitted</td></tr>
<tr><td>3.</td><td>Authorized Protocols/SOP for the product development</td><td>Submitted</td></tr>
<tr><td>4.</td><td>As per documents product developed from API batch no: RD-TG-201712111 having quanity of 1kg as per commercial invoice. However batch no: RD-TG-2018062 of API tested having quantity of 3 kg as per commercial invoice . Furthermore API testing have been performed after production of stability batches. Clarification is needed</td><td>COA of API by High Q batch no: RD-TG-201712111 submitted with testing date 18-04-2018.</td></tr>
<tr><td>5.</td><td>Stability studies of API according to Zone –IV-A is required</td><td>6 month real time stability data submitted
As per Stability studies of API according to Zone –IV-A submitted, initial testing done at july, 2018 while 3rd month testing done at Feb, 2019
Stament from Nantong Chanyoo Pharmatec co., Ltd
“ Since the stability study requires 3 batches of API ,</td></tr>
</table></td></tr>
</table>

		we did not arrange the stability study immediately after completion of the initial analysis of each batch. After 3 batches of API are collected and the stability study plan has been confirmed, the substances have been I into the stability study box. Before that, all the batches were stored in the warehouse in accordance with the storage conditions."
6.	Evidence of procurement of reference product Briliant	Submitted
7.	Submit complete auditrail for Assay, dissolution, comparative dissolution & method validation as submitted auditrail could not be verified	Submitted Audi trail could not be verified.
8.	Value of Q in dissolution at 75 minute is NLT 70% . Please justify	Stability report mentioning correct specifications for dissolution as "NLT 80% (Q) in 75 minutes"

Previous Decision: (M-292)

Registration Board deferred for clarification of following points:

- Audit trail reports of the analysis performed on HPLC during stability studies.
- Valid GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority.
- Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements of USP for Q at 45 minutes and at 60 minutes

S.no	**Deficiencies**	**Reply by Firm**
1	Audit trail reports of the analysis performed on HPLC during stability studies.	Still not verifiable. Time is not evident from provided auditrail.
2	Valid GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority	GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China by Jiangsu Food and Drug administration Jiangsu food and drug administration submitted. Nantong food and drug administration submitted. Certificate of GMP compliance by agency for medicinal products and medical devices of Republic of Solvenia on the basis of inspection conducted on 06-12-2014.
3	Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements of USP for Q at 45 minutes and at 60 minutes	Regarding applied dissolution limits, We would like to apprise you that the applied dissolution limit is taken from FDA approved dissolution method wherein the sampling time mentioned is 10, 20, 30, 45, 60 & 75 minutes. Generally, for an established dissolution method for film coated tablets the maximum sampling time is considered and used to define the limit.

Previous Decision: (M-293)

Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications as per that of the innovator product at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

Firm submitted Dissolution testing data with specification as per that of Innovator product i.e Q at 45 minutes at initial and 1st month time points at both Accelerated and real time stability for 2 batches

I. Batch# PD04/19
   Manufacturing date: March- 2020
   Date of commencement: 17-03-2020
II. Batch# PD05/19
   Manufacturing date: March- 2020
   Date of commencement: 17-03-2020

And results are satisfactory and with in limits **Decision:Registration Board decided to approve registration of Agranil 60mg Tablet (Ticagrelor…60 mg)with Innovator's specifications by M/s High-Q Pharmaceuticals**. **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**		
1076.	Name and address of manufacturer / Applicant	M/s. High-Q Pharmaceuticals, Plot 224/23 Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Agranil 90 mg
	Composition	Each film coated tablet contains: Ticagrelor… 90 mg
	Diary No. Date of R& I & fee	Dy.No 8184 dated 12-06-2098 Rs. 50,000/- Duplicate Dossier
	Pharmacological Group	Anti-coagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	BRILINTA of Astrazenica USFDA Approved.
	GMP status	Last inspection was conducted on 12-09-2018 for renewal / grant of GMP Certificate and the report concludes Good compliance of GMP.
	Remarks of the Evaluator[IV]	

STABILITY STUDY DATA

Drug	Agranil 90 mg tablet		
Name of Manufacturer	M/s. High-Q Pharmaceuticals, Plot 224/23 Korangi Industrial Area, Karachi		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Ro ad, Yangkou chemical industrial park, Rudong coastal economic developme nt zone, Nantong Jiangsu province 226407, PR china		
API Lot No.	RD-TG-201712111		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30°C ± 2° C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6,9 (month)		
Batch No.	PD01/18	PD02/18	PD03/18
Batch Size	1408 Tablets	1408 Tablets	1408 Tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	23-05-2018	23-05-2018	23-05-2018
No. of Batches	03		
Date of Submission	01-04-2019 (2312)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# RD-TG-201712111) from M/S Nantong Chanyoo Pharmatech Co., Ltd,

		China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued to M/s Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china. Issued by Nantong Food and drug administration. Valid up to 7-9-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice (invoice No. CY118070, dated: 08-03-2018) has been submitted, manufacturer is Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province china attested by ADC DRAP Karachi dated 20-03-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Basovir 400 mg tablet and Vesoft 400/100mg Tablets in its 279 & 284 Meeting. • Date of Inspection: 16-02-2018 & 12-07-2018. • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 20-03-2018, Copy of commercial invoice (invoice No. CY118070, dated: 08-03-2018) has been submitted, manufacturer is Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province china attested by ADC DRAP Karachi dated 20-03-2018.
3.	Documents for the procurement of reference standard and impurity standards.	Firm have certificate of analysis of API, working standard, and Impurities, all provided by Nantong Chanyoo, China.

<table>
<tr><td></td><td></td><td>The firm has clarified that the reference standard and impurity standards are provided free of cost along with the APIs' consignment and not separately by Nantong Chanyoo.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The firm has submitted GMP of M/s Nantong Chanyoo Pharmatech Co, Ltd China issued by Nantong food and Drug Adminstration. This certificate is valid until 07- 09, 2020.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has submitted
COA of API: Batch No. RD-TG-201712111
COA of Reference Standard: Batch No. WTG01-1409901
COA of Impurities:
TGE: Batch No. WTG02-140901
TGD1: Batch No. WTG03-140901
TGD2: Batch No. WTG04-140901
TG-16: Batch No. WTG05-140901
De-ethoxyl of TG: Batch No. WTG06-1409901
Acetyl TG: Batch No. WTG07-1409901</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for manufacturing`</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Agranil 60 mg Tablet</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>PD01/18</td><td>1408 tablets</td><td>05-2018</td></tr>
<tr><td>PD02/18</td><td>1408 tablets</td><td>05-2018</td></tr>
<tr><td>PD03/18</td><td>1408 tablets</td><td>05-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches.
The detail is as under:
<table>
<tr><td>Batch No.</td><td>Batch yeild</td><td>Stability samples</td><td>Qty used</td><td>Remaining Qty in Chamber</td><td>Retain sample</td></tr>
<tr><td>PD01/18</td><td>1295 Tablets</td><td>40×14's (560)</td><td>290</td><td>29×14's (406)</td><td>595</td></tr>
<tr><td>PD02/18</td><td>1267 Tablets</td><td>40×14's (560)</td><td>290</td><td>29×14's (406)</td><td>567</td></tr>
<tr><td>PD03/18</td><td>1338 tablets</td><td>40×14's (560)</td><td>290</td><td>29×14's (406)</td><td>638</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for Accelerated stability chamber from 16-05-2018 to 16-11-2018 and for Real Time</td></tr>
</table>

		stability chamber starting from 16-05-2018 to 16-05-2018
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of method used for analysis of APIs along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 & 09 months stability data Accelerated & Real Time respectively.
15.	Reports of stability studies of API from manufacturer.	**Ticagrelor:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) & **long term, 06 Months** (30°C ± 2°C & 60±5%RH) stability study reports of 03 batches.
16.	Analysis reports for excipients used.	The firm has submitted copy of COAs for the excipients used in the applied formulation.
17.	Drug-excipients compatibility studies.	The firm has submitted Drug-excipients compatibility studies.
18.	Record of comparative dissolution data.	Firm has submitted Comparative dissolution study of their product with Innovator's Brand " Brilinta". The details are as follows: **Feature** / **Reference product** / **Product of High-Q** Brand name / Brilinta 90mg tablet / Agranil 60mg tablet Batch No. / PS01092 / PD01/18 Comparative dissolution studies have been performed in following mediums: 1. Ph 1.2 HCl buffer 2. Ph 4.5 Acetate buffer 3. Ph 6.8 Phosphate buffer
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted Audi trail could not be verified.

Remarks of Evaluator:

S.no	Deficiencies/Shortcomings	Reply by Firm
1.	Which polymorphic form of ticagrelor is used in stability batches.	The product manufactured by us according to the synthetic route presented in the dossier is characterized as crystalline form II
2.	Submitt Commercial invoices for excipients	Submitted
3.	Authorized Protocols/SOP for the product development	Submitted.
4.	As per documents product developed from API batch no: RD-TG-201712111 having quanity of 1kg as per commercial invoice. However batch no: RD-TG-2018062 of API tested having quantity of 3 kg as per commercial invoice . Furthermore API testing have been performed after production of stability batches. Clarification is needed	COA of API by High Q batch no: RD-TG-201712111 submitted with testing date 18-04-2018.
5.	Stability studies of API according to Zone –IV-A is required	6 month real time stability data submitted As per Stability studies of API according to Zone – IV-A submitted, initial testing done at july, 2018 while 3rd month testing done at Feb, 2019 **Stament from Nantong Chanyoo Pharmatec co.,**

		Ltd **“** Since the stability study requires 3 batches of API , we did not arrange the stability study immediately after completion of the initial analysis of each batch. After 3 batches of API are collected and the stability study plan has been confirmed, the substances have been I into the stability study box. Before that, all the batches were stored in the warehouse in accordance with the storage conditions.”
6.	Evidence of procurement of reference product Briliant	Submitted
7.	Submit complete auditrail for Assay, dissolution, comparative dissolution & method validation as submitted auditrail could not be verified	Submitted auditrail could not be verified.
8.	Value of Q in dissolution at 75 minute is NLT 70% . Please justify	Stability report mentioning correct specifications for dissolution as “NLT 80% (Q) in 75 minutes”

Previous Decision: (M-292)

Registration Board deferred for clarification of following points:

- Audit trail reports of the analysis performed on HPLC during stability studies.
- Valid GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority.
- Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as “Shall comply with requirements of USP for Q at 45 minutes and at 60 minutes.

S.no	**Deficiencies**	**Reply by Firm**
1	Audit trail reports of the analysis performed on HPLC during stability studies.	Still not verifiable. Time is not evident from provided auditrail.
2	Valid GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority	GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China by Jiangsu Food and Drug administration Jiangsu food and drug administration submitted. Nantong food and drug administration submitted. Certificate of GMP compliance by agency for medicinal products and medical devices of Republic of Solvenia on the basis of inspection conducted on 06-12-2014.
3	Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as “Shall comply with requirements of USP for Q at 45 minutes and at 60 minutes	Regarding applied dissolution limits, We would like to apprise you that the applied dissolution limit is taken from FDA approved dissolution method wherein the sampling time mentioned is 10, 20, 30, 45, 60 & 75 minutes. Generally, for an established dissolution method for film coated tablets the maximum sampling time is considered and used to define the limit.

Previous Decision: (M-293)

Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications as per that of the innovator product at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

Firm submitted Dissolution testing data with specification as per that of Innovator product i.e Q at 45 minutes at initial and 1st month time points at both Accelerated and real time stability for 2 batches

I. Batch# PD04/19
   Manufacturing date: March- 2020
   Date of commencement: 17-03-2020
II. Batch# PD05/19

Manufacturing date: March- 2020
Date of commencement: 17-03-2020
And results are satisfactory and with in limits
Decision: Registration Board decided to approve registration of Agranil 90mg Tablet (Ticagrelor…90 mg)with Innovator's specifications by M/s High-Q Pharmaceuticals. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case no. 08 Miscellaneous cases

1077.	Name and address of manufacturer / Applicant	M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Neocin 60mg Powder
	Composition	Each 100g Powder contains: Neomycin Sulphate…60mg
	Diary No. Date of R& I & fee	Dy.No. 23245 dated 05-07-2018 Rs.20,000/- Dated 04-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Neocin-S Water Soluble Powder Of M/S Alina Combine
	GMP status	Last GMP inspection conducted on 12-12-2017 and report concludes that " No production activity have been observed during inspection. The mangment has informed they have not produced any batch since the grant of license I.e. Nov, 2016 and registeration i.e. Aug, 2017 Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the management agreed to rectify the shortcomings pointed during inspection and will submit compliance report"
	Previous Remarks of the Evaluator[IV]	
	Previous decision(s)	Deferred for following reasons: Registration Board referred the case to QA & LT Division for updated GMP status of the firm. (M-291)
	Evaluation by PEC	Last GMP inspection is conducted on 31-10-2019 and The report concludes that firm was considered to be operating at a reasonable level of GMP compliance.
	Previous Decision: Approved with innovator's specification.(**M-293)**	
	Due to typographical mistake incorrect strength mentioned Correct formulation Neocin 60gms Powder Each 100g Powder contains: Neomycin Sulphate…60gms	
	Decision: Approved with innovator's specification with following formulation **Neocin 60gms Powder** **Each 100g Powder contains:** **Neomycin Sulphate…60gms**	

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

a. New cases

1078.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Alitra 150mg/3ml Injection
	Composition	Each ml contains: Aceclofenac…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3913 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019 (#0561806)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	NA
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	Evidence of approval of applied formulation in RRA needed on communication of short comings firm provide reference of India.
	Decision: Deferred for following: **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
1079.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Onsetron 8mg Tablet
	Composition	Each Film coated tablet contains: Ondansetron Hcl Dihydrate eq to Ondansetron…8mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3914 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019 (#0561807)
	Pharmacological Group	Antiemetic and anti- nausea
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10's, 1x12's/ As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 8mg film coated tablet (MHRA approved)
	Me-too status	Zofran 8mg tablet of M/s GSK (Reg.#048026)
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1080.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Onsetron 8mg/4ml Injection
	Composition	Each 4ml contains: Ondansetron Hcl Dihydrate eq to Ondanserton…8mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3915 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019 (#0561808)

	Pharmacological Group	Antiemetic and anti- nausea
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	4 ml ampoule 1x5's, 1x1 As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 2 mg/ml Solution for Injection of Generics,in 4 ml glass ampoule (MHRA)
	Me-too status	Zofran Injection 8mg/4ml of Glaxo Wellcome, Karachi (Reg #066121)
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1081.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Graniset 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Granisetron as HCL…1mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2691 dated 21-01-2019 Rs.20,000/- Dated 21-01-2019 (#0004732)
	Pharmacological Group	Cytostatic
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved
	Me-too status	Graniset Tablets of M/s CCL Pharmaceuticals (Reg.#048026)
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	In RRA it is approved as granisetron as HCL but firm applied as granisetron HCL on communication they correct there master formulation.
	Decision: Approved with innovator's specification	
1082.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Graniset 3mg/3ml Injection
	Composition	Each 3ml ampoule contains: Granisetron as HCL…3mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3921 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019 (#0004733)
	Pharmacological Group	Cytostatic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x 3ml ampoule 5x3 ml ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	Granisetron 1mg/ml concentrate for solution for injection or infusion (MHRA approved)
	Me-too status	Granisetron 3mg/3ml injection of M/s Zejhang (R.#052271)

	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	In RRA it is approved as granisetron as HCL but firm applied as granisetron HCL on communication they correct there master formulation.
	Decision: Approved.	
1083.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Colysafe Injection 1MIU/Vial
	Composition	Each vial of dry "powder for injection"contains: Colistimethate sodium …1MIU
	Diary No. Date of R& I & fee	Form-5 Dy.No 3916 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019 (#0561809)
	Pharmacological Group	Polymixin
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Glass vial As per SRO
	Approval status of product in Reference Regulatory Authorities	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection (lyophilized powder in glass vial). Approved by MHRA
	Me-too status	Colistat powder for Injection. Reg. No. 76160
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1084.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Colysafe Injection 2MIU/Vial
	Composition	Each vial of dry "powder for injection"contains: Colistimethate …2MIU
	Diary No. Date of R& I & fee	Form-5 Dy.No 3916 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019 (#0561810)
	Pharmacological Group	Polymixin
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Glass vial As per SRO
	Approval status of product in Reference Regulatory Authorities	COLOMYCIN 2 million International Units (IU) (UK)
	Me-too status	Colistimethate Sodium powder for solution for IV injection/ infusion of M/s Mukhtar Enterprises Lahore
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	
	Decision: Deferred for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
1085.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Clarinac 500mg/Vial Injection
	Composition	Each vial of dry substance contains: Clarithromycin…500mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 3918 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019 (#0004730)
	Pharmacological Group	Antibiotic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	Glass vial As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 500 mg powder for concentrate for solution for infusion (Lyophilized) Approved by MHRA of UK
	Me-too status	Maclacin 500mg Injection by M/s Bosch, Karachi (Reg#061080)
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	In RRA each vial contains 739.5 mg clarithromycin lactobionate, corresponding to 500 mg in lyophilized form clarithromycin but firm applied as clarithromycin 500 mg on communication firm just revised there master formulation without fee
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.	
1086.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Planax 200mg Capsule
	Composition	Each Capsule Contains: Cefixime as trihydrate…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3922 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019 (#0004734)
	Pharmacological Group	Cephalosporin
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	1x5's As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefixima 200 mg capsulas by M/s Laboratorios Normon, S.A., Spain approved
	Me-too status	Secure 200mg Capsules by M/s Wilshire (Reg#034883)
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1087.	Name and address of manufacturer / Applicant	M/s Goodman Labortaries, Plot No 5, St No S-5, National Industrial Zone, Rawat, Islamabad BY M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Gerolac 30mg/ml Injection
	Composition	Each 1ml ampoule contains: Ketorolac Tromethamine……30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2700 dated 21-01-2019 Rs.50,000/- Dated 21-01-2019 (#0818613)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1ml in glass ampoule 5's/ As per SRO

	Approval status of product in Reference Regulatory Authorities	Toradol of M/S Atnahs Pharma (TGA; Australia Approved) for IM only
	Me-too status	Ketomal Injection of M/s Trigon Pharma (Reg. # 074193)
	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1088.	Name and address of manufacturer / Applicant	M/s Goodman Labortaries, Plot No 5, St No S-5, National Industrial Zone, Rawat, Islamabad BY M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Citiline Injection 1g/4ml
	Composition	Each 4ml ampoule contains: Citicoline as Citicoline Sodium……..1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2701 dated 22-01-2019 Rs.50,000/- Dated 21-01-2019 (#0818620)
	Pharmacological Group	Other psychostimulants and nootropics
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	4ml in glass ampoule 5's As per SRO
	Approval status of product in Reference Regulatory Authorities	Normon Citicoline 1000 mg, solution for injection EFG (Approved in Spain)
	Me-too status	Citolin 4ml Injection of M/s Global Pharma (Reg. # 030541)
	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1089.	Name and address of manufacturer / Applicant	M/s Goodman Labortaries, Plot No 5, St No S-5, National Industrial Zone, Rawat, Islamabad BY M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Genofer Injection 100mg/5ml
	Composition	Each ampoule 5ml contains: Iron sucrose complex eq to elemental iron…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2702 dated 21-01-2019 Rs.50,000/- Dated 21-01-2019 (#0818619)
	Pharmacological Group	Replenishes Hgb and depleted iron stores
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5ml glass vial As per SRO
	Approval status of product in Reference Regulatory Authorities	Venofer of Luitpold (USFDA) in 5 ml vial
	Me-too status	Axifer of Nova Med (Reg. # 076969)

	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	In form 5 the container is mentioned as glass vial as per RRA but in master formulation and manufacturing process ampoule is mentioned. On communiucation firm claimed that this is termanaly sterilized product for which amoule is better and innovator brand is also using ampoule in Europe and vial in America".
	Decision: Approved.	
1090.	Name and address of manufacturer / Applicant	M/s Goodman Labortaries, Plot No 5, St No S-5, National Industrial Zone, Rawat, Islamabad BY M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Oxidin 500mg Injection IM
	Composition	Each Vial Contains: Ceftriaxone sodium eq to Ceftriaxone…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2699 dated 21-01-2019 Rs.50,000/- Dated 21-01-2019 (#0818621)
	Pharmacological Group	Third generation cephalosporin
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's Glass vial As per SRO (IM)
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 500mg (IV). USFDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IV. Reg. No. 78097
	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1091.	Name and address of manufacturer / Applicant	M/s Goodman Labortaries, Plot No 5, St No S-5, National Industrial Zone, Rawat, Islamabad BY M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Meronem IV Injection 500mg
	Composition	Each Vial Contains: Meropenem…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3477 dated 21-01-2019 Rs.50,000/- Dated 21-01-2019 (#0818614)
	Pharmacological Group	Antibiotics
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's Glass vial As per SRO (IM)
	Approval status of product in Reference Regulatory Authorities	Meropenem 500 mg powder for solution for injection or infusion of (UK)
	Me-too status	Mopen 500mg Injection of M/s Hilton Pharma

	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	The composition in RRA is as meropenem trihydrate equivalent to meropenem (with sodium carbonate)….500mg but firm applied as meropanan 500 mg on communication firm claims that as meropaneum only comes in trihydrate so it's not necessary to mention trihydrate as it is understood. "Firm provides revised formulation and fee of Rs. 5000/- (# 2031636) dated 08-06-2020.
	Decision: Approved with following label claim: **Meropenem trihydrate equivalent to meropenem (with sodium carbonate)….500mg**	
1092.	Name and address of manufacturer / Applicant	M/s Goodman Labortaries, Plot No 5, St No S-5, National Industrial Zone, Rawat, Islamabad By M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Meronem IV Injection 1 g
	Composition	Each Vial Contains: Meropenem…1000 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2704 dated 21-01-2019 Rs.20,000/- Dated 21-01-2019 (#0818615)
	Pharmacological Group	Antibiotics
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's Glass vial As per SRO (IM)
	Approval status of product in Reference Regulatory Authorities	Meropenem 1 g powder for solution for injection or infusion (MHRA)
	Me-too status	Merem Injection 1 g Global
	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	The composition in RRA is as meropenem trihydrate equivalent to meropenem (with sodium carbonate) but firm applied as meropanan communication firm claims that as meropaneum only comes in trihydrate so it's not necessary to mention trihydrate as it is understood. "Firm provides revised formulation and fee of 500 (# 2031637) dated 08-06-2020.
	Decision: **Approved with following label claim: Meropenem trihydrate equivalent to meropenem (with sodium carbonate)….1000 mg**	
1093.	Name and address of manufacturer / Applicant	M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Oxitine CR 12.5mg Table
	Composition	Each controlled release tablet contains: Paroxetine as HCL…12.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8246 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 (#0808042)
	Pharmacological Group	SSRIs/ Anti- depressant

	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 20, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Paxil CR Tablet of M/s Apotex Technologies (USFDA Approved)
	Me-too status	Panox CR Tablet 12.5mg of M/s Regal Pharma (R.#081953)
	GMP status	M/s: Winilton The firm provides cGMP certificate dated 7-3-2019 showing compliance
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1094.	Name and address of manufacturer / Applicant	M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Oxitine 20 mg Table
	Composition	Each film coated release tablet contains: Paroxetine as paroxetine hcl anhydrous22.5mg equvelent to…..20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8245 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 (#0808040)
	Pharmacological Group	SSRIs/ Anti- depressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 20, 30's /As per SRO
	Approval status of product in Reference Regulatory Authorities	Paxil Tablet of M/s Apotex Technologies (USFDA Approved)
	Me-too status	Neoxetine Tablets 20mg of M/s Neomedix (Reg. # 081407)
	GMP status	M/s: Winilton The firm provides cGMP certificate dated 7-3-2019 showing compliance
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1095.	Name and address of manufacturer / Applicant	M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lusim 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8243 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 (#0808044)
	Pharmacological Group	Benzamides
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10, 30's /As per SRO
	Approval status of product in Reference Regulatory Authorities	SOLIAN 50 amisulpride 50 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 50mg Tablet (Reg# 76060)
	GMP status	M/s: Winilton The firm provides cGMP certificate dated 7-3-2019 showing compliance
	Remarks of Evaluator [VII]	
	Decision: Approved.	

1096.	Name and address of manufacturer / Applicant	M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lusim 100mg Tablet
	Composition	Each Tablet Contains: Amisulpride…100 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8244 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 (#0808045)
	Pharmacological Group	Benzamides
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10, 20, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	SOLIAN 100 amisulpride 100 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 100mg Tablet (Reg# 76061)
	GMP status	M/s: Winilton The firm provides cGMP certificate dated 7-3-2019 showing compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1097.	Name and address of manufacturer / Applicant	M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Winpick 25mg Tablet
	Composition	Each film coated release tablet contains: Topiramate…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8241 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 (#0808038)
	Pharmacological Group	Anti-epileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 20, 30, 60's As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax 25 mg by Janssen Approved by MHRA of UK
	Me-too status	Topamid 25mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 062310)
	GMP status	M/s: Winilton The firm provides cGMP certificate dated 7-3-2019 showing compliance
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1098.	Name and address of manufacturer / Applicant	M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Winpick 50mg Tablet
	Composition	Each film coated release tablet contains: Topiramate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8242 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 (#0808039)
	Pharmacological Group	Anti-epileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 20, 30,60 's As per SRO

	Approval status of product in Reference Regulatory Authorities	Topamax 50 mg by Janssen Approved by MHRA of UK
	Me-too status	Topamid 50mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 069778)
	GMP status	M/s: Winilton The firm provides cGMP certificate dated 7-3-2019 showing compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1099.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Neb 2.5mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 37600 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756256)
	Composition	Each Film Coated Tablet Contains: Nebivolol…2.5mg
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1x10',2x7, 2x14's As per SRO
	Approval status of product in Reference Regulatory Authorities	NA BYSTOLIC uncoated tablet Nebivolol as hydrochloride (USFDA approved)
	Me-too status	NA Nibovo Tablets 2.5mgM/s. Dyson Research Laboratories (Reg.# 078846)
	GMP status	M/S Ciba Certificate of GMP, Date: 7th august 2019 (tablet,capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	Reference product in approved as uncoated tablet Nebivolol as hydrochloride…2.5mg. on communication firm provided the Revised form 5 with composition Each film coated tablet contain nebivolol HCl
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.	
1100.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Neb 5mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 37601 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756257)
	Composition	Each Film Coated Tablet Contains: Nebivolol…5mg
	Pharmacological Group	Anti Hypertensive
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1x10',2x7, 2x14's As per SRO
	Approval status of product in Reference Regulatory Authorities	NA BYSTOLIC uncoated tablet Nebivolol as hydrochloride (USFDA approved)
	Me-too status	NA Nibovo Tablets 5 mgM/s. Dyson Research Laboratories (Reg.# 078842)

	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet,capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	Reference product in approved as uncoated tablet Nebivolol as hydrochloride…2.5mg. on communication firm provided the Revised form 5 with composition Each film coated tablet contain nebivolol HCl
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.	
1101.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Vildag-M 50/1000 mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 37609 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756260)
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin…1000mg
	Pharmacological Group	Antihyperglycemic agent
	Form	Form-5
	Finished product Specifications	Manufacturere
	Pack size & Demanded Price	10x1,7x2, 14x2 As per SRO
	Approval status of product in Reference Regulatory Authorities	Vildagliptin/metformin 50mg/1000mg film-coated tablets (MHRA)
	Me-too status	Galmet 50mg/1000mg Table M/s Vision Pharma (Ref# 081907)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet,capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	• Reference product in approved as Vildagliptin and metformin hydrochloride, but firm applied in Form 5, as Metformin. On communication firm revised there form 5 method of manufacturing etc. without fee.
	Decision: Deferred for submission of requisite fee for revision of formulation.	
1102.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Vildag-M 50/850 mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 37608 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756259)
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin…850mg
	Pharmacological Group	Antihyperglycemic agent
	Form	Form-5
	Finished product Specifications	Manufacturere
	Pack size & Demanded Price	10x1,7x2, 14x2 As per SRO
	Approval status of product in Reference Regulatory Authorities	Vildagliptin/metformin 50mg/850mg film-coated tablets (MHRA)
	Me-too status	Galmet 50mg/850mg Table M/s Vision Pharma (R# 081906)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet,capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	Reference product in approved as Vildagliptin and metformin

		hydrochloride, but firm applied in Form 5, as Metformin. On communication firm revised there form 5, method of manufacturing etc. without fee
	Decision: Deferred for submission of requisite fee for revision of formulation.	
1103.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Vildag 50mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 37607 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756258)
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg
	Pharmacological Group	Antihyperglycemic agent
	Form	Form-5
	Finished product Specifications	Manufacturere
	Pack size & Demanded Price	10x1,7x2, 14x2 As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUS (Vildagliptin 50 mg tablets un-coated) by Novartis Pharmaceuticals Australia Pty Ltd. TGA approved
	Me-too status	V- Glip 50mg uncoated tablet of M/s Wellborne Pharma (Reg. # 080908)
	GMP status	M/S Ciba Certificate of GMP, Date: 7th august 2019 (tablet, capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	• Reference product in approved as Vildagliptin uncoated tablet, but firm has applied in Form 5, as film coated tablet. On communication firm attached the reference of 292 meeting for film coated tablet which can't be verified
	Decision: Deferred for revision of formulation to uncoated tablet as per the reference product along with submission of fee for revision of formulation or the evidence of film coated tablet in RRA.	
1104.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Lochol 5mg Tablets
	Diary No. Date of R& I & fee	Form-5 Dy.No 37604 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756263)
	Composition	Each Film Coated Tablet Contains: Rosuvastatin…5mg
	Pharmacological Group	HMG CoA reductase inhibitors
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 5 mg film coated Tablets, Astrazeneca UK , Ltd.(MHRA Approved)
	Me-too status	Rovista 5mg Tablets M/s Getz Pharma, Karachi (Reg#044043)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet,capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	Reference product in approved as 5 mg rosuvastatin (as rosuvastatin calcium) but firm applied in Form 5, as Rosuvastatin…5mg on communication firm revised form 5 & method of manufacturing without fee.
	Decision: Deferred for submission of requisite fee for revision of formulation	

1105.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Lochol 10mg Tablets
	Diary No. Date of R& I & fee	Form-5 Dy.No 37605 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756264)
	Composition	Each Film Coated Tablet Contains: Rosuvastatin…10mg
	Pharmacological Group	HMG CoA reductase inhibitors
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 10mg film coated Tablets, Astrazeneca UK , Ltd.(MHRA Approved)
	Me-too status	Rovista 10mg Tablets M/s Getz Pharma, Karachi (Reg#044044)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet,capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	Reference product in approved as 10 mg rosuvastatin (as rosuvastatin calcium) but firm applied in Form 5, as Rosuvastatin…10 mg on communication firm revised form 5 & method of manufacturing without fee.
	Decision: Deferred for submission of requisite fee for revision of formulation	
1106.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Lochol 20 mg Tablets
	Diary No. Date of R& I & fee	Form-5 Dy.No 37606 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756267)
	Composition	Each Film Coated Tablet Contains: Rosuvastatin…20 mg
	Pharmacological Group	HMG CoA reductase inhibitors
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 20 mg film coated Tablets, Astrazeneca UK , Ltd.(MHRA Approved)
	Me-too status	Rovista 20 mg Tablets M/s Getz Pharma, Karachi (Reg#044045)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet,capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	Reference product in approved as 20 mg rosuvastatin (as rosuvastatin calcium) but firm applied in Form 5, as Rosuvastatin…20mg on communication firm revised form 5 & method of manufacturing without fee.
	Decision: Deferred for submission of requisite fee for revision of formulation	
1107.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Cibta-M 50/1000 mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 37598 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip# 0756274)
	Composition	Each film coated tablet contains: Sitagliptin phosphate monohydrate equivalent to 50 mg of sitagliptin …… 50mg

		Metformin …… 1000mg
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	2x7's As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet 50 mg/1000 mg film-coated tablets Approved by MHRA of UK
	Me-too status	Tagipmet 50/1000 Tablets by M//s. Highnoon Laboratories, (Reg.# 059787)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet, capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	• Reference product in approved as Metformin hydrochloride but firm applied in Form 5, as metformin without salt form. On communication firm revised the form 5 and method of manufacturing without fee.
	Decision: Deferred for submission of requisite fee for revision of formulation	
1108.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Cibta-M 50/500 mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 38396 dated 22-11-2018 Rs.20,000/- Dated 22-11-2018 (Slip#0756272)
	Composition	Each film coated tablet contains: Sitagliptin phosphate monohydrate equivalent to 50 mg of sitagliptin …… 50mg Metformin …… 500mg
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	2x7's As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet 50 mg/1000 mg film-coated tablets Approved by MHRA of UK
	Me-too status	Tagipmet 50/1000 Tablets by M//s. Highnoon Laboratories, (Reg.# 059787)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet,capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	• Reference product in approved as Metformin hydrochloride but firm applied in Form 5, as metformin without salt form. On communication firm revised the form 5 and method of manufacturing without fee.
	Decision: Deferred for submission of requisite fee for revision of formulation	
1109.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Cibta 50mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 38395 dated 22-11-2018 Rs.20,000/- Dated 22-11-2018 (Slip#0756271)
	Composition	Each Film Coated Tablet Contains: Sitagliptin phosphate monohydrate, equivalent to sitagliptin…….. 50 mg
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	14's As per SRO
	Approval status of product in Reference Regulatory Authorities	Januvia 50mg film-coated tablets Approved by MHRA of UK
	Me-too status	Duvel 50mg Tablet by M/s Martin Dow Ltd. (Reg#079615)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet, capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	
	Decision: Approved	
1110.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Cibta-M 50/850 mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 38395 dated 22-11-2018 Rs.20,000/- Dated 22-11-2018 (Slip#0756271)
	Composition	Each Film Coated Tablet Contains: Sitagliptin…50mg Metformin…850mg
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	Innovators
	Pack size & Demanded Price	14's As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet 50/850 tablets of (TGA approved)
	Me-too status	S-Gliptin Plus Tablets of M/s Barrett Hodgson (Reg#081619)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet, capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	Reference product in approved as Metformin hydrochloride but firm applied in Form 5, as metformin without salt form. On communication firm revised the form 5 and method of manufacturing without fee.
	Decision: Deferred for submission of requisite fee for revision of formulation	
1111.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Pantop 40mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 38388 dated 22-11-2018 Rs.20,000/- Dated 22-11-2018 (Slip#0756275)
	Composition	Each Film Coated Tablet Contains: Pantoprazole sodium…40mg
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	Innovators
	Pack size & Demanded Price	14's As per SRO
	Approval status of product in Reference Regulatory Authorities	NA (Approved by MHRA as delayed released tablet)
	Me-too status	NA Cantrofast Tablets delayed relaease of M/s Candid Pharmaceuticals (Reg.#082031)
	GMP status	M/S Ciba Certificateof GMP, Date: 7th august 2019 (tablet, capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	Reference product in approved as 40 mg pantoprazole (as pantoprazole sodium sesquihydrate) gastro resistant tablet but

		firm had applied in Form 5, as Pantoprazole sodium…40mg as film coated tablet. On communication firm revised the form 5 for, Each enteric coated tablet contain Pantoprazole as sodium sesquihydrate…40mg and method of manufacturer without fee
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.	
1112.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Respeval Tablets 1mg
	Composition	Each Film Coated Tablet contains: Risperidone…….1mg
	Diary No. Date of R& I & fee	D#3459, 25-1-2019; Rs. 20,000/- (#0817908)
	Pharmacological Group	Antipsychotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,18,20,30,50's As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 1mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg, 4mg)) by M/s Novartis, Reg No. 48831
	GMP status	Last GMP inspection was conducted on 20-04-2018 Keeping in view of the above facts on record, document reviewed and people met during inspection the panel unanimously recommend the grant of additional section i.e., Soft gelatin capsule as well as the renewal of DML no.000496 of M/s Valor Islamabad except the tablet psychotropic section which was not operative at the time of inspection though built as per approved layout plan 453 sq. It was advised to regularize the layout plan for tablet psychotropic section as per schedule B-I of the drugs (L, R &A) rules 1976. The firm has voluntarily stopped production as per their undertaking. in tablet psychotropic section of all registered products granted in favor of this psychotropic section till rectification and verification of the observations pointed out during inspection."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1113.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Respeval Tablets 2mg
	Composition	Each Film Coated Tablet contains: Risperidone…….2mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3460 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0817909)
	Pharmacological Group	Antipsychotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,18,20,30,50's As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 2mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg,

		4mg)) by M/s Novartis, Reg No. 048833
	GMP status	Last GMP inspection was conducted on 20-04-2018 "Same as Above."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1114.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Respeval Tablets 3mg
	Composition	Each Film Coated Tablet contains: Risperidone…….3mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3461 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0817910)
	Pharmacological Group	Antipsychotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,12, 18,20,30,50's As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 3mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg, 4mg)) by M/s Novartis, Reg No. 048833
	GMP status	Last GMP inspection was conducted on 20-04-2018 "Same as Above."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1115.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Respeval Tablets 4mg
	Composition	Each Film Coated Tablet contains: Risperidone…….4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3462 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0766699)
	Pharmacological Group	Antipsychotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,12, 18,20,30,50's As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 3mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg, 4mg)) by M/s Novartis, (Reg No. 048834)
	GMP status	Last GMP inspection was conducted on 20-04-2018 "Same as Above."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1116.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Amlosartan Tablets 10mg/160 mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Valsartan…160mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3458 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0755600)

	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,14,20,28, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Tablets (USFDA Approved)
	Me-too status	Exforge Tablets by M/s Novartis, (Reg No. 047571)
	GMP status	Last GMP inspection was conducted on 20-04-2018 "Same as Above."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1117.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Amlosartan Tablets 5mg/160 mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 764 dated 07-01-2019 Rs.20,000/- Dated 07-01-2019 (#0755600)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,14,20,28, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Tablets by Novartis (USFDA Approved)
	Me-too status	Exforge Tablets by M/s Novartis, Reg No. 047570
	GMP status	Last GMP inspection was conducted on 20-04-2018 "Same as Above."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1118.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Amlosartan Tablets 5mg/80 mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 763 dated 07-01-2019 Rs.20,000/- Dated 07-01-2019 (#0828203)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,14,20,28, 30's/As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge film-coated tablet 5/80mg (TGA approved)
	Me-too status	VALTAN -M 85 PLUS TABLET. Reg. No. 77204
	GMP status	Last GMP inspection was conducted on 20-04-2018 "Same as Above."
	Remarks of Evaluator [VII]	
	Decision: Approved	

1119.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	V-Coxib 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 760 dated 07-01-2019 Rs.20,000/- Dated 07-01-2019 (#0828201)
	Pharmacological Group	Anti-inflammatory and anti-rheumatic drugs
	Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10, 20,30, 60's As per SRO
	Approval status of product in Reference Regulatory Authorities	Etoricoxib by Glenmark Pharmaceuticals (MHRA Approved)
	Me-too status	Etoria 60mg Table of M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080818)
	GMP status	Last GMP inspection was conducted on 20-04-2018 "Same as Above."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1120.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Valovan Tablets 160mg
	Composition	Each Film Coated Tablet Contains: Valsartan…160mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 761 dated 07-01-2019 Rs.20,000/- Dated 07-01-2019 (#0828202)
	Pharmacological Group	Angiotensin-II receptor antagonist
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 14,20, 28,30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Valsartan 160mg Film-coated Tablets (Approved by MHRA)
	Me-too status	Diovan 160 film coated tablets (Reg# 027347)
	GMP status	Last GMP inspection was conducted on 20-04-2018 "Same as Above."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1121.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Glunol Tablets 80/80mg
	Composition	Each sugar coated tablet contains: Phloroglucinol…80mg Trimethylphloroglucinol…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3478 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0810185)
	Pharmacological Group	Antispasmodic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	3x10's As per SRO

	Approval status of product in Reference Regulatory Authorities	Spasfon sugar- coated tablet by M/s Teva Health (ANSM) France Approved
	Me-too status	Anafortan Plus Tablets Each sugar coated tablet of M/s Ali Gohar (Reg.# 024504)
	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	In ANSM it is approved as anhydrous phloroglucinol 62.233 mg in the form of: hydrated phloroglucinol 80 mg but firm applied as phloroglucinol 80 mg.
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.	
1122.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Glunol Injection 40/0.04mg
	Composition	Each 4ml contains: Dihydrated Phloroglucinol…40mg Trimethylphloroglucinol…0.04mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3477 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0810186)
	Pharmacological Group	Antispasmodic.
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	4 ml in glass ampoule 6 and 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Spasfon injection by M/s Teva Health (ANSM) France Approved (4 ml glass ampoule)
	Me-too status	Spasrid Injection of Barrett Hodgson Pakistan (Pvt) Ltd (Reg.# 034744)
	GMP status	GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of Evaluator [VII]	In ANSM it is approved as anhydrous phloroglucinol 31.12 mg in the form of: phloroglucinol dihydrate but firm applied as Dihydrated Phloroglucinol…40mg
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.	
1123.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore By M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ferison 750mg/15ml Injection
	Composition	Each 15ml Vial Contains: Ferric carboxymaltose…750mg (50 mg/ml)
	Diary No. Date of R& I & fee	Form-5 Dy.No 509 dated 04-01-2019 Rs.20,000/- Dated 03-01-2019 (#0820820)
	Pharmacological Group	Iron deficiency anemia
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	15 ml Glass vial

		As per SRO
	Approval status of product in Reference Regulatory Authorities	INJECTAFER® (ferric carboxymaltose injection), for intravenous use (750mg/15ml). USFDA approved.
	Me-too status	Ferinject Injectable (500mg/10ml). Reg No. 72548
	GMP status	The firm was granted GMP certificate based upon inspection conducted on 11-12-2017 & 10-01-2018 and recommended for renewal of DML.
	Remarks of Evaluator [VII]	The Firm is applying for contract manufacturing with medisave pharma but the fee submitted was 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing	
1124.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Cornicor 10mg Tablet
	Composition	Each Tablet Contains: Nicorandil…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3483 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#084247)
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	IKOREL Nicorandil 10mg tablet un-coated. TGA approved
	Me-too status	Nicogina 10mg Tablet. Reg. No. 67049
	GMP status	GMP inspection dated 31-01-2018, firm was operating under good compliance of cGMP on the day of inspection.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1125.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Cornicor 20 mg Tablet
	Composition	Each Tablet Contains: Nicorandil…20 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3492 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0842473)
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	IKOREL Nicorandil 20mg tablet un-coated. TGA approved
	Me-too status	Nicogina 20mg Tablet. Reg. No. 067050
	GMP status	GMP inspection dated 31-01-2018, firm was operating under good compliance of cGMP on the day of inspection.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1126.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Lesicu 200mg tablet
	Composition	Each Film Coated Tablet Contains: Lesinurad…200mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 3495 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0842487)
	Pharmacological Group	Selective inhibitor of uric acid
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Zurampic by Ironwood Pharms Inc (USFDA) Discontinued |
	Me-too status	NA
	GMP status	GMP inspection dated 31-01-2018, firm was operating under good compliance of cGMP on the day of inspection.
	Remarks of Evaluator [VII]	Evidence in RRA (as in FDA it is discontinued) and Me too status
	Decision: Deferred for following: **• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** **• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
1127.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Roflutab 500mcg Tablet
	Composition	Each Film Coated Tablet Contains: Roflumilast…500mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3491 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0842472)
	Pharmacological Group	Phosphodiesterase-4 Inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	10, 14,28,30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Daliresp (USFDA) approved
	Me-too status	NA
	GMP status	GMP inspection dated 31-01-2018, firm was operating under good compliance of cGMP on the day of inspection.
	Remarks of Evaluator [VII]	Evidence of me to Submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by registration board in its 251st& 278th meeting respectively
	Decision: Deferred for following submissions: **Application on Form 5-D along with differential fee of Rs. 30,000/-.** **Stability study data as per the guidelines provided in 278th meeting of Registration Board.**	
1128.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Azildo 20mg Tablet
	Composition	Each Tablet Contains: Azilsartan Medoxomil as potassium…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3491 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0842472)
	Pharmacological Group	Angiotensin II receptor Inhibitor)
	Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	10, 14,28,30's; As per SRO

	Approval status of product in Reference Regulatory Authorities	Edarbi by takeda pharma (Approved by MHRA)
	Me-too status	NA
	GMP status	GMP inspection dated 31-01-2018, firm was operating under good compliance of cGMP on the day of inspection.
	Remarks of Evaluator [VII]	Evidence of me to Submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by registration board in its 251st& 278th meeting respectively
	Decision: Deferred for following submissions: **Application on Form 5-D along with differential fee of Rs. 30,000/-.** **Stability study data as per the guidelines provided in 278th meeting of Registration Board.**	
1129.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Azildo 40mg Tablet
	Composition	Each Tablet Contains: Azilsartan Medoxomil as potassium…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3497 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0813832)
	Pharmacological Group	Angiotensin II receptor Inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	10, 14,28,30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Edarbi by takeda pharma (Approved by MHRA)
	Me-too status	NA
	GMP status	GMP inspection dated 31-01-2018, firm was operating under good compliance of cGMP on the day of inspection.
	Remarks of Evaluator [VII]	Evidence of me to Submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by registration board in its 251st& 278th meeting respectively
	Decision: Deferred for following submissions: **Application on Form 5-D along with differential fee of Rs. 30,000/-.** **Stability study data as per the guidelines provided in 278th meeting of Registration Board.**	
1130.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Azildo 80mg Tablet
	Composition	Each Tablet Contains: Azilsartan Medoxomil as potassium…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3497 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0813833)
	Pharmacological Group	Angiotensin II receptor Inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	10, 14,28,30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Edarbi by takeda pharma (Approved by MHRA)
	Me-too status	NA
	GMP status	GMP inspection dated 31-01-2018, firm was operating under good compliance of cGMP on the day of inspection.
	Remarks of Evaluator [VII]	Evidence of me to Submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by

		registration board in its 251st& 278th meeting respectively
	Decision: Deferred for following submissions: • **Application on Form 5-D along with differential fee of Rs. 30,000/-.** • **Stability study data as per the guidelines provided in 278th meeting of Registration Board.**	
1131.	Name and address of manufacturer / Applicant	M/s The Searle Company Limited. 1st Floor, N.I.C.L Building, Abbasi Shaheed Road, Shahrah-e-Faisal, Karachi
	Brand Name +Dosage Form + Strength	Xadine 30mg/5ml Suspension
	Composition	Each 5ml Contains: Fexofenadine HCL…30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2687 dated 21-01-2019 Rs.20,000/- Dated 18-01-2019 (#0799839)
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1x60 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	TELFAST ORAL LIQUID fexofenadine hydrochloride 6 mg/mL oral suspension bottle. TGA approved
	Me-too status	Telfast Suspension by M/s Sanofi Aventis (Reg. # 058699)
	GMP status	Last GMP inspection report dated 13-2-2018: Follow-up, as per the data provided by QALT Division.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1132.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vildamet-M 50/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3172 dated 23-01-2019 Rs.20,000 Dated 22-01-2019 (#0572026)
	Pharmacological Group	Antihyperglycemic agent
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of Novartis Pharmaceuticals (TGA Approved)
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	GMP certificate issued on the basis of inspection 30.09.2019
	Remarks of Evaluator [VII]	Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil polyvinylchloride/ aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with innovator's specification.	
1133.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vildamet-M 50/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…500mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 3171 dated 23-01-2019 Rs.20,000 Dated 22-01-2019 (#0572022)
	Pharmacological Group	Antihyperglycemic agent
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Tablet Of Novartis Pharmaceuticals (TGA Approved)
	Me-too status	Vilget-M 50mg+500 mg Tablet M/s Getz
	GMP status	GMP certificate issued on the basis of inspection 30.09.2019
	Remarks of Evaluator [VII]	Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil polyvinylchloride/ aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with innovator's specification.	
1134.	Name and address of manufacturer / Applicant	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Nitroscot Flash Tablet
	Composition	Each Sublingual Tablet Contains: Glyceryl Trinitrate…0.5 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2690 dated 21-01-2019 Rs.20,000/- Dated 21-01-2019 (#0817763)
	Pharmacological Group	Vasodilators used in cardiac diseases (Organic nitrates)
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1x10's, 3x10's, 6x10's, 3x7's, 2x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Glyceryl Trinitrate tablets 500 microgram by M/s Accord (MHRA Approved)
	Me-too status	Angilingual Sublingual Tablets by M/S Zafa (Reg# 025544)
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1135.	Name and address of manufacturer / Applicant	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Winny-V 500mcg Injection
	Composition	Each ml Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2691 dated 21-01-2019 Rs.20,000/- Dated 21-01-2019 (#0817762)
	Pharmacological Group	Vitamin B-12
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	1ml x10's, 1 mlx5's As per SRO
	Approval status of product in Reference Regulatory Authorities	Comezengen injection 500 µg of M/s Tatsumi Chemical (PMDA Japan Approved)
	Me-too status	Flench injection of M/s Tabros Pharma (Reg. # 029050)
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.

	Remarks of Evaluator [VII]	No USP, BP, IP or JP monograph is available for the applied formulation.
	Decision: Approved with innovator's specification.	
1136.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore,
	Brand Name +Dosage Form + Strength	Cefpro 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 1691 dated 14-01-2019 Rs.20,000/- Dated 10-01-2019 (#0801947)
	Pharmacological Group	Cephalosporin Antibiotics
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	6, 10, 12, .20, 24, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime Proxetil Tablet of Aurobindo Pharma (USFDA)
	Me-too status	Orisbro Tablet of Tabros Pharma (Reg # 044350)
	GMP status	As per last inspection report dated 08/03/2019, the firm had maintained conformance to GMP compliance in manufacturing and quality control operations. Sections: Tablet General Encapsulation cephalosporin Oral dry powder suspension cephalosporin Sterile dry powder injection & infusions Cephalosporin *Only cephalosporin dry powder injectable section was operational at the time of inspection.
	Remarks of Evaluator [VII]	
	Decision: Deferred for confirmation of requisite facility (Cephalosporin tablet section).	
1137.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore,
	Brand Name +Dosage Form + Strength	Cefpro 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 1690 dated 14-01-2019 Rs.20,000/- Dated 10-01-2019 (#0801946)
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	6,10,12.20,24, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime Proxetil Tablet of Aurobindo Pharma (USFDA)
	Me-too status	Prelox Tablets of Bosh Pharma. (Reg. No. 027155)
	GMP status	As per last inspection report dated 08/03/2019, Same as Above.
	Remarks of Evaluator [VII]	
	Decision: Deferred for confirmation of requisite facility (Cephalosporin tablet section).	
1138.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore,
	Brand Name +Dosage Form + Strength	Cefpro DS 100mg/5ml Oral Suspension

	Composition	Each 5ml Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 1694 dated 14-01-2019 Rs.20,000/- Dated 10-01-2019 (#0004734)
	Pharmacological Group	Cephalosporin
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vantin by Pharmacia and Upjohn USFDA Approved
	Me-too status	Qink Dry Suspension of M/s Wilshire (Reg. # 053636)
	GMP status	As per last inspection report dated 08/03/2019, Same as Above.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1139.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore,
	Brand Name +Dosage Form + Strength	Cefpro DS 50mg/5ml Oral Suspension
	Composition	Each 5ml Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 1693 dated 14-01-2019 Rs.20,000/- Dated 10-01-2019 (#0801949)
	Pharmacological Group	Cephalosporin
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50, 75, 100 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime proxetil 50mg / 5 ml powder for oral suspension of USFDA approved
	Me-too status	Qink Dry Suspension of M/s Wilshire Laboratories (Reg. # 053636)
	GMP status	As per last inspection report dated 08/03/2019, Same as Above.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1140.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore,
	Brand Name +Dosage Form + Strength	Cefpro DS 40mg/5ml Oral Suspension
	Composition	Each 5ml Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 1692 dated 14-01-2019 Rs.20,000/- Dated 10-01-2019 (#0801948)
	Pharmacological Group	Cephalosporin
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50, 75, 100 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime 40 mg/5 ml oral by Aurobindo pharma (MHRA)
	Me-too status	Prelox of Bosch Pharma
	GMP status	As per last inspection report dated 08/03/2019, Same as Above.

	Remarks of Evaluator [VII]	In RRA it is approved as granules for suspension
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is granules for suspension need detail outline of granulation process.	
1141.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nixworm 500mg Tablet
	Composition	Each Tablet Contains: Mebendazole…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 1880 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019 (#0815205)
	Pharmacological Group	Anthelmintics (Benzimidazole derivatives)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	60's, 300's As per SRO
	Approval status of product in Reference Regulatory Authorities	Vermox 500mg chewable tablet of M/s Janssen Pharms (Discontinued in USFDA)
	Me-too status	Almeb Tablets 500mg of M/s Alsons Pharmaceuticals
	GMP status	Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1142.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Blamir XR Tablet 50mg
	Composition	Each extended release tablet contains: Mirabegron…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 1880 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019 (#0815249)
	Pharmacological Group	Anthelmintics (Benzimidazole derivatives)
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	10,20,30's As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	NA
	GMP status	Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
	Remarks of Evaluator [VII]	The applied formulation needs submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board.	
1143.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Blamir XR Tabley 25 mg
	Composition	Each extended release tablet contains: Mirabegron…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 3708 dated 28-01-2019 Rs.20,000/- Dated 28-01-2019 (#00)
	Pharmacological Group	Anthelmintics (Benzimidazole derivatives)

	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	10,20,30's As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	NA
	GMP status	Last inspection report dated 02/08/2018 concludes the GMP compliance as good.
	Remarks of Evaluator [VII]	The applied formulation needs submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board.	
1144.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Misoben 200mcg Tablet
	Composition	Each Tablet Contains: Misoprostol…200mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 314 dated 02-01-2019 Rs.20,000/- Dated 02-01-2019 (#0828501)
	Pharmacological Group	Prostaglandin
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	10,20 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec (USFDA)
	Me-too status	Cytotol by Saffron pharma
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of Evaluator [VII]	In reference tablet is approved as Each Tablet Contains: Misoprostol HPMC dispersion eq to Misoprostol(USP)……200mcg but firm applied with just misoprostol On communbication firm claim that *"according to USFDA approved cytotec 200 mg tablet monograph where it is claimed that each tablet contain misoprostol 200mcg the same monograph was submitted at the time of initial application and is enclosed agin for delebration"*
	Decision: Deferred for following: **a. confirmation of manufacturing site as reported DML is invalid.** **b. revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.**	
1145.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Benfol-F Tablet
	Composition	Each Film Coated Tablet Contains: Ferrous Fumarate…150mg Folic Acid…0.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 313 dated 02-01-2019 Rs.20,000/- Dated 02-01-2019 (#0769029)
	Pharmacological Group	Iron supplement

	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Folfe tablets by M/S Wilshire Laboratories (R#041769)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of Evaluator [VII]	
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1146.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works. 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Istat Tablet 100mg
	Composition	Each Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4224 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019 (#0610573)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	10x10's in blister and 100, 200 500 tablets in jar Decontrolled?
	Approval status of product in Reference Regulatory Authorities	Aceclofenac Film coated tablet of Accord (MHRA approved)
	Me-too status	Acfonac 100mg Tablets M/s Medicraft Pharmaceuticals (R# 081743)
	GMP status	GMP inspection report of M/s ISIS Pharma dated 08-07-2019 showed good level of GMP compliance.
	Remarks of Evaluator [VII]	In RRA approved as film coated tablet but firm applied as uncoated. In price decontrolled is mentioned
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.	
1147.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works. 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Novotrin L Ointment
	Composition	Each gram contains: Bacitracin…500units Polymixin Sulphate…5000units Neomycin base as neomycin sulphate…3.5mg Lidocaine…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4225dated 30-01-2019 Rs.20,000/- Dated 29-01-2019 (#0610572)
	Pharmacological Group	Analgesic (according to Form 5)
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	NA

	GMP status	GMP inspection report of M/s ISIS Pharma dated 08-07-2019 showed good level of GMP compliance.
	Remarks of Evaluator [VII]	Evidence of me too and in RRA Price is mentioned as decontrolled
	Decision: Deferred for following: **• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** **• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
1148.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works. 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Isgesic Tablet 450/35mg Tablet
	Composition	Each Tablet Contains: Paracetamol…650mg Orphenadrine Citrate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4226 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019 (#0610574)
	Pharmacological Group	Central anticholinergic (skeletal muscle relaxant)
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Nuberol Forte tablet of M/s Searle
	GMP status	GMP inspection report of M/s ISIS Pharma dated 08-07-2019 showed good level of GMP compliance.
	Remarks of Evaluator [VII]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
1149.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works. 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Gentamicin Eye Drops
	Composition	Each ml contains: Gentamicin sulphate …3 mg (0.3%)
	Diary No. Date of R& I & fee	Form-5 Dy.No 4223 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019 (#0610568)
	Pharmacological Group	Antibiotic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	7.5 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Gentamicin sulphate ophthalmic solution 0.3% of Akron Inc. USFDA
	Me-too status	Optagen eye drops 0.3% w/v of M/s Remington Pharmaceuticals (R# 011261)
	GMP status	GMP inspection report of M/s ISIS Pharma dated 08-07-2019 showed good level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved.	

1150.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Rivarox 20mg Tablet
	Composition	Each Film coated tablet Contains: Rivaroxaban…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2955 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786385)
	Pharmacological Group	Anti- thrombotic agent/ Anticoagulant
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x14's 2989 per pack
	Approval status of product in Reference Regulatory Authorities	Xarelto film-coated tablets (2.5mg, 10mg, 15mg, 20mg) by M/s JANSSEN PHARMS by USFDA Approved.
	Me-too status	Rivaxo 20mg tablet of M/s Getz Pharma (Reg. # 080791)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1151.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Rivarox 15 mg Tablet
	Composition	Each Film coated tablet Contains: Rivaroxaban…15 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2954 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786384)
	Pharmacological Group	Anti- thrombotic agent/ Anticoagulant
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x 14's 2989/per pack
	Approval status of product in Reference Regulatory Authorities	Xarelto film-coated tablets (2.5mg, 10mg, 15mg, 20mg) by M/s JANSSEN PHARMS by USFDA Approved.
	Me-too status	Roxaban 15mg Tablet by M/s Genetics Pharmaceuticals (Pvt) Ltd, Reg. no. 85165
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1152.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Rivarox 10 mg Tablet
	Composition	Each Film coated tablet Contains: Rivaroxaban…10 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2953 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786383)
	Pharmacological Group	Anti- thrombotic agent/ Anticoagulant
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto film-coated tablets (2.5mg, 10mg, 15mg, 20mg) by M/s JANSSEN PHARMS by USFDA Approved.

	Me-too status	Roxaban 20mg Tablet by M/s Genetics Pharmaceuticals (Pvt) Ltd, Reg. no. 85164
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1153.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Tirace 500mg Tablet
	Composition	Each Film coated Tablet Contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2962 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786392)
	Pharmacological Group	Anti-epileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3x10, 1x10's Rs 40.6 per tablet
	Approval status of product in Reference Regulatory Authorities	Keppra 500 mg film-coated tablets by M/s UCB Pharma S.A, MHRA Approved.
	Me-too status	Keppra Tablets 500mg by M/s AGP (Pvt.) Ltd, Karachi (imported) (Reg. No. 045685)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved	
1154.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Tirace 250mg Tablet
	Composition	Each Film coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2961 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786391)
	Pharmacological Group	Anti-epileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3x10, 1x10's Rs 24.5/0 per tablet
	Approval status of product in Reference Regulatory Authorities	Keppra 250 mg film-coated tablets by M/s UCB Pharma S.A, MHRA Approved.
	Me-too status	Keppra Tablets 250mg by M/s AGP (Pvt.) Ltd, Karachi (imported) (Reg. No. 045684)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1155.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Terasin 2mg Tablet
	Composition	Each Tablet Contains: Terazosin hydrochloride equivalent to terazosin…2mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2959 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786389)

	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3x10's Rs 11.86 per tablet
	Approval status of product in Reference Regulatory Authorities	Terazosin Tablets 1mg, 2mg, 5mg and 10mg of Accord Approved by MHRA of UK
	Me-too status	Hyzosin Tablet 2mg by M/s English Pharm. (Reg.# 068007)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved	
1156.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Terasin 1mg Tablet
	Composition	Each Tablet Contains: Terazosin hydrochloride equivalent to terazosin …1mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2958 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786388)
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3x10's Rs 5.93 per tablet
	Approval status of product in Reference Regulatory Authorities	Terazosin Tablets 1mg, 2mg, 5mg and 10mg of Accord Approved by MHRA of UK
	Me-too status	Lopros Tablet 1 mg by M/s Standpharm Pakistan. (Reg.# 020283)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved	
1157.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Terasin 5mg Tablet
	Composition	Each Tablet Contains: Terazosin hydrochloride equivalent to terazosin …5 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2960 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786390)
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3x10's/ Rs 28.4 per tablet
	Approval status of product in Reference Regulatory Authorities	Terazosin Tablets 1mg, 2mg, 5mg and 10mg of Accord Approved by MHRA of UK
	Me-too status	Hyzosin Tablet 5 mg by M/s English Pharm
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved	

1158.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Xeropain 8mg Tablet
	Composition	Each Film coated tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2966 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786396)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1x10's Rs 13.2 per tablet
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Film tabletten by M/s Takeda Pharma AG (Swiss Medic approved)
	Me-too status	Atcam 8mg tablet of M/s Atco (Ref # 073723)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1159.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Xeropain 4mg Tablet
	Composition	Each Film coated tablet Contains: Lornoxicam…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2965 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786395)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1x10's Rs 6.6 per tablet
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG (Swiss Medic approved)
	Me-too status	Acabel 4mg Tablet by M/s Continental Pharma (Reg No:061603)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1160.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Roximass 300mg Tablet
	Composition	Each Film coated tablet Contains: Roxithromycin…300mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2957 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786387)
	Pharmacological Group	Macrolide
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	3x10's Rs 11.86 per tablet

	Approval status of product in Reference Regulatory Authorities	ROXIMYCIN 300mg film coated tablet (TGA Approved)
	Me-too status	Roxisafe 300mg Tablet by Safe Pharma (Reg # 076101)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1161.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Roximass 150mg Tablet
	Composition	Each Film coated tablet Contains: Roxithromycin…150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2956 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786386)
	Pharmacological Group	Macrolide
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1x10's Rs 205 per pack
	Approval status of product in Reference Regulatory Authorities	ROXIMYCIN 150mg film coated tablet (TGA Approved)
	Me-too status	Roxisafe 150mg Tablet by Safe Pharma (Reg # 067639)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1162.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Zoltrip 2.5mg Tablet
	Composition	Each Film coated tablet Contains: Zolmitriptan…2.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2952 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786382)
	Pharmacological Group	Anti- migraine preparation
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1x3's Rs 567 per pack
	Approval status of product in Reference Regulatory Authorities	Zolmitriptan 2.5 mg film-coated tablets of M/s Accord UK (MHRA Approved)
	Me-too status	Zomig Tablets 2.5mg of M/s ICI (Reg. # 021149)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1163.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Buxostat 40mg Tablet
	Composition	Each Film coated tablet Contains: Febuxostat…40mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 2967 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786397)
	Pharmacological Group	Xanthine oxidase inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	2x10's Rs 18 per tablet
	Approval status of product in Reference Regulatory Authorities	Uloric (Febuxostat) by Takeda Pharms (USFDA)
	Me-too status	Zurig 40mg Tablet of M/s Getz (Reg#067291)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1164.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Buxostat 80mg Tablet
	Composition	Each Film coated tablet Contains: Febuxostat…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2950 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786398)
	Pharmacological Group	Xanthine oxidase inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	2x10's Rs 32.95 per tablet
	Approval status of product in Reference Regulatory Authorities	Uloric (Febuxostat) by Takeda Pharms (USFDA)
	Me-too status	Zurig 80mg Tablet of M/s Getz (Reg#067290)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1165.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Ez-Tab 10mg Tablet
	Composition	Each Tablet Contains: Ezetimibe…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2951 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786380)
	Pharmacological Group	Other lipid modifying agents
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10's Rs 63.7 per tablet
	Approval status of product in Reference Regulatory Authorities	ZETIA (ezetimibe) Tablets. USFDA approved
	Me-too status	Ezemibe Tablets 10mg. (Reg No. 35815)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	

	Decision: Approved	
1166.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Cardox 4mg Tablet
	Composition	Each Tablet Contains: Doxazosin as Mesylate…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2964 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786394)
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2x10's Rs 27 per tablet
	Approval status of product in Reference Regulatory Authorities	CARDURA® tablets USFDA Approved
	Me-too status	Oxiz Tablet M/s NOA Hemis Pharmaceuticals (Reg No. 057796)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved	
1167.	Name and address of manufacturer / Applicant	M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore
	Brand Name +Dosage Form + Strength	Cardox 2mg Tablet
	Composition	Each Tablet Contains: Doxazosin as Mesylate…2mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2963 dated 22-01-2019 Rs.20,000/- Dated 18-01-2019 (#0786393)
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2x10's Rs 13.7 per tablet
	Approval status of product in Reference Regulatory Authorities	CARDURA (1,2, 4,8 mg as base) tablets USFDA Approved
	Me-too status	Oxiz Tablet M/s NOA Hemis Pharmaceuticals (Reg No. 057796)
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of Evaluator [VII]	
	Decision: Approved	
1168.	Name and address of manufacturer / Applicant	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Nevab Tablets 5mg/80mg
	Composition	Each Film Coated Tablet Contains: Nebivolol…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Form-5D Dy.No 4222 dated 30-01-2019 Rs.50,000/- Dated 29-01-2019 (#0785115)
	Pharmacological Group	Beta adrenergic blocker/ Angiotensin II receptor blocker)
	Form	Form-5D

	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	14's 510/14's
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	NA
	GMP status	M/s Martin Dow, Karachi: Last GMP inspection was conducted on 06-12-2018 and the report concludes good level of GMP compliance.
	Remarks of Evaluator [VII]	Submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by registration board in its 251st& 278th meeting respectively In USFDA this product is discontinued
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board.	
1169.	Name and address of manufacturer / Applicant	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan By M/s Seatle Pvt Ltd. 45 Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Taxat 400mg Capsule
	Composition	Each Capsule Contains: Cefixime Trihydrate Eq. to Cefixime…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2925 dated 22-01-2019 Rs.50,000/- Dated 22-01-2019 (#0792708)
	Pharmacological Group	Cephalosporin
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX 400mg capsules by M/s Lupin Pharma (USFDA Approved)
	Me-too status	Soxime Capsule 400 mg by Swat Pharmaceuticals (Reg#060128)
	GMP status	M/s Martin Dow, Quetta: Last GMP inspection was conducted on 12-07-2019 and the report concludes good level of GMP compliance. M/s Seatle Pharma: Firm has submitted latest GMP inspection report dated 25-10-2018 which specifies good compliance to GMP.
	Remarks of Evaluator [VII]	Total products on contract manufacturing= 25 Total sections of martin dow=7
	Decision: Approved.	
1170.	Name and address of manufacturer / Applicant	M/s Martin Dow Marker Limited.7, Jail Road, Quetta, By M/s Seatle Pvt Ltd. 45 Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Taxat 100mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefixime Trihydrate Eq. to Cefixime…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2924 dated 22-01-2019 Rs.50,000/- Dated 22-01-2019 (#0792707)
	Pharmacological Group	Third-generation cephalosporin

	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30 ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefixime 100 mg/5 ml Powder for Oral Suspension. (MHRA approved)
	Me-too status	Elixime Dry Suspension 100mg. Reg. No. 53729
	GMP status	M/s Martin Dow, Quetta: Last GMP inspection was conducted on 12-07-2019 and the report concludes good level of GMP compliance. M/s Seatle Pharma: Firm has submitted latest GMP inspection report dated 25-10-2018 which specifies good compliance to GMP.
	Remarks of Evaluator [VII]	Total products on contract manufacturing= 25 Total sections of martin dow=7
	Decision: Approved.	
1171.	Name and address of manufacturer / Applicant	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan By M/s Seatle Pvt Ltd.45 Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Taxat 200mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefixime Trihydrate Eq. to Cefixime…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 2924 dated 22-01-2019 Rs.50,000/- Dated 22-01-2019 (#0792710)
	Pharmacological Group	Third-generation cephalosporin
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX® (cefixime) for oral suspension. USFDA approved
	Me-too status	Elixime Dry Suspension 200mg. Reg. No. 53730
	GMP status	M/s Martin Dow, Quetta: Last GMP inspection was conducted on 12-07-2019 and the report concludes good level of GMP compliance. M/s Seatle Pharma: Firm has submitted latest GMP inspection report dated 25-10-2018 which specifies good compliance to GMP.
	Remarks of Evaluator [VII]	Total products on contract manufacturing = 25 Total sections of martin dow = 7
	Decision: Approved.	
1172.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form+ Strength	Bony 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine HCl eq to Memantine…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9258 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621838)
	Pharmacological Group	Anti-dementia drugs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 20, 30's As per SRO

	Approval status of product in Referen Regulatory Authorities	Ymana 20 mg of MHRA Approved
	Me-too status	Memura Tablet by Pharmevo (Reg. No. 055485)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1173.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bony 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine HCl eq to Memantine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9272 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621837)
	Pharmacological Group	Anti-dementia drugs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 20, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Ymana 10 mg of MHRA Approved
	Me-too status	Memura Tablet by Pharmevo (Reg. No. 055485)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1174.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vidglip Plus Tablet 50mg
	Composition	Each Tablet Contains: Vildagliptin…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9262 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621826)
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Galvus 50mg tablet of M/s Novartis Pharmaceuticals, UK Ltd (MHRA Approved)
	Me-too status	Galvus 50mg tablet of M/s Novartis Pharmaceuticals, Karachi (Reg # 059038)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	

1175.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vidglip Plus Tablet 50mg/850mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…850mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9263 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621827)
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	GALVUMET 50/850 by Novartis. (TGA Approved)
	Me-too status	Galvus Met 50mg/850mg Tablet of M/s Novartis (Reg.#066106)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1176.	Name and address of manufacturer Applicant	**M/s Swiss Pharmaceuticals Pvt Ltd.** **A-159, S.I.T.E Super Highway, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Iride 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride HCl…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9271 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621846)
	Pharmacological Group	Prokinetics
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	30, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved
	Me-too status	ITP of M/s Sami Pharmaceuticals
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1177.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Colchi Capsule 4mg
	Composition	Each hard gelatin capsule contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9259 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621850)
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Form	Form-5

	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10, 20's As per SRO
	Approval status of product in Referen Regulatory Authorities	MYOPLEGE 4 mg hard capsule of M/s Genevrier SA Laboratories approved by ANSM of France
	Me-too status	Muscodid 4mg Capsule M/s Regal Pharmaceuticals, Rawat (Reg #081968)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1178.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Levopride 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9260 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621833)
	Pharmacological Group	Gastroprokinetic / psychosis / Neuroleptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	20, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Levopraid 25 mg tablet of AIFA italy
	Me-too status	Nauvomit Tablets of M/s Saaaf Pharma (Reg#059377)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1179.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Levopride 50 mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9267 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621834)
	Pharmacological Group	Gastroprokinetic / psychosis / Neuroleptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	20, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Levopraid 50 mg tablet of AIFA italy
	Me-too status	Nauvomit Tablets of M/s Safe Pharma (Reg# 068312)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.

	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1180.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	ABCD 20mg Tablet
	Composition	Each Tablet Contains: Piroxicam as beta cyclodextrin…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9261 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621848)
	Pharmacological Group	Anti- inflammatory agents, Non- steroids
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	20, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	ANSM, France Approved
	Me-too status	Piroxibet 20mg Tablets of M/s Lawari International (Reg. # 054939)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1181.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Amiride 100mg Tablet
	Composition	Each Tablet Contains: Amisulpride…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9255 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621836)
	Pharmacological Group	Benzamides
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	20, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	SOLIAN 100 amisulpride 100 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 100mg Tablet (Reg# 76061)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1182.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Amiride 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9256 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621835)
	Pharmacological Group	Benzamides

	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	20, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	SOLIAN amisulpride 50 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 50mg Tablet (Reg# 76060)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1183.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Letam 100mg/ml Oral Solution
	Composition	Each ml contains: Levetiracetam…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9264 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621841)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30, 60 120 ml As per SRO
	Approval status of product in Referen Regulatory Authorities	LEVETIRACETAM (Levetiracetam100mg/ml) Solution; oral By M/s TARO. USFDA Approved.
	Me-too status	Levotam Oral solution 100mg/ml By M/s Platinum, Karachi. (Reg.# 070837)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1184.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zulid 2mg/ml Infusion
	Composition	Each ml contains: Linezolid…2mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9264 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621842)
	Pharmacological Group	Antibiotic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	300 vial 1,5,10 's As per SRO
	Approval status of product in Referen Regulatory Authorities	Linezolid 2 mg/ml solution for infusion by Mylan (MHRA)
	Me-too status	Zolrest Infusion 600mg/300ml by M/s Bosch (Reg#055916)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report

		concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	In MHRA its in 300 ml infusion bag
	Decision: Approved with innovator's specification.	
1185.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tdol 50mg/ml Injection
	Composition	Each ampoule contains: Tramadol…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9268 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621839)
	Pharmacological Group	Opioid Analgesic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2 ml (Ampoule) 1,5,10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Tremomed 100mg injection by M/s Medicraft Pharmaceuticals (Pvt.) Ltd. (Reg#064484)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	In RRA it is approved as tramadol Hcl
	Decision: Deferred for revision of formulation as per the reference product along with submission requisite fee for revision of formulation.	
1186.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Edrine 60mg/2ml Injection
	Composition	Each 2ml vial contains: Orphenadrine citrate…60mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9254 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621844)
	Pharmacological Group	Opioid Analgesic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2 ml (Vial) 1's/ As per SRO
	Approval status of product in Referen Regulatory Authorities	NA
	Me-too status	NA
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	Reference in RRA and DRAP as provided reference can't be verified
	Decision: **Deferred for following:** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too statu alongwith registration number, brand name and name of firm**	

	• **Evidence of approval of applied formulation in reference regulatory authorities/agenc which were declared/approved by the Registration Board**	
1187.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Rolac 30mg/ml Injection
	Composition	Each ampoule contains: Ketorolac Tromethane…30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9270 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621843)
	Pharmacological Group	NSAID
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 ml (Ampoule) 1,5, 10 ’s As per SRO
	Approval status of product in Referen Regulatory Authorities	Ketorolac tromethamine 30mg/ml (usfda)
	Me-too status	Toralac Injection 30mg of M/s Vision Pharmaceuticals (Ref # 050290)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1188.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Letam 100mg/ml Oral Solution
	Composition	Each 1 ml ampoule contains: Levetiracetam…100 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9264 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621840)
	Pharmacological Group	Antiepilaptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5 ml (vial) As per SRO
	Approval status of product in Referen Regulatory Authorities	KEPPRA (levetiracetam) injection, for intravenous use. (USFDA)
	Me-too status	Lerace Injection 500mg/5ml/ Reg. No. 66949
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1189.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cinpride 1mg Tablet
	Composition	Each Tablet Contains: Cinitapride as hydrogen tartrate…1mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9256 dated 28-02-2019 Rs.20,000/- Dated

		28-02-2019 (#0621847)
	Pharmacological Group	Propulsive / Prokinetic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	50, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Cidine 1 mg uncoated tablet by Almirall, SA (Spain Approved)
	Me-too status	Cidine Tablets by M/s Highnoon Lab (Reg. # 052940)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: **Approved with innovator's specification.**	
1190.	Name and address of manufacturer Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Dice 50mg Capsule
	Composition	Each hard gelatin capsule contains: Diacerin…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 9257 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019 (#0621849)
	Pharmacological Group	Anthraquinone
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Diacerein Biogaran 50 mg Hard Capsule by M/s Biogaran (ANSM, France approved).
	Me-too status	Dibro 50mg capsules by M/s Winbrain Research Lab (R#071639)
	GMP status	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1191.	Name and address of manufacturer Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Amicell 100mg Tablet
	Composition	Each Tablet Contains: Amisulpride…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6531 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811874)
	Pharmacological Group	Benzamides
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	1x 10, 3x10's, 6x10's As per SRO
	Approval status of product in Referen Regulatory Authorities	SOLIAN 100 amisulpride 100 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 100mg Tablet (Reg# 76061)

	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	
	Decision: Approved	
1192.	Name and address of manufacturer Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Amicell 150mg Tablet
	Composition	Each Tablet Contains: Amisulpride…150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6532 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811875)
	Pharmacological Group	Benzamides
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	1x 10, 3x10's, 6x10's As per SRO
	Approval status of product in Referen Regulatory Authorities	NA
	Me-too status	NA
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	Evidence in RRA and DRAP
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too statu alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agenc which were declared/approved by the Registration Board**	
1193.	Name and address of manufacturer Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Amicell 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6530 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811873)
	Pharmacological Group	Benzamides
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	1x 10, 3x10's, 6x10's As per SRO
	Approval status of product in Referen Regulatory Authorities	SOLIAN 50 amisulpride 50 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 50mg Tablet (Reg# 76060)
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section

	Remarks of Evaluator [VII]	
	Decision: Approved	
1194.	Name and address of manufacturer Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lacos 100mg Tablet
	Composition	Each film coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6528 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811871)
	Pharmacological Group	Anticonvulsant
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	1x14's As per SRO
	Approval status of product in Referen Regulatory Authorities	Vimpat oral tablet of UCB Inc, USFDA Approved.
	Me-too status	Lacolep tablet of Hilton Pharma (Reg. No# 073858).
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1195.	Name and address of manufacturer Applicant	M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Lacos 150mg Tablet
	Composition	Each film coated Tablet Contains: Lacosamide…150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6529 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019 (#0811872)
	Pharmacological Group	Anticonvulsant
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	1x14's As per SRO
	Approval status of product in Referen Regulatory Authorities	Vimpat oral tablet of UCB Inc, USFDA Approved.
	Me-too status	Lalap tablet of Hilton pharma (Reg # 070472)
	GMP status	M/s: Siam Pharmaceuticals Islamabad 16-02-2018 Keeping in view the above facts on record, the panel unanimously recommend grant renewal of DML 000711 for approved tablet general and Capsule general section
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1196.	Name and address of manufacturer Applicant	M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Oxitine CR 12.5mg Table
	Composition	Each controlled release tablet contains: Paroxetine as HCL…12.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8246 dated 25-02-2019 Rs.20,000/- Dated

		25-02-2019 (#0808042)
	Pharmacological Group	SSRIs/ Anti- depressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 20, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Paxil CR Tablet of M/s Apotex Technologies (USFDA Approved)
	Me-too status	Panox CR Tablet 12.5mg of M/s Regal Pharma (Reg.#081953)
	GMP status	M/s: Winilton The firm was last inspected on 06.10.2017, wherein the panel concluded the GMP compliance as FAIR.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1197.	Name and address of manufacturer Applicant	M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Oxitine 20 mg Table
	Composition	Each film coated release tablet contains: 20mg Paroxetine as paroxetine hcl anhydrous 22.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8245 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 (#0808040)
	Pharmacological Group	SSRIs/ Anti- depressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 20, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Paxil Tablet of M/s Apotex Technologies (USFDA Approved)
	Me-too status	Neoxetine Tablets 20mg of M/s Neomedix (Reg. # 081407)
	GMP status	M/s: Winilton The firm was last inspected on 06.10.2017, wherein the panel concluded the GMP compliance as FAIR.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1198.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Deptine CR Tablet 25mg
	Composition	Each enteric film coated controlled release tablet contains: Paroxetine Hcl eq to Paroxetine…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8753 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019 (#0791426)
	Pharmacological Group	SSRIs/ Anti- depressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Paxil Tablet of M/s Apotex Technologies (USFDA Approved)
	Me-too status	Neoxetine Tablets 20mg of M/s Neomedix (Reg. # 081407)

	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1199.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Deptine CR Tablet 12.5 mg
	Composition	Each enteric film coated controlled release tablet contains: Paroxetine Hcl eq to Paroxetine…12.5 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8752 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019 (#0791425)
	Pharmacological Group	SSRIs/ Anti- depressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Paxil CR Tablet of M/s Apotex Technologies (USFDA Approved)
	Me-too status	Panox CR Tablet 12.5mg of M/s Regal Pharma (Reg.#081953)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1200.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Camroid Tablet 20mg
	Composition	Each Tablet Contains: Piroxicam as beta cyclodextrin…191.2 eq to Piroxicam…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8751 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019 (#0791424)
	Pharmacological Group	Anti- inflammatory agents, Non- steroids
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	20, As per SRO
	Approval status of product in Referen Regulatory Authorities	Cycladol 20 mg scored tablet. ANSM, France Approved
	Me-too status	Piroxibet 20mg Tablets of M/s Lawari International (Reg. # 054939)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1201.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lacpril Capsule 50mg

	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5163 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019 (#0791417)
	Pharmacological Group	Anti-epileptics
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Referen Regulatory Authorities	LYRICA (pregabalin) Capsules 50mg by M/s PF Prism (USFDA Approved)
	Me-too status	Gabica 50mg Capsule by M/s Getz Pharma (Reg#048725)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1202.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sytrix Tablet 100 mg
	Composition	Each Film Coated Tablet Contains: Sertraline as HCL…100 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5167 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019 (#0791421)
	Pharmacological Group	Antidepressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2x10's, As per SRO
	Approval status of product in Referen Regulatory Authorities	LUSTRAL 100mg film coated tablets by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Zoloft Tablets 100mg by M/s Pfizer (Reg#020856)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1203.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sytrix Tablet 50 mg
	Composition	Each Film Coated Tablet Contains: Sertraline as HCL…50 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5166 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019 (#0791421)
	Pharmacological Group	Antidepressant
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2x10's, As per SRO
	Approval status of product in Referen Regulatory Authorities	LUSTRAL 50 mg film coated tablets by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Zoloft Tablets 50mg of M/s Pfizer Laboratories (Reg. # 020855)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that

		firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1204.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dromodic Tablet 40mg
	Composition	Each uncoated tablet contains: Drotaverine HCL…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5168 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019 (#0791422)
	Pharmacological Group	Anti-spasmodic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	2x10's, As per SRO
	Approval status of product in Referen Regulatory Authorities	Approved in three (03) EMA states as un-coated tablets in Lithuania, Hungary and Latvia.
	Me-too status	Drotarine 40mg tablet Mfd. by Selmore pharma. (Reg.# 064737)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1205.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dromodic Tablet 80mg
	Composition	Each uncoated tablet contains: Drotaverine HCL…80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5169 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019 (#0791423)
	Pharmacological Group	Anti-spasmodic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	2x10's, As per SRO
	Approval status of product in Referen Regulatory Authorities	Approved in three (03) EMA states as un-coated tablets in Lithuania, Hungary and Latvia.
	Me-too status	No-Spa Forte 80mg tablet by M/s. Sanofi Aventis (Reg#029431)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1206.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ciquent Tablet 2mg
	Composition	Each Film Coated Tablet Contains: Risperidone…2mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8754 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019 (#0791427)

	Pharmacological Group	Anti-psycotic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	2x10's, As per SRO
	Approval status of product in Referen Regulatory Authorities	Risperdal 2mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg, 4mg)) by M/s Novartis, (Reg No. 48832)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1207.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ciquent Tablet 4mg
	Composition	Each Film Coated Tablet Contains: Risperidone…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8755 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019 (#0791428)
	Pharmacological Group	Anti-psychotic
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Referen Regulatory Authorities	Risperdal 4mg film coated tablet by M/s Janssen-Cilag Ltd, MHRA approved.
	Me-too status	Risperidone-sandoz film coated tablet (1mg, 2mg, 3mg, 4mg)) by M/s Novartis, (Reg No. 48832)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1208.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dusant Capsule 20mg
	Composition	Each Capsule Contains: Enteric coated pellets Duloxetine Hcl eq to Duloxetine…20mg (Source of pellets **Vision pharma**)
	Diary No. Date of R& I & fee	Form-5 Dy.No 8756 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019 (#0791429)
	Pharmacological Group	Antidepressant (SSNRI)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Referen Regulatory Authorities	Duloxetine 20 mg gastro-resistant capsules of M/s Consilient Health Ireland
	Me-too status	Duprex Capsule 20mg of M/s CCL
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that

		firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1209.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dusant Capsule 60mg
	Composition	Each Capsule Contains: Enteric coated pellets Duloxetine Hcl eq to Duloxetine…60mg (Source of pellets **Vision pharma**)
	Diary No. Date of R& I & fee	Form-5 Dy.No 8757 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019 (#0791430)
	Pharmacological Group	Antidepressant (SSNRI)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Referen Regulatory Authorities	Cymbalta (USFDA approved)
	Me-too status	Swenta 60mg Capsule by M/s Martin Dow
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1210.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Hisave Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Topiramate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5165 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019 (#0791419)
	Pharmacological Group	Other antiepileptics
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2x10s, As per SRO
	Approval status of product in Referen Regulatory Authorities	Topamax® 50 mg film-coated tablets. MHRA approved
	Me-too status	Topister Tablet 50mg. (Reg. No. 82548)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1211.	Name and address of manufacturer Applicant	M/s Nawan Laboratories (Pvt.) Ltd. Plots No.136-138, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Hisave Tablet 25 mg
	Composition	Each Film Coated Tablet Contains: Topiramate…25 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5164 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019 (#0791418)

	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2x10's, As per SRO
	Approval status of product in Referen Regulatory Authorities	Topamax® 25 mg film-coated tablets. MHRA approved
	Me-too status	Erbro 25mg Tablet. (Reg. No. 80384)
	GMP status	M/S Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1212.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Perflex 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCL…60mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8256 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0846594)
	Pharmacological Group	Antihistamines for systemic use
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	2x7 As per SRO
	Approval status of product in Referen Regulatory Authorities	Fexotabs 60mg tablet Approved in TGA
	Me-too status	Fanoxin Tablets 60mg of Jawa Pharmaceutical
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1213.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Perflex 120mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCL…120 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8257 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0846595)
	Pharmacological Group	Antihistamines for systemic use
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	2x7 /As per SRO
	Approval status of product in Referen Regulatory Authorities	Fexotabs 120 mg tablet Approved in TGA
	Me-too status	Epodin 120mg Tablet M/s Epoch Pharma
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.

	Remarks of Evaluator [VII]	
	Decision: Approved	
1214.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Perflex 30mg/5ml Syrup
	Composition	Each 5ml contains: Fexofenadine HCL…30mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8263 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0846586)
	Pharmacological Group	Antihistamines for systemic use
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	USFDA Approved
	Me-too status	Fexofast Oral Suspension 30mg/ 5ml of M/s Platinum Pharma (Reg.# 055703)
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1215.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Sicamin 50/1000mg Tablets
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8636-A dated 26-02-2019 Rs.20,000/- Dated 26-02-2019 (#0846591)
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x10, 2x7, 3x10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Janumet 50/1000 mg film coated Tablet by Merck (USFDA Approved)
	Me-too status	Treviamet 50mg + 1000mg Tablet by Getz (Reg# 055444)
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1216.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd.Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Sicamin 50/500mg Tablets
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin HCl…500mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 8635-A dated 26-02-2019 Rs.20,000/- Dated 26-02-2019 (#0846590)
	Pharmacological Group	Anti-diabetic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x10, 2x7, 3x10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Janumet 50/500 mg film coated Tablet by Merck (USFDA Approved)
	Me-too status	S-Gliptin Plus Tablets of M/s Barrett Hodgson (Reg# 076344)
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1217.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Podicef Tablet 200mg
	Composition	Each Film coated Tablet Contains: Cefpodoxime as Cefpodoxime Proxetil…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6745 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0818175)
	Pharmacological Group	Cephalosporin Antibiotics
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x14. 28. 56's As per SRO
	Approval status of product in Referen Regulatory Authorities	Cefpodoxime Proxetil Tablet of Aurobindo Pharma (USFDA)
	Me-too status	Orisbro Tablet of Tabros Pharma (Reg # 044350)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Deferred for confirmation of requisite facility (Cephalosporin tablet section).	
1218.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Podicef 100mg/5ml Granules for oral suspension
	Composition	Each 5ml contains: Cefpodoxime as Cefpodoxime Proxetil
	Diary No. Date of R& I & fee	Form-5 Dy.No 6744 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0818174)
	Pharmacological Group	Cephalosporin Antibiotics
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Vantin by Pharmacia and Upjohn USFDA Approved
	Me-too status	Qink Dry Suspension of M/s Wilshire (Reg. # 053636)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report

		concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved	
1219.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vimed Tablet 200mg
	Composition	Each Film coated tablet Contains: Lacosamide…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6736 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0818173)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x14, 28, 56's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) Tablet, Film Coated USFDA Approved.
	Me-too status	Atcomid 200mg Tablet Atco Lab. Karachi. (Reg. # 075950)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1220.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vimed Tablet 100mg
	Composition	Each Film coated tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6736 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0841082)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x14, 28, 56's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) Tablet, Film Coated USFDA Approved.
	Me-too status	Atcomid 100mg Tablet Atco Lab. Karachi. (Reg. # 075948)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1221.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vimed Tablet 50mg
	Composition	Each Film coated tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6732 dated 15-02-2019 Rs.20,000/- Dated

		15-02-2019 (#0818170)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x14, 28, 56's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) Tablet, Film Coated USFDA Approved.
	Me-too status	Atcomid 50mg Tablet Atco Lab. Karachi. (Reg. # 075947)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1222.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vimed Tablet 150mg
	Composition	Each Film coated tablet Contains: Lacosamide…150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6732 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0818172)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	1x14, 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) Tablet, Film Coated USFDA Approved.
	Me-too status	Atcomid 150mg Tablet Atco Lab. Karachi. (Reg.#075949)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1223.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vimed Infusion 200mg/20ml
	Composition	Each 20ml contains: Lacosamide…200mg (IV)
	Diary No. Date of R& I & fee	Form-5 Dy.No 6736 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0808079)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	Glass vial As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT lacosamide 200 mg/20 mL injection 20 ml vial. TGA approved
	Me-too status	Vicomid Injection 200mg/20mL. Reg. No. 85176

	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1224.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Topage 25mg Tablet
	Composition	Each Film coated tablet Contains: Topiramate…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6746 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0818178)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Topamax 25 mg Tablets MHRA Approved
	Me-too status	Topirat tablets 25mg of M/s Gray's Pharma (Reg. # 040867)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved	
1225.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Tricetam Injection 100 mg/ml
	Composition	Each ml contains: Levetiracetam…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6737 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0808074)
	Pharmacological Group	Antiepileptic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5 ml glass vial, As per SRO
	Approval status of product in Referen Regulatory Authorities	Levetiracetam 100 mg/ ml solution for infusion MHRA Approved
	Me-too status	Lumark Injection M/s Searle Pak, Karachi (Reg. # 075873)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved	
1226.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Mestine 10mg Tablet

	Composition	Each Film coated tablet Contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6740 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0818177)
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	EBASTINE ARROW 10 mg film-coated tablets (MHRA)
	Me-too status	Atmos Tablets 10mg of M/s Scotmann Pharmaceuticals (Reg. # 056116)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved	
1227.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Mestine 20 mg Tablet
	Composition	Each Film coated tablet Contains: Ebastine…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6741 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0818179)
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Kestine Netherland Approved.
	Me-too status	"Lobastin Tablet 20mg (Reg. # 080844)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved	
1228.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zolmed Injection 5mg
	Composition	Each Vial Contains: Zoledronic Acid…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6742 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019 (#0808077)
	Pharmacological Group	Bisphosphonates
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	5ml vial & As per SRO
	Approval status of product in Referen Regulatory Authorities	NA

	Me-too status	NA
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	Reference in RRA and DRAP Available references are as 4 mg, 4mg/5 ml, 5 mg/100 ml, 4 mg/100 ml Volume of vial not mentioned
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too statu alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agenc which were declared/approved by the Registration Board**	
1229.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cetra-Med 200mg tablet
	Composition	Each tablet Contains: Piracetam…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8329 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8562 R & I dated 22-04-2020 (#0818199)
	Pharmacological Group	Antiprotozoal
	Form	Form-5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	NA
	Me-too status	NA
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too statu alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agenc which were declared/approved by the Registration Board**	
1230.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ecitopra 20mg Tablet
	Composition	Each Film coated tablet Contains: Escitalopram as Oxalate Escitalopram…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8330 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8572 R & I dated 22-04-2020 (#0818185)
	Pharmacological Group	Selective Serotonin Reuptake inhibitor
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Referen Regulatory Authorities	Escitalopram Oxalate by Teva USFDA
	Me-too status	Escital tablet of M/s Helix Pharma (Reg. # 061635)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved. Registration Board further decided that verification of fee challan may be do as per decision of 285th meeting of Registration Board.	
1231.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ropi-Med 0.5mg Tablet
	Composition	Each Film coated tablet Contains: Ropinirole as HCL…0.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8327 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8566 R & I dated 22-04-2020 (#0818186)
	Pharmacological Group	Antiparkinson drugs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Requip by GSK USFDA
	Me-too status	NA (Ronirole 0.5 mg, # 047377 Could not be confirmed)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	DRAP evidence is needed
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generi me-too status) alongwith registration number, brand name and name of firm.	
1232.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ropi-Med 2mg Tablet
	Composition	Each Film coated tablet Contains: Ropinirole as HCL…2 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8336 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8568 R & I dated 22-04-2020 (#0818189)
	Pharmacological Group	Antiparkinsonian drugs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Requip by GSK (0.25,0.5, 1, 2,5, 3, 4 mg) USFDA
	Me-too status	Ronirol by M/S Hilton Pharma (0.25, 1, 2)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	

	Decision: Approved. Registration Board further decided that verification of fee challan may be do as per decision of 285th meeting of Registration Board.	
1233.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ropi-Med 0.25mg Tablet
	Composition	Each Film coated Tablet Contains: Ropinirole as HCL…0.25 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8333 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8565 R & I dated 22-04-2020 (#0818188)
	Pharmacological Group	Antiparkinsonian drugs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Requip by GSK (0.25,0.5, 1, 2,5, 3, 4 mg) USFDA
	Me-too status	Ronirol by M/S Hilton Pharma (0.25, 1, 2)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved. Registration Board further decided that verification of fee challan may be do as per decision of 285th meeting of Registration Board.	
1234.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ropi-Med 1mg Tablet
	Composition	Each Film coated tablet Contains: Ropinirole as HCL…1 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8334 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8567 R & I dated 22-04-2020 (#0818187)
	Pharmacological Group	Antiparkinsonian drugs
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Requip by GSK (0.25,0.5, 1, 2,5, 3, 4 mg) USFDA
	Me-too status	Ronirol by M/S Hilton Pharma (0.25, 1, 2)
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved. Registration Board further decided that verification of fee challan may be do as per decision of 285th meeting of Registration Board.	
1235.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Gliflozin 25mg Tablet
	Composition	Each Film coated Tablet Contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	(Duplication)

		Form-5 Dy.No 8331 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0818196)
	Pharmacological Group	Antidiabetic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Jardiance By Boehringer Ingelheim USFDA
	Me-too status	NA
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	Submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by registration board in its 251st& 278th meeting respectively
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registrati Board.	
1236.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Gliflozin 10 mg Tablet
	Composition	Each Film coated Tablet Contains: Empagliflozin…10 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8326 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8569 R & I dated 22-04-2020 (#0818200)
	Pharmacological Group	Antidiabetic
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Jardiance By Boehringer Ingelheim USFDA
	Me-too status	NA
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	Submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by registration board in its 251st& 278th meeting respectively
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registrati Board.	
1237.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cetra-Med 400mg Tablet
	Composition	Each film coated tablet Contains: Piracetam…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8322 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8563 R & I dated 22-04-2020 (#0818197)
	Pharmacological Group	Nootropic / Corical Myoclonus
	Form	Form-5

	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Biogaran film-coated 400mg (ANSM, France Approved)
	Me-too status	Ceremin tablet 400mg of M/s Schazoo Pharma Approved in 268th DRB meeting
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification. Registration Board further decided that Verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1238.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cetra-Med 800 mg Tablet
	Composition	Each Film coated tablet Contains: Piracetam…800mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8325 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019 Duplicate File bearing Dy No 8564 R & I dated 22-04-2020 (#0818198)
	Pharmacological Group	Nootropic / Corical Myoclonus
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Piracetam 800mg film-coated tablet. MHRA approved
	Me-too status	Nootropil Tablet 800mg. Reg. No. 82277
	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification. Registration Board further decided th verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
1239.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Clariper 500mg Table
	Composition	Each Film Coated Tablet Contains: Clarithromycin…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8255 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (# 0846593)
	Pharmacological Group	Macrolide
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Clarithromycin 500 mg Film-coated Tablets. MHRA approved
	Me-too status	Clarital 500mg Tablet.(Reg. No. 85500)

	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1240.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Clariper 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8254 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (# 0846592)
	Pharmacological Group	Macrolide
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Clarithromycin 250 mg Film-coated Tablets. MHRA approved
	Me-too status	Clarital 250mg Tablet.(Reg. No. 85501)
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1241.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Perkoten 6mg/25mg Capsule
	Composition	Each Capsule Contains: Olanzapine…6mg Fluoxetine HCL eq to Fluoxetine…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8628-A dated 26-01-2019 Rs.20,000/- Dated 26-01-2019 (Reg # 084660)
	Pharmacological Group	SSRI/Thienobenzodiazepine
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	SYMBYAX capsule by M/s Eli Lilly and Company. (USFDA Approved)
	Me-too status	Olanzo–F 6/25 Capsule by M/s Regal Pharma, Reg No.81974
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1242.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Perkoten 3mg/25mg Capsule
	Composition	Each Capsule Contains: Olanzapine…3mg Fluoxetine HCL eq to Fluoxetine…25mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 8261 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (Reg # 0846599)
	Pharmacological Group	SSRI/Thienobenzodiazepine
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Symbyax 3mg/25 mg Capsules by Ms/ Eli Lilly, USA (USFDA approved).
	Me-too status	Olanco Capsules by Genome Pharma. (Reg. # 079388)
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved	
1243.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk
	Brand Name +Dosage Form + Strength	Didol 325/37.5mg Tablet
	Composition	Each film coated tablet Contains: Paracetamol…325mg Tramadol…37.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8260 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Analgesic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved
	Me-too status	Tramal Plus tablet by M/s Searle Company limited, Reg No.77129
	GMP status	M/S Perk Pharma Last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1244.	Name and address of manufacturer Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ecitopra 5mg Tablet
	Composition	Each Film coated tablet Contains: Escitalopram as Oxalate Escitalopram…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 8335 dated 25-01-2019 Rs.20,000/- Dated 25-01-2019 (#0818183)
	Pharmacological Group	Selective Serotonin Reuptake inhibitor
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Escitalopram Oxalate by Teva USFDA
	Me-too status	Escital tablet of M/s Helix Pharma (Pvt.) Ltd (Reg. # 061635)

	GMP status	M/S Mediate Pharma Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of Evaluator [VII]	
	Decision: Approved	
1245.	Name and address of manufacturer Applicant	M/s Medisynth Pharmaceuticals Plot no 55, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acnezyle 20mg Capsule
	Composition	Each capsule contains: Isotretinoin…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7047 dated 19-02-2019 Rs.20,000/- Dated 29-01-2019 (#0801726)
	Pharmacological Group	Anti- acne preparation/ Retinoids
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	ABSORICA 20 mg by Sun pharma USFDA Approved
	Me-too status	Isotret Capsules of M/s CCL Pharma (Reg. # 045959)
	GMP status	M/S Medisynth Pharma Last inspection conducted on 5-10-2017 for renewal of DML
	Remarks of Evaluator [VII]	Stability data as per directions of 278th meeting of Registration Board shall be submitted.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registrati Board.	
1246.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dynamide 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5826 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519161)
	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 200mg Tablet film-coated. Reg. No. 83978
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1247.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dynamide 150 mg Tablet

	Composition	Each Film Coated Tablet Contains: Lacosamide…150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5825 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519160)
	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 150mg Tablet film-coated. Reg. No. 83977
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1248.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dynamide 50 mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5823 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519158)
	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 50mg Tablet film-coated. Reg. No. 083979
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1249.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dynamide 100 mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5824 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519159)
	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 100mg Tablet film-coated. Reg. No. 83976
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML

	Remarks of Evaluator VII	
	Decision: Approved with innovator's specification.	
1250.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Beta H 8mg Tablet
	Composition	Each Tablet Contains: Betahistine dihydrochloride…8mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5827 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#019162)
	Pharmacological Group	Histamine Analogue
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Betahistine 8mg tablet by M/s Aurobindo Pharma-Milpharm Ltd, MHRA Approved.
	Me-too status	VR-tigo 8mg tablet by M/s Himont Pharma (Reg No. 79703)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator VII	
	Decision: Approved	
1251.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Beta H 16mg Tablet
	Composition	Each Tablet Contains: Betahistine dihydrochloride…16 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5827 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519163)
	Pharmacological Group	Histamine Analogue
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Betahistine 16mg tablet by M/s Aurobindo Pharma-Milpharm ltd, MHRA Approved.
	Me-too status	VR-tigo 16mg tablet by M/s Himont Pharma Reg No. 79704
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator VII	
	Decision: Approved	
1252.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Beta H 24mg Tablet
	Composition	Each uncoated Tablet Contains: Betahistine dihydrochloride…24 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5829 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519164)
	Pharmacological Group	Histamine Analogue
	Form	Form-5

	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Betahistine 24 mg tablet by M/s Aurobindo Pharma-Milpharm ltd, MHRA Approved.
	Me-too status	Stabler 24mg tablet by M/s Nabi Qasim Reg No. 83937
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1253.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dyonate 150mg Tablets
	Composition	Each Film Coated Tablet Contains: Ibandronic Acid as ibandronic sodium monohydrate …150mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5833 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519168)
	Pharmacological Group	Bisphosphonate
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Franjic 150mg Tablet of M/s Martin Dow Ltd. Karachi.(Reg.# 081130)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1254.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dyonate 50mg Tablets
	Composition	Each Film Coated Tablet Contains: Ibandronic Acid as ibandronic sodium monohydrate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5832 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519167)
	Pharmacological Group	Bisphosphonate
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	NA
	Me-too status	NA
	GMP status	M/S Dynatis Pharma Last GMP inspection report d ated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	Evidence of me too and RRA
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too statu**	

	alongwith registration number, brand name and name of firm • **Evidence of approval of applied formulation in reference regulatory authorities/agenc which were declared/approved by the Registration Board**	
1255.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Fusid-B Cream
	Composition	Each gram Contains: Fusidic acid…2% Betamethasone Valerate…0.1%
	Diary No. Date of R& I & fee	Form-5 Dy.No 5837 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0742350)
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Xemacort 20 mg/g + 1 mg/g cream (MHRA Approved)
	Me-too status	Beta-F Cream by Atco Laboratories (Reg# 082104)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	In RRA applied product is as "1 mg betamethasone corresponding to 1,214 mg betamethasone valerate" firm revised its formulation as per RRA (Betamethasone as valerate)
	Decision: Approved with innovator's specification.	
1256.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Fusid 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Sodium Fusidate…250mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5836 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0742347)
	Pharmacological Group	Steroid antibacterial
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Sodium Fusidate Mylan 250 mg film-coated tablets. ANSM approved
	Me-too status	Pandate 250mg Tablets, film-coated. (Reg. No. 81426)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1257.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dyquin 2% Cream
	Composition	Each Gram Contains: Hydroquinone…2%

	Diary No. Date of R& I & fee	Form-5 Dy.No 5834 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0810769)
	Pharmacological Group	Melanin Synthesis Inhibitor
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Symba Skin Toner Cream by M Sarner (1969) Limited. MHRA approved
	Me-too status	Safoquin Cream 2% by Saffron Pharmaceuticals. (Reg. No. 46441)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved	
1258.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dynacort 0.1%+1% Cream
	Composition	Each Gm Contains: Diflucortolone Valerate…0.1% Isoconazole Nitrate…1%
	Diary No. Date of R& I & fee	Form-5 Dy.No 5821 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0742348)
	Pharmacological Group	Corticosteroid, Antifungal (Imidazole derivative)
	Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Travocort 0.1 + 1% w/w Cream by M/s Bayer Limited (HPRA Ireland Approved)
	Me-too status	Travocort 0.1 + 1% w/w Cream by M/s Bayer Healthcare (Reg#005830)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1259.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Pirodyx 20mg Tablet
	Composition	Each Tablet Contains: Piroxicam as beta cyclodextrine…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5831 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519166)
	Pharmacological Group	Anti- inflammatory agents, Non- steroids
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	20, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Cycladol uncoated tablet (ANSM approved)
	Me-too status	Pirujin Tablet M/s Jupiter Pharma

	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1260.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dystine 20mg Tablet
	Composition	Each tablet Contains: Ebastine…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5835 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0742346)
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	1x10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Kestine 20 mg tablet (Approved in Ireland)
	Me-too status	Antine tablets 20 mg of M/s Wise Pharma (Reg. # 068792)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	In RRA film coated tablet, but in manufacturing method provided by firm had no coating step. Firm revised its master formulation for film coating
	Decision: Approved.	
1261.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dystine 10mg Tablet
	Composition	Each Film coated tablet Contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5839 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519169)
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	EBASTINE ARROW 10 mg film-coated tablets
	Me-too status	Atmos Tablets 10mg of M/s Scotsman Pharmaceuticals (Reg. #)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	In RRA film coated tablet, but in manufacturing method provided by firm had no coating step. Firm revised its master formulation for film coating
	Decision: Approved.	
1262.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dyphene 50mg Tablet

	Composition	Each Tablet Contains: Clomiphene Citrate…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5830 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0519168)
	Pharmacological Group	Anti – Oestrogen
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Clomid 50 mg Tablet by Aventis Pharma Limited. (MHRA approved)
	Me-too status	Ovafin 50 mg Tablet by M/s OBS (Reg#019173)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1263.	Name and address of manufacturer Applicant	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dynakomb Ointment
	Composition	Each Gm Contains: Triamcinolone Acetonide…1mg Neomycin Sulphate…2.5mg Gramicidin…0.25mg Nystatin…100,000 Units
	Diary No. Date of R& I & fee	Form-5 Dy.No 5822 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0742349)
	Pharmacological Group	Antibiotic, antifungal glucocorticoid
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Kenacomb ointment by M/s Aspen Pharma Pty Ltd (TGA Approved)
	Me-too status	Kenacomb ointment by M/s GSK (Reg#005026)
	GMP status	M/S Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1264.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Glusit 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate eq base…25mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5801 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0820356)
	Pharmacological Group	Antidiabetic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	7, 14, 21, 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	Januvia™ (Sitagliptin Phosphate) Film Coated Tablets USFDA Approved.

	Me-too status	"Sitagen Tablets 25mg. "Ferozsons Laboratories, Amangarh, Nowshera." (Reg#064195)
	GMP status	M/S Daneen Pharma As per last inspection report dated 08/03/2019, the firm had maintained conformance to GMP compliance in Manufacturing and quality control operations. Sections: Tablet General Encapsulation cephalosporin Oral dry powder suspension cephalosporin Sterile dry powder injection & infusions Cephalosporin *Only cephalosporin dry powder injectable section was operational at the time of inspection.
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1265.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Glusit 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate eq base…50 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7010 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0820357)
	Pharmacological Group	Antidiabetic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	7, 14, 21, 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	Januvia™ (Sitagliptin Phosphate) Film Coated Tablets USFDA Approved.
	Me-too status	"Sitagen Tablets 50mg. "Ferozsons Laboratories, Nowshera." (Reg# 064196)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1266.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Glusit 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate eq base…100 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7011 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0820358)
	Pharmacological Group	Antidiabetic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	7, 14, 21, 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	Januvia™ (Sitagliptin Phosphate) Film Coated Tablets USFDA Approved.
	Me-too status	"Sitagen Tablets 100 mg. "Ferozsons Laboratories, Amangarh, Nowshera." (Reg# 064197)

	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1267.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Perdip 8/5 mg Tablet
	Composition	Each Tablet Contains: Perindopril Tert-Butylamine Eq. to Perindopril 6.68mg…8mg Amlodipine Besylate Eq. to Amlodipine…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5799 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0841059)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	STADA 8/5 mg MHRA Approved
	Me-too status	Coversam Tablet of M/s Servier Research Pharma (Reg. No.065961)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1268.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Perdip 4/10 mg Tablet
	Composition	Each Tablet Contains: Perindopril Tert-Butylamine Eq. to Perindopril 3.34mg…4mg Amlodipine Besylate Eq. to Amlodipine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5798 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0841058)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10,14,20,28,30 As per SRO
	Approval status of product in Referen Regulatory Authorities	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065959)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1269.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Perdip 8/10 mg Tablet

	Composition	Each Tablet Contains: Perindopril Tert-Butylamine Eq. to Perindopril 6.68mg…8mg Amlodipine Besylate Eq. to Amlodipine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5798 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0841060)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10,14,20, 28,30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Perindopril/Amlodipine 8 mg/10 mg tablets MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065960)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1270.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Perdip 4/5 mg Tablet
	Composition	Each Tablet Contains: Perindopril Tert-Butylamine Eq. to Perindopril 3.34mg…4mg Amlodipine Besylate Eq. to Amlodipine…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5797 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 (#0841057)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10,14,20,28,30's As per SRO
	Approval status of product in Referen Regulatory Authorities	STADA 4/5 mg tablet MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065962)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1271.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Lecart 50/12.5/200 mg Tablet
	Composition	Each Film Coated Tablet Contains: Levodopa…50mg Carbidopa…12.5mg Entacapone …200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6293 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0841075)
	Pharmacological Group	Anti-parkinson dopaminergic agent
	Form	Form-5
	Finished product Specifications	Manufacturer specifications

	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Referen Regulatory Authorities	STALEVO 50/12.5/200 mg combination film-coated tablet bottle. USFDA approved
	Me-too status	Obsonerv 12.5/50/200mg Film-coated Tablet R.No.070442
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1272.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Lecart 150/37.5/200 mg Tablet
	Composition	Each Film Coated Tablet Contains: Levodopa…150mg Carbidopa…37.5mg Entacapone …200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6292 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0841076)
	Pharmacological Group	Anti-parkinson dopaminergic agent
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	STALEVO 150/37.5/200 mg combination film-coated tablet bottle. USFDA approved
	Me-too status	Obsonerv 37.5/150/200mg tablet of M/s OBS Pakistan (Reg.# 070443)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1273.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Lecart 100/25/200 mg Tablet
	Composition	Each Film Coated Tablet Contains: Levodopa…100mg Carbidopa…25mg Entacepone…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6291 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0841077)
	Pharmacological Group	Anti-parkinson dopaminergic agent
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	STALEVO 25/100/200mg combination film-coated tablet bottle. USFDA approved
	Me-too status	Obsonerv 25/100/200mg tablet of M/s OBS Pakistan (Reg. # 070444)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	

1274.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Lacos 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6300 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0713966)
	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14' 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 200mg Tablet film-coated. Reg. No. 83978
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1275.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Lacos 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6297 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0841081)
	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14, 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 50mg Tablet film-coated. Reg. No. 083979
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1276.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore,
	Brand Name +Dosage Form + Strength	Lacos 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6289 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0742349)
	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 100mg Tablet film-coated. Reg. No. 83976

	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1277.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Lacos 150 mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…150 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6299 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0841083)
	Pharmacological Group	Other antiepileptic
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14' 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 150mg Tablet film-coated. Reg. No. 83977
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1278.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Vals-H 80/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6295 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0841079)
	Pharmacological Group	Angiotensin II Receptor Antagonist and diuretic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14' 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	Co-Diovan® 80/12.5 mg film-coated tablets. (MHRA Approved)
	Me-too status	Co-Diovan Tablets by Novartis (027359)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1279.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Deptaz Tablet 30 mg
	Composition	Each Film coated Tablet Contains: Mirtazapine…30 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7020 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841091)
	Pharmacological Group	Antidepressants
	Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	20's As per SRO
	Approval status of product in Referen Regulatory Authorities	MHRA Approved
	Me-too status	Elaxine 30 mg Tablets of M/s Standpharm (Reg. # 041965)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1280.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Vilfor Tablets 50mg/1000mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7026 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841089)
	Pharmacological Group	Antihyperglycemic agent
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Galvumet Tablet (TGA Approved)
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	Same As Above
	Remarks of Evaluator [VII]	Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foilpolyvinylchloride/ aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with innovator's specification.	
1281.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Vilfor Tablets 50mg/850mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7025 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841087)
	Pharmacological Group	Antihyperglycemic agent
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	10, 14's As per SRO
	Approval status of product in Referen Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+850mg Tablet M/s Getz
	GMP status	Same As Above
	Remarks of Evaluator [VII]	Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foilpolyvinylchloride/

		aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with innovator's specification.	
1282.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Vilfor Tablets 50mg/500mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7024 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841084)
	Pharmacological Group	Antihyperglycemic agent
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	14 & 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	Galvumet Tablet Of (TGA Approved)
	Me-too status	Galmet 50mg/500mg Table M/s Vision Pharmaceuticals
	GMP status	Same As Above
	Remarks of Evaluator [VII]	Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foilpolyvinylchloride/ aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with innovator's specification.	
1283.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Solin Tablets 10mg
	Composition	Each film coated Tablet Contains: Solifenacin Succinate eq to Solifenacin…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7023 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841097)
	Pharmacological Group	Muscarinic antagonist
	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	10, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Vesicare® (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too status	Solifen Tablet 10mg by M/s GetzPharma, Reg. No. 61203
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1284.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Solin Tablets 5mg
	Composition	Each Film coated Tablet Contains: Solifenacin Succinate eq to Solifenacin…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7022 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841095)
	Pharmacological Group	Muscarinic antagonist

	Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	10, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Vesicare® (5mg& 10mg) film-coated tablet by M/s Astellas Pharma Ltd, MHRA Approved.
	Me-too status	Solifen Tablet 5mg by M/s GetzPharma, Reg. No. 61202
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1285.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Pitava Tablet 4mg
	Composition	Each Film coated Tablet Contains: Pitavastatin Calcium eq to Pitavastatin …4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7019 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (# 0841093)
	Pharmacological Group	Lipid Modifying Agents, Plain
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Livalo film-coated tablet of 1, 2, 4 mg of pitavastatin as calcium (USFDA Approved)
	Me-too status	Pitalo 4mg Tablet by Genix Pharma Reg. No073687
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1286.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Pitava Tablet 1mg
	Composition	Each Film coated Tablet Contains: Pitavastatin Calcium eq to Pitavastatin …1mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7017 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841094)
	Pharmacological Group	Lipid Modifying Agents, Plain
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Livalo film-coated tablet of 1, 2, 4 mg of pitavastatin as calcium (USFDA Approved)
	Me-too status	Pitastin tablet of Atco Lab. Karachi.Reg. No
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	

1287.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Pitava Tablet 2mg
	Composition	Each film coated Tablet Contains: Pitavastatin Calcium eq to Pitavastatin …2mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7018 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (# 0841096)
	Pharmacological Group	Lipid Modifying Agents, Plain
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Livalo film-coated tablet of 1, 2, 4 mg of pitavastatin as calcium (USFDA Approved)
	Me-too status	Pitalip Tablets 2mgBy Hilton Karachi (Reg # 070656)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1288.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Donep 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Donepezil Hydrochloride…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7013 dated 19-12-2019 Rs.20,000 Dated 19-02-2019 (#0841088)
	Pharmacological Group	Anticholinesterases
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10'sAs per SRO
	Approval status of product in Referen Regulatory Authorities	ARICEPT® (donepezil hydrochloride) 10mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Nepezil 10mg film-coated Tablet. Reg No. 83286Pitalip Tablets 2mg By Hilton Karachi (Reg # 070656)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1289.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Donep 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Donepezil Hydrochloride…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7012 dated 19-12-2019 Rs.20,000 Dated 19-02-2019 (# 0841090)
	Pharmacological Group	Anticholinesterases
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's As per SRO

	Approval status of product in Referen Regulatory Authorities	ARICEPT® (donepezil hydrochloride) 5mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Nepezil 5mg film-coated Tablet. Reg No. 83285
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1290.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ondan Tablets 8mg
	Composition	Each Film coated Tablet Contains: Ondansetron HCL Dihydrate eq to Ondasetron…8mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7015 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841085)
	Pharmacological Group	Serotonin (5HT3) antagonists
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	12,10's As per SRO
	Approval status of product in Referen Regulatory Authorities	ZOFRAN (USFDA Approved
	Me-too status	Ondonix 8mg Tablet M/s Genix Pharma
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1291.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ondan Tablets 4mg
	Composition	Each film coated Tablet Contains: Ondasetron HCL Dihydrate eq to Ondasetron…4mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7014 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0841086)
	Pharmacological Group	Serotonin (5HT3) antagonists
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	ZOFRAN film coated 4 mg tablets (USFDA Approved
	Me-too status	Ondonix 4mg Tablet M/s Genix Pharma
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1292.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Buter Tablet 10mg
	Composition	Each Tablet Contains: Bambuterol HCl…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7938 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0836957)

	Pharmacological Group	Selective Beta 2 agonist
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Bambec Tablet by Astrazaneca (MHRA Approved)
	Me-too status	Bambuscot tablet by scotmann (Reg # 029927)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1293.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Buter Tablet 20mg
	Composition	Each Tablet Contains: Bambuterol hcl…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7939 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0742349)
	Pharmacological Group	Selective Beta 2 agonist
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Bambec Tablet by Astrazaneca (MHRA Approved)
	Me-too status	Bambuscot tablet by scotmann
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1294.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Febux Tablet 40mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7939 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0836956)
	Pharmacological Group	Anti-Gout preparation
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	20, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Uloric 40mg Tablet of (USFDA approved)
	Me-too status	Febuxin 40mg Tablet of M/s AGP
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	

1295.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Febux Tablet 120 mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…120 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7942 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0836954)
	Pharmacological Group	Anti-Gout preparation
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	20, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Adenuric 120 mg film-coated tablets Approved by MHRA
	Me-too status	Gouric 120mg Tablets of M/s PharmEvo Pvt Ltd (Reg.#080284)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1296.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Febux Tablet 80 mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…80 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7941 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0836955)
	Pharmacological Group	Anti-Gout preparation
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	20, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Approved in USFDA
	Me-too status	Febuxin 80mg Tablet of AGP Pvt. Ltd. Karachi
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1297.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Harod Tablets 750mg
	Composition	Each Film Coated Tablet Contains: Ciprofloxacin as HCL…750mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7952 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0548108)
	Pharmacological Group	Fluroquinolones
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Referen Regulatory Authorities	Ciprofloxacin 750 mg film coated tablets. MHRA Approved
	Me-too status	CIP Tablets 750 mg. Reg. No. 79347
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1298.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Fordim Tablets 750mg
	Composition	Each Film Coated Tablet Contains: Levofloxacin as hemihydrate…750mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7949 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0548109)
	Pharmacological Group	Fluroquinolones
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's As per SRO
	Approval status of product in Referen Regulatory Authorities	LEVAQUIN® (levofloxacin) tablets (250mg, 500mg, 750mg) film-coated, for oral use. USFDA approved
	Me-too status	Warior 750mg tablet film-coated. Reg. No. 84744
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1299.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Mesart 10 mg tablet
	Composition	Each film-coated tablet contains: Olmesartan Medoxomil……10mg
	Diary No. Date of R& I & fee	D#15714, 20-9-2017; Rs. 20,000/- (#0614797)
	Pharmacological Group	Angiotensin-II Antagonist
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10,14,20,28,30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Olmetec 10mg film-coated tablets (MHRA Approved)
	Me-too status	Olmie 10mg tablet of M/s Getz Pharma (Reg. # 050716)
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved.	

1300.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Mesart 20 mg tablet
	Composition	Each film-coated tablet contains: Olmesartan Medoxomil……20mg
	Diary No. Date of R& I & fee	D#15739, 20-9-2017; Rs. 20,000/-(0614796)
	Pharmacological Group	Angiotensin-II Antagonist
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10,14,20,28,30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Olmetec 20mg film-coated tablets (MHRA Approved)
	Me-too status	Bensar of Pharmevo (Pvt) Ltd
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved.	
1301.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Mesart 40 mg tablet
	Composition	Each film-coated tablet contains: Olmesartan Medoxomil……40mg
	Diary No. Date of R& I & fee	D#15749, 20-9-2017; Rs. 20,000/- (#0614800)
	Pharmacological Group	Angiotensin-II Antagonist
	Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10,14,20,28,30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Olmetec 40mg film-coated tablets (MHRA Approved)
	Me-too status	Olmie 40mg tablet of M/s Getz Pharma (#050718)
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1302.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Zyto 500 mg tablet
	Composition	Each film-coated tablet contains:

		Azithromycin (as dihydrate)….500mg
	Diary No. Date of R& I & fee	D#15753, 20-9-2017; Rs. 20,000/-
	Pharmacological Group	Macrolide (Antibiotics)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3,6,12, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Azithromycin 500 mg Film-coated Tablets Approved in (MHRA)
	Me-too status	Azogil of Glitz Pharm (#060196)
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1303.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Zyto 250 mg capsules
	Composition	Each Capsule contains: Azithromycin (as dihydrate)…….250 mg
	Diary No. Date of R& I & fee	D#15754, 20-9-2017; Rs. 20,000/- (0722234)
	Pharmacological Group	Macrolide (Antibiotics)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	6,10,12, 20 100's As per SRO
	Approval status of product in Referen Regulatory Authorities	Azithromycin 250 mg Capsules Approved in (MHRA)
	Me-too status	Azofas of Fassgen Pharmaceuticals (#060291)
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1304.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ezolin 100 mg/5 ml
	Composition	Each 5ml suspension contains: Linezolid…100mg

	Diary No. Date of R& I & fee	D#15757, 20-9-2017; Rs. 20,000/-(Slip#0722235)
	Pharmacological Group	Antibacterial
	Form	Form-5
	Finished product Specifications	Manufacturers specifications
	Pack size & Demanded Price	60ml / 120ml: As per SRO
	Approval status of product in Referen Regulatory Authorities	Zyvox Dry Suspension by Pharmacia (USFDA Approved)
	Me-too status	Nezolid 100mg Suspension by Searle (Reg# 050326)
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1305.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Irbesar Tablet 150 mg
	Composition	Each film coated tablet contains: Irbesartan … 150 mg
	Diary No. Date of R& I & fee	D#15716, 20-9-2017; Rs. 20,000/- (Slip# 0614799)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10, 14,20,28, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Irbesartan 150 mg Film coated tablet by Accord Healthcare Limited, UK (MHRA approved)
	Me-too status	Gooday 150 mg by Wilson's
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	Firm revise their formulation as film coated tablet alongwith fee of Rs. 5000/- (deposit slip # 1983752) dated 10-06-2020.
	Decision: Approved.	
1306.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Irbesar Tablet 75 mg
	Composition	Each film coated tablet contains: Irbesartan ……. 75 mg
	Diary No. Date of R& I & fee	D#15715, 20-9-2017; Rs. 20,000/- (Slip #0614795)
	Pharmacological Group	Antihypertensive
	Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	10, 14,20,28, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Irbesartan 75 mg Film coated tablet by Accord Healthcare Limited, UK (MHRA approved)
	Me-too status	Gooday 75 mg by Wilson's (#043735)
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	Firm revise their formulation as film coated tablet alongwith fee of Rs. 5000/- (deposit slip # 1983753) dated 10-06-2020.
	Decision: Approved.	
1307.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Mesazone Tablet 400 mg
	Composition	Each modified release tablet contains: Mesalazine.....400 mg
	Diary No. Date of R& I & fee	D#15714, 20-9-2017; Rs. 20,000/- (0722224)
	Pharmacological Group	Aminosalicylate
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,14,20, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Asacol 400mg MR Tablets Approved by MHRA of UK
	Me-too status	Colinil Tablets 400mg by
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1308.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Mesazone Tablet 800 mg
	Composition	Each modified release tablet contains: Mesalazine.....800 mg
	Diary No. Date of R& I & fee	D#15714, 20-9-2017; Rs. 20,000/- (#0722223)
	Pharmacological Group	Amino salicylate
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10,14,20,30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Octasa 800 mg Modified Release Tablets (MHRA of UK)

	Me-too status	Masacol 800mg Tablet by M/s Getz Karachi (Reg#061348)
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved	
1309.	Name and address of manufacturer Applicant	M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad
	Brand Name +Dosage Form + Strength	Amcard 10 mg Tablets
	Composition	Each Tablet Contains: Amlodipine Besylate Eq. to Amlodipine…10 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38416 dated 22-11-2018 Rs.20,000/- Dated 22-11-2018 (# 0570012)
	Pharmacological Group	Calcium channel blocker
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3x10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Norvasc 10 mg by M/S Pfizer (USFDA Approved)
	Me-too status	Amlobest of Pearl Pharmaceuticals (Reg# 026736)
	GMP status	Last GMP inspection was conducted on 07-12-2017 Conclusion: M/s Magns Pharmaceuticals Faisalabad was considered to be operating at good level of compliance with GMP compliance of the firm.
	Remarks of Evaluator [VII]	
	Decision : Approved	
1310.	Name and address of manufacturer Applicant	M/s High-Q Pharmaceuticals, Plot No.224, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Sulfazone 500 mg tablet
	Composition	Each enteric coated tablet contains: Sulfasalazine…….500mg
	Diary No. Date of R& I & fee	D#15757, 20-9-2017; Rs. 20,000/- (Slip# 0722222)
	Pharmacological Group	Aminosalicylic acid
	Form	Form-5
	Finished product Specifications	Innovators
	Pack size & Demanded Price	10, 14, 20, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	Salazopyrin Tablets (MHRA approved)
	Me-too status	Salazodine of M/s Ferozsons (#010358)
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concluded "Based on the areas inspected, the people

		met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of Evaluator [VII]	
	Decision: Approved with innovator's specification.	
1311.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk Manufactuered by Mediate Pharmaceutical (Pvt.) Ltd., Plot # 150, 151 Sector 24, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Ximper 200mg/5ml Dry Suspension
	Diary No. Date of R& I & fee	Form-5 Dy.No 38386 dated 22-11-2018 Rs.50,000/- Dated 22-11-2018 (Slip# 0562625)
	Composition	Each 5ml Contains: Cefixime as Cefixime Trihydrate…200mg
	Pharmacological Group	Third generation cephalosporin antibiotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Cefixime for suspension belcher pharms USFDA Approved
	Me-too status	Cefim-Ds suspension of M/s Hilton Pharma (Reg.# 029082).
	GMP status	Mediate Pharmaceuticals Pvt Ltd Karachi: 02-04-2019. conclusion: The firm is operating at an acceptable level of good compliance with GMP guidelines.
	Remarks of Evaluator [VII]	Contract agreement attached No of Section of applicant: 04 Products on contract manufacturing: Nil
	Decision: Approved	
1312.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk Manufactuered by Mediate Pharmaceutical (Pvt.) Ltd., Plot # 150, 151 Sector 24, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Ximper 100mg/5ml Dry Suspension
	Diary No. Date of R& I & fee	Form-5 Dy.No 38385 dated 22-11-2018 Rs.50,000/- Dated 22-11-2018 (Slip# 0562624)
	Composition	Each 5ml Contains: Cefixime as Cefixime Trihydrate…100mg
	Pharmacological Group	Third generation cephalosporin antibiotic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Cefixime 100 mg/5 ml Powder for Oral Suspension by M/s Generics Ltd (MHRA Approved)
	Me-too status	Cefim Suspension 100mg/5ml by M/s Hilton Pharma (Reg#022108)
	GMP status	Mediate Pharmaceuticals Pvt Ltd Karachi: 02-04-2019. conclusion:

		The firm is operating at an acceptable level of good compliance with GMP guidelines.
	Remarks of Evaluator [VII]	Contract agreement attached No of Section of applicant: 04 Products on contract manufacturing: Nil
	Decision: Approved	
1313.	Name and address of manufacturer Applicant	M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk Manufactuered by Mediate Pharmaceutical (Pvt.) Ltd., Plot # 150, 151 Sector 24, Korangi Industrial Area, Karachi,
	Brand Name +Dosage Form + Strength	Ximper 400mg Capsule
	Diary No. Date of R& I & fee	Form-5 Dy.No 38387 dated 22-11-2018 Rs.50,000/- Dated 22-11-2018 (Slip# 0562626)
	Composition	Each Capsule Contains: Cefixime as Cefixime Trihydrate…400mg
	Pharmacological Group	Third generation cephalosporin antibiotic
	Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	SUPRAX® (cefixime) capsules, for oral use by Lupin Ltd for Lupin Pharma. Approved by (US-FDA)
	Me-too status	Dispel Capsules 400 mg of M/s Fynk Pharmaceuticals (Reg.# 062702)
	GMP status	Mediate Pharmaceuticals Pvt Ltd Karachi: 02-04-2019. conclusion: The firm is operating at an acceptable level of good compliance with GMP guidelines.
	Remarks of Evaluator [VII]	Contract agreement attached No of Section of applicant: 04 Products on contract manufacturing: Nil
	Decision: Approved	
1314.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Loneb 5mg Tablet
	Composition	Each Tablet Contains: Nebivolol HCl Eq. to Nebivolol…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6301 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0713969)
	Pharmacological Group	Beta-1 receptor blocker
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10, 14, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	BYSTOLIC® (nebivolol 5mg) tablets, for oral use by Allergan Sales LLC. US-FDA approved
	Me-too status	Bynevol 5mg Tablet by Atco Lab Karachi. Reg No. 81099
	GMP status	Same As Above
	Remarks of Evaluator [VII]	In RRA it is approved as uncoated tablet but firm applied as film coated on communication firm revised its formulation and form 5 with 5000 fee (Slip #2029176)
	Decision: Approved with innovator's specification.	

1315.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Loneb 10 mg Tablet
	Composition	Each Tablet Contains: Nebivolol HCl Eq. to Nebivolol…10 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6303 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0713968)
	Pharmacological Group	Beta-1 receptor blocker
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14's As per SRO
	Approval status of product in Referen Regulatory Authorities	BYSTOLIC® (nebivolol 10mg) tablets, for oral use by Allergan Sales LLC. US-FDA approved
	Me-too status	Bynevol 10mg Tablet by Atco Lab Karachi. Reg No. 81562
	GMP status	Same As Above
	Remarks of Evaluator [VII]	In RRA it is approved as uncoated tablet but firm applied as film coated on communication firm revised its formulation and form 5 with 5000 fee (Slip #2029177)
	Decision: Approved with innovator's specification.	
1316.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Loneb 2.5 mg Tablet
	Composition	Each Tablet Contains: Nebivolol HCl Eq. to Nebivolol…2.5 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 6302 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019 (#0713967)
	Pharmacological Group	Beta-1 receptor blocker
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10, 14, 30's As per SRO
	Approval status of product in Referen Regulatory Authorities	BYSTOLIC® (nebivolol 2.5 mg) tablets, for oral use by Allergan Sales LLC. US-FDA approved
	Me-too status	Bynevol 2.5mg Tablet by Atco Lab Karachi. Reg No. 81561
	GMP status	Same As Above
	Remarks of Evaluator [VII]	In RRA it is approved as uncoated tablet but firm applied as film coated on communication firm revised its formulation and form 5 with 5000 fee (Slip #2029175)
	Decision: Approved with innovator's specification.	
1317.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Alfac Tablet 0.5mcg
	Composition	Each Tablet Contains: Alfacalcidol…0.5mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7944 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0742349)
	Pharmacological Group	Vitamin D and analogues
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's As per SRO

	Approval status of product in Referen Regulatory Authorities	One alpha tablet 0.5 µg by Teijin Pharma Corporation. PMDA
	Me-too status	Itoride Tablet by Lexicon Pharmaceutical. Reg No. 42040
	GMP status	Same As Above
	Remarks of Evaluator [VII]	In contrary to reference product which is available as uncoated tablet firm has applied for film coated tablet. Upon communication of above observations firm has submitted revised form 5 for uncoated tablets along with submission of fee of Rs.5,000/- vide deposit slip#2029178
	Decision: Approved with innovator's specification.	
1318.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Alfac Tablet 0.25mcg
	Composition	Each Film Coated Tablet Contains: Alfacalcidol…0.25mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7943 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0742349)
	Pharmacological Group	Vitamin D and analogues
	Form	Form-5
	Finished product Specifications	Manufacturere specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Alfacalcidol PMDA Japan
	Me-too status	A-bone by Evergreen Pharma
	GMP status	Same As Above
	Remarks of Evaluator [VII]	In contrary to reference product which is available as uncoated tablet firm has applied for film coated tablet. Upon communication of above observations firm has submitted revised form 5 for uncoated tablets along with submission of fee of Rs.5,000/- vide deposit slip#2029179
	Decision: Approved with innovator's specification.	
1319.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Alfac Tablet 1 mcg
	Composition	Each Film Coated Tablet Contains: Alfacalcidol…1 mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7945 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0836959)
	Pharmacological Group	Vitamin D and analogues
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Calfina tablet, uncoated (1mcg). PMDA approved
	Me-too status	Alfason 1mcg Tablets. Reg. No. 85190
	GMP status	Same As Above
	Remarks of Evaluator [VII]	In contrary to reference product which is available as uncoated tablet firm has applied for film coated tablet. Upon communication of above observations firm has submitted revised form 5 for uncoated tablets along with submission of fee of Rs.5,000/- vide deposit slip#2029180

	Decision: Approved with innovator's specification.	
1320.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Doxo Tablet 400mg
	Composition	Each Tablet Contains: Doxofylline…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7016 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019 (#0830203)
	Pharmacological Group	Systemic drugs for obstructive airway diseases
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's As per SRO
	Approval status of product in Referen Regulatory Authorities	DOXOFILLINA ABC 400 mg uncoated tablet by M/s ABC FARMACEUTICI SpA - Corso Vittorio, AIFA (Italy)
	Me-too status	Profylline tablet 400mg by M/s Kaizen, Reg no. Antine tablets 20 mg of M/s Wise Pharma (Reg. # 73744)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	In contrary to reference product which is available as uncoated tablet firm has applied for film coated tablet in form 5. Upon communication of above observations firm has submitted that our applied formulation is uncoated as there is no coating material in method of manufacturing but typographically we mentioned film coated in form 5 were attached BMR is of uncoated tablet.
	Decision: Deferred for submission of fee for revision of formulation	
1321.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart A Tablet 80mg/10mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine as besylate Amlodipine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7998 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0847614)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan and Amlodipine Tablets 10mg/80mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too status	Misar-Am 80/10mg Tablet of M/s Highnoon Pharma (Pvt) Ltd (Reg. # 069151)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision: Deferred for submission of Installation Qualification (IQ), Performance Qualification (P Reports of required manufacturing equipment i.e. tablet biayered machine.	

1322.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart A Tablet 40mg/10mg
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine as besylate Amlodipine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7397 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0847613)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan and Amlodipine Tablets 10mg/40mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too status	Amtas 10mg + 40mg Tablet of M/s Getz Pharma (Pvt) Ltd (Reg. # 066945)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision: Deferred for submission of Installation Qualification (IQ), Performance Qualification (P Reports of required manufacturing equipment i.e. tablet biayered machine.	
1323.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart A Tablet 80mg/5mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine as besylate Amlodipine…5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7953 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0548110)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan and Amlodipine Tablets 5mg/80mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too status	Amtas 5mg + 80mg Tablet of M/s Getz Pharma (Pvt) Ltd (Reg. # 0669434)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision: Deferred for submission of Installation Qualification (IQ), Performance Qualification (P Reports of required manufacturing equipment i.e. tablet biayered machine.	
1324.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart A Tablet 40mg/5mg
	Composition	Each bilayer Tablet Contains: Telmisartan…40mg Amlodipine as besylate Amlodipine…5mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 7396 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0798433)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan and Amlodipine Tablets 5mg/40mg by M/s Mylan Pharms Inc. (USFDA Approved).
	Me-too status	Amtas 5mg + 40mg Tablet of M/s Getz Pharma (Pvt) Ltd Karachi. (Reg. # 066943)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision: Deferred for submission of Installation Qualification (IQ), Performance Qualification (P Reports of required manufacturing equipment i.e. tablet biayered machine.	
1325.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart Tablet 20mg
	Composition	Each uncoated Tablet Contains: Telmisartan…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7393 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#07498429)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Telmisartan 20mg tablets. MHRA approved
	Me-too status	Telsan 20mg Tablets. Reg. No. 47221
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1326.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart Tablet 40mg
	Composition	Each uncoated Tablet Contains: Telmisartan…40 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7394 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0798430)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	Micardis 40 mg tablets Approved by MHRA of UK
	Me-too status	Telday 40 Tablets of M/s. Novamed Pharmaceuticals, 28-Km, Ferozepur Road, Lahore (Reg.#077141)
	GMP status	Same As Above

	Remarks of Evaluator [VII]	
	Decision: Approved	
1327.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart Tablet 80mg
	Composition	Each Tablet Contains: Telmisartan…80 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7395 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0742349)
	Pharmacological Group	Anti-Hypertensive
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Referen Regulatory Authorities	MICARDISÒ (telmisartan) Tablets, 40 mg and 80 mg (USFDA Approved)
	Me-too status	Misar 80mg Tablets of M/S Highnoon Laboratories
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1328.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Telart H Tablets 40mg/12.5mg
	Composition	Each Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7399 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0798432)
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic)
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status	Cresar–H 40/12.5mg Tablet of M/S Tabros Pharma
	GMP status	Same As Above
	Remarks of Evaluator [VII]	It's a bilayer tablet so Status of Availability of Bilayer compression tablet facility have to confirm. Firm provides the invoice of purchase of rotary tablet press machine (Blest industries) was provided.
	Decision: Deferred for submission of Installation Qualification (IQ), Performance Qualification (P Reports of required manufacturing equipment i.e. tablet biayered machine.	
1329.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Sovil Tablet 100mg/400mg
	Composition	Each Film coated Tablet Contains: Sofosbuvir…400mg Velpatasvir…100mg

	Diary No. Date of R& I & fee	Form-5 Dy.No 7936 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0742349)
	Pharmacological Group	Antivirals
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	7, 14, 28's As per SRO
	Approval status of product in Referen Regulatory Authorities	EPCLUSA® (sofosbuvir and velpatasvir) tablets, (USFDA approved)
	Me-too status	Abriva forte by M/s CCL.
	GMP status	Same As Above
	Remarks of Evaluator [VII]	Submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by registration board in its 251st& 278th meeting respectively
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registrati Board.	
1330.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Valclo Tablet 1g
	Composition	Each Film coated Tablet Contains: Valacyclovir as Hcl eq to Valacyclovir…1g
	Diary No. Date of R& I & fee	Form-5 Dy.No 7937 dated 20-02-2019 Rs.20,000/- Dated 20-02-2019 (#0836958)
	Pharmacological Group	Anti-viral
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5, 10's As per SRO
	Approval status of product in Referen Regulatory Authorities	Valaciclovir 1000 mg film-coated tablets MHRA approved
	Me-too status	Valacloz 1 gby highnoon labs (043842)
	GMP status	Same As Above
	Remarks of Evaluator [VII]	
	Decision: Approved	
1331.	Name and address of manufacturer Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Dicpro delayed release tablet 50mg/200mcg
	Composition	Each Delayed release Tablet Contains: Diclofenac Sodium…50mg Misoprostol…200mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 7950 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019 (#0836970)
	Pharmacological Group	NSAID/Prostaglandins
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's As per SRO
	Approval status of product in Referen Regulatory Authorities	Arthrotec 50 modified-release tablets (MHRA)
	Me-too status	Erwin 50mg of M/s Sami Pharmaceuticals (Reg # 024492)
	GMP status	Same As Above

	Remarks of Evaluator [VII]	The formulation contains misoprostol 1% HPMC dispersion and the formulation contains inner enteric coated layer of diclofenac sodium surrounded by misoprostol dispersion coating and the method of manufacturing submitted is in line with the innovator product.
	Decision: Deferred for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.	

b. Deferred cases

1332.	Name and address of manufacturer / Applicant	Al Fazal Pahrma Industries Pvt) Ltd, 20-21-22 Defense industrial zone-Moman Pura, 16 km sheikupura Road Lahore, (Duplicate)
	Brand Name +Dosage Form + Strength	O-zole 40mg Capsules
	Composition	Omeprazole Pallets (8.5% Enteric Coated)
	Diary No. Date of R& I & fee	Form 5 Not confirmed Not Confirmed Rs. 20,000/- (Duplicate)
	Pharmacological Group	Proton Pump Inhibitor
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14‘s As per SRO
	Approval status of product in Reference Regulatory Authorities	Losec 40 mg hard gastro-resistant capsules 20mg by Astra Zeneca UK Ltd.(MHRA)
	Me-too status	Losec 40mg capsule by M/s Barrett Hodgson
	GMP status	Inspection dated 25-10-2017, Firm need further improvement regarding documentation, SOP, validation process of manufacturing and quality control. However overall up gradation condition was satisfactory
	Remarks of Evaluator [VII]	Source of pellets Missing
	Decision of 281: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. Remarks of evaluator [VII] Source of pellet is provided as Vision pharmaceuticals Islamabad. **Decision: Approved**	
1333.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi.
	Brand Name+ Dosage Form+ Strength	Imuvir 250mg Injection
	Composition	Each vial contains: Ganciclovir sodium equavent Ganciclovir…….250mg (Lyophilized in container)
	Diary No. Date of R&I & fee	Duplicate/Via Letter No. F.1-2/2019-Reg-I dated 12th July 2019, Originally received at 30-12-2014, Rs.Rs.20,000/- (5-11-2014) (Duplicate)
	Pharmacological Group	Antiviral (Nucleoside analogue)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer’s Specification
	Pack Size & Demanded Price	1’s As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Genvir 0.25gm injection (Reg.# 063906)

	GMP status	Last inspection report dated 02-08-2018 concluded that based on the area inspected, people met, and documents reviewed and considering the finding of the inspection, M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of cGMP Requirements at the time of inspection.
	Remarks of Evaluator [VII]	Provided evidence of approval of applied formulation in USFDA as CYTOVENE-IV (ganciclovir sodium) for injection could not be confirmed in 250 mg. Firm provided reference of hungry and switzerland
	Decision of 293: Deferred for evidence of approval of applied formulation in reference regulatory Authorities / agencies which were adopted by the Registration Board in its 275th meeting. Remarks of evaluator [VII] Provided reference is of Switzerland but it could not be confirmed from Swiss medics site. **Decision: Deferred for evidence of approval of applied formulation in reference regulatory Authorities / agencies which were adopted by the Registration Board in its 275th meeting.**	
1334.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi.
	Brand Name+ Dosage Form+ Strength	Imuvir 500 mg Injection
	Composition	Each vial contains: Ganciclovir sodium equavent to Ganciclovir…….500 mg (Lyophylized in container)
	Diary No. Date of R&I & fee	Duplicate/Via Letter No. F.1-2/2019-Reg-I dated 12th July 2019, Originally received at 30-12-2014, Rs.Rs.20,000/- (5-11-2014) (Duplicate)
	Pharmacological Group	Antiviral (Nucleoside analogue)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	1's As per SRO
	Approval status of product in Reference Regulatory Authorities	CYTOVENE-IV (USFDA) in a vile
	Me-too status	Ciganclor freeze dried for injection (Reg#047562)
	GMP status	Last inspection report dated 02-08-2018 concluded that M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of cGMP Requirements at the time of inspection.
	Remarks of Evaluator [VII]	No of contract manufactured products:29
	Decision of 293: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. Remarks of evaluator [VII] The Firm responded that as the innovators product cymevene IV is as sterile lyophilized powder so there product is also in sterile lyophilized powder form. Approval of lyophilized vial section was also provided. **Decision: Deferred for clarification of applied dosage form whether manufactured by way of lyophilization or using ready to fill prelyophilized powder.**	
1335.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Demnac 75/200mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 26421 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017
	Composition	Each Tablet Contains: Diclofenac Sodium…75mg Misoprostol…200Ug

	Pharmacological Group	(Cytoprotactant/NSAID)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x12's As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Arthrotec 75 modified-release tablets (MHRA) but as gastro resistant
	Me-too Status	ARTHO PLUS of Shaigan
	GMP status	Last GMP Inspection of Conducted on …. cGMP certificate is provided.
	Remarks of the Evaluator.	Each tablet consists of a gastro-resistant core containing 75 mg diclofenac sodium surrounded by an outer mantle containing 200 micrograms misoprostol But firm applied as film coated tablet
	Decision of 286: Deferred for revision of formulation and label claim as per the USFDA approved Reference product. Remarks of evaluator [VII] Revised Form 5, and formulation as gestro resistant core containing 75 mg diclofenac sodium surrounding by an outer mantle of 200 microgram of misoprostol along with the fee of 5000/-(Deposit slip # 0820236, dated:31-1-2019) is submitted. Decision of 288: Deferred for confirmation of availability of double compression machine Remarks of evaluator [VII] The firm provided the invoice of dual tablet machine (ZP-33 Dual core) **Decision:** **Deferred for submission of Installation Qualification (IQ), Performance Qualification (PQ) Reports of required manufacturing equipment i.e. tablet biayered machine.**	
1336.	Name and address of manufacturer / Applicant	M/s Karsons Pharmaceuticals.Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Merotech 500mg Injection
	Composition	Each Vial Contains: Meropenem as mixture of Sodium Carbonate Eq. to Meropenem…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38241 dated 20-11-2018 Rs.50,000/- Dated 20-11-2018 (Slip # 0713462)
	Pharmacological Group	Carbapenems
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's As per SRO
	Approval status of product in Reference Regulatory Authorities	Meropenem 500 mg powder for solution for injection or infusion (MHRA)
	Me-too status	Merem Injection 500 mg Global
	GMP status	M/s Rotex pharma: 19-09-2018, Conclusion: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didont possess required machinery and equipments for said purpose.
	Remarks of evaluator	• In RRA formulation is as Meropenem trihydrate (anhydrous) with sodium carbonate as excipient

		• Evidence of applied formulation/drug already approved by DRAP. As provided me too is as Meropenem trihydrate (anhydrous) eq to 1 g not with sodium carbonate. On communication the firm responded that the same formulation of rotex is already approved in 275 meeting. • 4 sections of Karson pharma, 6 products on contract manufacturer
	Decision of 293: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. Remarks of evaluator VII Firm revised form 5 and master formulation as meropenem trihydrate eq to meropenem (Sterile powder) **Decision: Approved.**	
1337.	Name and address of manufacturer / Applicant	M/s Karsons Pharmaceuticals.Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Merotech 1gm Injection
	Composition	Each Vial Contains: Meropenem as mixture of Sodium Carbonate Eq. to Meropenem…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 38242 dated 20-11-2018 Rs.50,000/- Dated 20-11-2018 (Slip # 0713461)
	Pharmacological Group	Carbapenems
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's As per SRO
	Approval status of product in Reference Regulatory Authorities	Meropenem 1 g powder for solution for injection or infusion (MHRA)
	Me-too status	Merem Injection 1 g Global
	GMP status	20-02-2018, Conclusion: Based on the areas inspected the document reviewed and considering the finding of inspection M/s Aspin Pharma is considered to be operating at satis factory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012.
	Remarks of evaluator	In RRA formulation is as Meropenem trihydrate (anhydrous) eq to 500 mg with sodium carbonate as excipient Evidence of applied formulation/drug already approved by DRAP. As provided me too is as Meropenem trihydrate (anhydrous) eq to 500 mg not with sodium carbonate. On communication the firm responded that the same formulation of Rotex is already approved in 275 meeting. 4 sections of Karson pharma, 6 products on contract manufacturer
	Decision of 293: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility. Remarks of evaluator VII Firm revised form 5 and master formulation as meropenem trihydrate eq to meropenem (Sterile	

	powder) **Decision: Approved**	
1338.	Name and address of manufacturer / Applicant	M/s Ciba pharmaceuticals (pvt) Ltd.Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi
	Brand Name +Dosage Form + Strength	Cibadol 500mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 37596 dated 13-11-2018 Rs.20,000/- Dated 12-11-2018 (Slip#0756254)
	Composition	Each Film Coated Tablet Contains: Paracetamol…500mg
	Pharmacological Group	Analgesic
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100, 200, 250, 500's As per SRO
	Approval status of product in Reference Regulatory Authorities	Panadol Advance 500 mg Tablets (MHRA)
	Me-too status	Panadol tablet 500mg by M/s GSK (reg#000817)
	GMP status	M/S Ciba Certificate of GMP, Date: 7th august 2019 (tablet, capsule, oral powder syrup; antibiotics , sachet and ointment gel section (general and steroid)
	Remarks of the Evaluator.	In RRA it is as Uncoated
	Decision of 293: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Remarks of evaluator VII Firm submit that due to typographical error it was written as film coated tablet but in actual it was uncoated tablet. Firm submitted revised form 5, revised master formulation and revised manufacturing method without fee. **Decision: Deferred for submission of fee for revision of formulation**	
Sterile Liquid Ampoule (Steroid)		
1339.	Name and address of manufacturer / Applicant	M/s Novex Phamaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name +Dosage Form + Strength	Durabone 50 mg/ml injection
	Diary No. Date of R& I & fee	Form-5 Dy.No 13671 dated 7-3-2019 Rs.20,000/- Dated 7-3-2019 (Slip#1900342)
	Composition	Each ml ampoule contains:- Nandrolone Decanoate …. 50mg
	Pharmacological Group	Anabolic Steroid
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1`s (1ml) / As per SRO
	Approval status of product in Reference Regulatory Authorities	Deca Duraboli, by Aspen Pharma (1 ml type I ampoules) MHRA approved
	Me-too status	Deca-Durabolin by organon (1ml) (Reg. No.002443)
	GMP status	Panel inspection conducted on 12-02-2019 & 21-02-2019, and the report concludes that the panel unanimously Recommended M/s Novex Pharmaceuticals for the grant of DML
	Remarks of the Evaluator.	The firm don't have Steroidal hormone section
	Decision of 293: Deferred for confirmation of required manufacturing facility / section from Licensing Division Remarks of evaluator VII	

	Firm submit the inspection report in which Sterile Liquid Ampoule (Steroid) is mentioned but The firm don't have Steroidal hormone section **Decision: Deferred for confirmation of manufacturing requisite facility (Steroidal hormone section).**	
Eye Drops Section		
1340.	Name and address of manufacturer / Applicant	M/s Novex Pharmaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name +Dosage Form + Strength	Novocrom 4%w/v ophthalmic solution
	Diary No. Date of R& I & fee	Form-5 Dy.No 13676 dated 7-3-2019 Rs.20,000/- Dated 7-3-2019 (Slip#1900338)
	Composition	Each ml ophthalmic solution contains:- Sodium Cromoglicate …. 40 mg
	Pharmacological Group	Antihistamine
	Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	15 and 10 ml polyethylene bottle As per SRO
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	NA Cromosol Eye Drops 4% M/S polyfine (#032455) Deferred in 292
	GMP status	Panel inspection conducted on 12-02-2019 & 21-02-2019, and the report concludes that the panel unanimously Recommended M/s Novex Pharmaceuticals for the grant of DML
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in same strength and volume in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Letter issued on 23th December 2019.
	Decision of 293: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm •Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Boardi Remarks of evaluator VII Firm submit the following RRA reference of cromolyn sodium: (Cromolyn sodium ophthalmic Drops 4% Akorn USFDA) Me too in DRAP: Ethicrom 4% by M/S Ethical (#013156) **Decision: Approved with innovator's specification.**	
1341.	Name and address of manufacturer / Applicant	Applicant: M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi. Manufacturer: M/s Surge laboratories (Pvt) Ltd., 10km, Faisalabad road Bikhi, Sheikhupura.
	Brand Name+ Dosage Form+ Strength	Isomalt 200mg/2ml Injection
	Composition	Each 2ml contains: Iron as Iron (III) Isomaltoside 1000……200 mg
	Diary No. Date of R&I & fee	Duplicate/Via Letter No. F.1-2/2019-Reg-I dated 12th July 2019, Originally received at 30-12-2014, Rs.Rs.50,000/- (5-11-2014) (Duplicate)
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	2ml amber glass ampoule; 5's and 10's

		As per PRC
	Approval status of product in Reference Regulatory Authorities	Monofer 200 mg/2 ml by Pharmacosmos (Danmark) in glass ampoule
	Me-too status	Monofer by M/s. Allmed Pharmaceuticals (R.No. 072501) Imported product
	GMP status	Last inspection report of surge dated 05-05-2019, Concludes Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Surge Lab, it was concluded that M/s Surge Lab is operating at a good level of cGMP compliance on the day of inspection as per Drugs Act, 1976 and rules framed there under.
	Remarks of Evaluator [VII]	Even after communication of shortcoming firm again claim that 2% overage is added to compensate the loss that occur during manufacturing. The TOC and LPC are available.
	Decision of 293: Deferred for justification on scientific grounds on addition of overage alongwith for confirmation no of already contract manufactured products Remarks of evaluator [VII] Firm submit the letter of commitment for addition of no overage. **Decision: Approved with innovator's specification.**	
1342.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals., Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Brand Name +Dosage Form+ Strength	Thiocol capsule 4 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5059E dated 7-6-2017 Rs 20,000/- Dated 2-6-2017 (Slip#0608270)
	Composition	Each Capsule Contains: Thiocolchicoside as sustained release pellets eq Thiocolchicoside…4mg
	Pharmacological Group	Muscle relaxant
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Myoplege 4mg capsule France (ANSM approved)
	Me-too status	Ezoside capsule 4mg of M/s Akhai Pharma (Reg. # 070427)
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed as sustained release pellets. If indeed applied as pellets then source of pellets is required to be submitted. Letter issued on24th Dec 2019
	Decision of 293: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Remarks of evaluator [VII] Firm submit the revised dossier for each capsule contain Thiocolchicoside …4mg (Without fee) RRA: Myoplege 4mg capsule France (ANSM approved) Me to: Ezoside capsule 4mg of M/s Akhai Pharma	

	(Reg. # 070427) **Decision: Deferred for submission of requisite fee for revision of formulation from Each Capsule Contains: Thiocolchicoside as sustained release pellets eq** **Thiocolchicoside…4mg to each capsule contain Thiocolchicoside …4mg**	
1343.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals., Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Brand Name +Dosage Form+ Strength	Duloxisave capsule 30 mg
	Diary No. Date of R& I & fee	**Duplicate:** Form-5 Dy.No 5059E dated 7-6-2017 Rs 20,000/- Dated 2-6-2017 (Slip#0608274)
	Composition	Each capsule contains: Duloxetine as Duloxetine HCl enteric coated pellets (22.5%)……..…30mg
	Pharmacological Group	Serotonin and noradrenaline reuptake inhibitor
	Form	Form-5
	Finished product Specifications	Manufacturer
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta Capsules by Lilly (USFDA Approved)
	Me-too status	Lyta 30mg Capsules by GETZ Pharmaceuticals (Reg. # 066917)
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	Source of pellets, in case of imported pellets differential fee and stability data of pallets along with valid GMP of manufacturer of pellets is needed. Letter issued on24th Dec 2019
	Decision of 293: Deferred for source of pellets, along with stability studies data, GMP certificate of Supplier and differential fee in case of import of pellets. Remarks of evaluator [VII] Source of pellets is surge laboratories limited **Decision:** **Approved with innovator's specification. Fee shall be verified as per procedure adopted in 285th meeting.**	
1344.	Name and address of manufacturer / Applicant	Applicant: M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi. Manufacturer: M/s Surge laboratories (Pvt) Ltd., 10km, Faisalabad road Bikhi, Sheikhupura.
	Brand Name+ Dosage Form+ Strength	Isomalt 100mg/ml Injection
	Composition	Each 1ml contains: Iron as Iron (III) Isomaltoside 1000……100 mg
	Diary No. Date of R&I & fee	Duplicate/Via Letter No. F.1-2/2019-Reg-I dated 12th July 2019, Originally received at 30-12-2014, Rs.Rs.50,000/- (5-11-2014) (Duplicate)
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	1ml amber glass ampoule; 5's and 10's As per PRC
	Approval status of product in Reference Regulatory Authorities	Monofer 200 mg/2 ml by Pharmacosmos (Danmark) in glass ampoule
	Me-too status	Monofer by M/s. Allmed Pharmaceuticals (Reg.No. 072501)

	GMP status	Last inspection report of surge dated 05-05-2019, Concludes Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Surge Lab, it was concluded that M/s Surge Lab is operating at a good level of cGMP compliance on the day of inspection as per Drugs Act, 1976 and rules framed there under.
	Remarks of Evaluator [VII]	Even after communication of shortcoming firm again claim that 2% overage is added to compensate the loss that occur during manufacturing.
	Decision of 293: Deferred for justification on scientific grounds on addition of overage alongwith for confirmation no of already contract manufactured products Remarks of evaluator [VII] Firm submit the letter of commitment for addition of no overage. **Decision: Approved with innovator's specification.**	
1345.	Name and address of manufacturer / Applicant	Applicant: M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi. Manufacturer: M/s Surge laboratories (Pvt) Ltd., 10km, Faisalabad road Bikhi, Sheikhupura.
	Brand Name+ Dosage Form+ Strength	Isomalt 1000mg/10 ml Injection
	Composition	Each 10 ml contains: Iron as Iron (III) Isomaltoside 1000……1000 mg
	Diary No. Date of R&I & fee	Duplicate/Via Letter No. F.1-2/2019-Reg-I dated 12th July 2019, Originally received at 30-12-2014, Rs.Rs.50,000/- (5-11-2014) (Duplicate)
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10 ml amber glass ampoule; 5's As per PRC
	Approval status of product in Reference Regulatory Authorities	Monofer 1000 mg/10 ml by Pharmacosmos (Danmark) in glass ampoule
	Me-too status	Monofer by M/s. Allmed Pharmaceuticals (R.No. 072501)
	GMP status	Last inspection report of surge dated 05-05-2019, Concludes Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Surge Lab, it was concluded that M/s Surge Lab is operating at a good level of cGMP compliance on the day of inspection as per Drugs Act, 1976 and rules framed there under.
	Remarks of Evaluator [VII]	
	Decision of 293: Deferred for confirmation of already contract manufactured products Remarks of evaluator [VII] Firm has 16 products on contract and 9 new are applied now (Total sections 14) **Decision: Approved with innovator's specification.**	
1346.	Name and address of manufacturer / Applicant	Applicant: M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi. Manufacturer: M/s Surge laboratories (Pvt) Ltd., 10km, Faisalabad road Bikhi, Sheikhupura.
	Brand Name+ Dosage Form+ Strength	Isomalt 500 mg/5 ml Injection
	Composition	Each 5 ml contains: Iron as Iron (III) Isomaltoside 1000……500 mg
	Diary No. Date of R&I & fee	Duplicate/Via Letter No. F.1-2/2019-Reg-I dated 12th July

		2019, Originally received at 30-12-2014, Rs.Rs.50,000/- (5-11-2014) (Duplicate)
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	5 ml amber glass ampoule;2's and 5's As per PRC
	Approval status of product in Reference Regulatory Authorities	Monofer 500 mg/5ml by Pharmacosmos (Danmark) in glass ampoule
	Me-too status	Monofer by M/s. Allmed Pharmaceuticals (Reg# 072501)
	GMP status	Last inspection report of surge dated 05-05-2019, Concludes Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Surge Lab, it was concluded that M/s Surge Lab is operating at a good level of cGMP compliance on the day of inspection as per Drugs Act, 1976 and rules framed there under.
	Remarks of Evaluator [VII]	
	Decision of 293: Deferred for confirmation of already contract manufactured products Remarks of evaluator [VII] Firm has 16 products on contract and 9 new are applied now (14 sections) **Decision: Approved with innovator's specification.**	
1347.	Name and address of manufacturer / Applicant	M/s Wellborne Pharmachem and Biologicals, Plot No. 51/1, 52/2 phase I & II, Industrial Estate, Hattar.
	Brand Name +Dosage Form+ Strength	Colotek injection
	Composition	Each vial contains: Colistimethate Sodium (Lyophilized powder for reconstitution….. (1 Million IU)
	Diary No. Date of R& I & fee	D#15009, 14-9-2017; Rs. 20,000/-
	Pharmacological Group	Antibiotics
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Colistimethate sodium 1 MIU, powder for solution for injection by M/s Panmedica (MHRA Approved) Each vial contains 1 million International Units (IU) which is approximately equivalent to 80 mg of colistimethate sodium
	Me-too status	Colistat powder for Injection 1MIU by M/s Medisure Lab (Reg#076160)
	GMP status	Last GMP inspection was conducted on 27-6-2018 concluded good GMP
	Remarks of evaluator	

	Decision of 283: Deferred for confirmation of manufacturing facility for "Lyophilization Injection (General) section" Remarks of evaluator [VII] Firm has provided the approval letter dated 25 feb 2015 of additional section of "Dry powder vials injectable (general) at place of already approved lyoplized injectable vials general)" approved in 239 meeting of CLB. It is submitted that our facility has dry powder vial injectable general. This product is available as dry powder in MHRA and in Pakistan, Pharmasol. In light of above they undertake that they will not use the label of lyoplized in there finished pack. **Decision: Approved.**

Evaluator PEC-VIII

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

a. New cases

1348.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	jenserk tablets 16mg
	Composition	Each Tablet Contains: Betahistine dihydrochloride …16 mg
	Diary No. Date of R& I & fee	Dy.No 40298 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-vertigo preparations
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)(uncoated)
	Me-too status	Betahistine dihydrochloride 16 mg tablet of M/s. Pulse Pharmaceuticals.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1349.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jenfine Tablets 250mg
	Composition	Each Tablet Contains: Terbinafine (as hydrochloride) … 250mg
	Diary No. Date of R& I & fee	Dy.No 40286 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Antifungals for systemic use
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(uncoated tablet)
	Me-too status	Logirid Tablet 250mg of Lowitt Pharmaceutical (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1350.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jenton 25 mg Tablets

	Composition	Each Film Coated Tablet Contains: Agomelatine…. 25 mg
	Diary No. Date of R& I & fee	Dy.No 40289 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Valdoxan 25mg Tablet of M/S. SERVIER RESEARCH AND PHARMACEUTICALS
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1351.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Erdojen Capsules 300mg
	Composition	Each Capsule Contains: Erdosteine… 300mg
	Diary No. Date of R& I & fee	Dy.No 40290 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Mucolytic agent
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (emc) Erdotin Capsules 300mg BY Edmond Pharma Italy
	Me-too status	Mucostin Capsule 300mg of M/s. Highnoon Laboratories.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1352.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Claritro Tablets 250mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin…250 mg
	Diary No. Date of R& I & fee	Dy. No. 40288 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Macrolide, Anti-Bacterial
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Claramet -250 Tablets of M/s Metro Pharmaceuticals.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1353.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Claritro Tablets 500mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin: 500 mg
	Diary No. Date of R& I & fee	Dy.No 40299 dated 05-12-2018 Rs.20,000/-

	Pharmacological Group	Macrolide, Anti-Bacterial
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Claramet -500 Tablets of M/s Metro Pharmaceuticals.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1354.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Itrajen Capsules 100mg
	Composition	Each Capsule Contains: Itraconazole….100mg (as IR Pellets)
	Diary No. Date of R& I & fee	Dy.No 40849 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antimycotics for systemic use, triazole derivatives
	Type of Form	Form-5
	Finished product Specification	As per Innovator Specifications
	Pack size & Demanded Price	04's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Itrax Capsule 100mg of Ferozsons Labs.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	• COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred for COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	
1355.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Ursojen 250 mg Capsules
	Composition	Each Capsule Contains: Ursodeoxycholic Acid: 250 mg
	Diary No. Date of R& I & fee	Dy.No 40844 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Bile Acid
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA Ursofalk Capsules 250 mg BY Dr. Falk Gemany
	Me-too status	Triptor Capsules 250 mg by CCL
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1356.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Aprejen 80 mg Capsules
	Composition	Each Capsule Contains: Aprepitant… 80 mg

	Diary No. Date of R& I & fee	Dy.No 40845 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(emc)
	Me-too status	Apritus 80mg Capsule of S.J&G Karachi
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1357.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jencept 10 mg Tablets
	Composition	Each Film Coated Tablet Contains: Rivaroxaban… 10 mg
	Diary No. Date of R& I & fee	Dy.No 40847 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-Coagulant
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Xarelto 10 mg Tabs by Bayer
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	Mention isomeric form of rivaroxaban.(S enantiomer)
	Decision: Approved with innovator's specification.	
1358.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Zenzip 30 mg Tablets
	Composition	Each Film Coated Tablet Contains: Mirtazapine…30 mg
	Diary No. Date of R& I & fee	Dy.No 40840 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Presynaptic Alpha II Adrenoceptor antagonist
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Elaxine 30 mg Tablets by Standpharm
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1359.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Zenzip 15 mg Tablets
	Composition	Each Film Coated Tablet Contains: Mirtazapine….15 mg
	Diary No. Date of R& I & fee	Dy.No 40846 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antidepressant

	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Actizipine 15mg Tablet of Zanctok
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1360.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Aprejen 125 mg Capsules
	Composition	Each Capsule Contains: Aprepitant…125 mg
	Diary No. Date of R& I & fee	Dy. No. 40841 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	2's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Apritus 125mg Capsule of S.J&G Karachi
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1361.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Histajen Tablets 20mg
	Composition	Each Film Coated Tablet Contains: Ebastine… 20 mg
	Diary No. Date of R& I & fee	Dy.No 40842 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Systemic Antihistamine
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Swedish Medical agency
	Me-too status	Lobastin Tablet 20mg of Lowitt Pharmaceutical
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
1362.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Levectam Tablets 750mg
	Composition	Each Film Coated Tablet Contains: Levetiracetam … 500 mg
	Diary No. Date of R& I & fee	Dy.No 40851 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA Levetiracetam Sandoz 750 mg Tablets by Sandoz UK
	Me-too status	Fitzloc 750mg Tablet of OBS
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	Strength on fee challan is 750 mg but form 5 is 500mg. Clarify.
	Decision: Approved.	
1363.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jencept 15mg Tablets
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
	Diary No. Date of R& I & fee	Dy.No 40853 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-Coagulant
	Type of Form	Form-5
	Finished product Specification	Innovator' s Specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	072549 "Xarelto 15mg Tablets "M/s. Bayer Pakistan (Private) Limited, Karachi."
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved with innovator's specification.	
1364.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jencept 20 mg Tablets
	Composition	Each Film Coated Tablet Contains: Rivaroxaban… 20 mg
	Diary No. Date of R& I & fee	Dy. No. 40850 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-Coagulant
	Type of Form	Form-5
	Finished product Specification	Innovator' s Specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Rivox Tablet 20 mg of CSH, Pharmaceutical
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	Mention isomeric form of rivaroxaban.(Innovator's isomeric form: S enantiomer)
	Decision: Approved with innovator's specification.	
1365.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Sovistat Tablets 20mg
	Composition	Each film coated tablet contains: Rosuvastatin (as calcium)…. 20mg
	Diary No. Date of R& I & fee	Dy. No. 40838 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Hypolipidaemic, Statin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference	Approved in MHRA (emc)

	Regulatory Authorities.	
	Me-too status	Apollo 20mg Tablets of M/s. Dyson Research Laboratories (Pvt) Ltd,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved as per innovator's specification.	
1366.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Sovistat Tablets 10mg
	Composition	Each film Coated Tablet Contains: Rosuvastatin (as calcium)…. 10mg
	Diary No. Date of R& I & fee	Dy.No 40295 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Hypolipidaemic, Statin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (emc) Crestor 10mg Tablets by AstraZeneca UK
	Me-too status	Apollo 10mg Tablets of M/s. Dyson Research Laboratories (Pvt) Ltd,
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved as per innovator's specification.	
1367.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Valsan 05/80mg Tablets
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)…5 mg Valsartan…80 mg
	Diary No. Date of R& I & fee	Dy.No 41810 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Calcium Antagonist/ Angiotensin II antagonist, (Anti-Hypertensive)
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Amlodine Tablet 5/80 mg of M/s Jupiter Pharma
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1368.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Valsan 5/160mg Tablets
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)…5 mg Valsartan: 160 mg
	Diary No. Date of R& I & fee	Dy.No 41809 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Calcium Antagonist/ Angiotensin II antagonist, (Anti-Hypertensive)
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's, As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Co-Valzaar 5mg/160mg Tablet of Vision Pharmaceuticals.
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	
	Decision: Approved.	
1369.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Valsan 10/160mg Tablets
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)… 10 mg Valsartan…160 mg
	Diary No. Date of R& I & fee	Dy.No. 41811 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Calcium Antagonist/ Angiotensin II antagonist, (Anti-Hypertensive)
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge Of US-FDA
	Me-too status	Amlodine Tablet 10/160mg of M/s Jupiter Pharma
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1370.	Name and address of Manufacturer / Applicant	"M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan"
	Brand Name +Dosage Form +Strength	Tanisol 325/37.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Tramadol hydrochloride…37.5mg Acetaminophen…325mg"
	Diary No. Date of R&I & fee	Dy.No 42003 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Opioid Analgesic/ Analgesic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Radol-P Tablet 325/37.5 mg of M/s Regal Pharmaceuticals
	GMP status	The firm is granted GMP certificate based on inspection dated 20-05-2019.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1371.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Zeepan 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Zolmitriptan…5mg"
	Diary No. Date of R&I & fee	Dy.No 41570 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Selective serotonin (5HT1) agonists
	Type of Form	Form-5

	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	3's ,10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Migzor 5mg Tablet of Hilton Pharma
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1372.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Acirox 25mg Capsule
	Composition	"Each Capsule Contains: Acitretin…25mg"
	Diary No. Date of R&I & fee	Dy.No 41064 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Retinoids for treatment of psoriasis
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	NEOTIGASON CAPSULE 25mg Of MULLER &PHIPPS KARACHI
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didont possess required machinery and equipments for said purpose.
	Remarks of Evaluator (VIII)	
	Decision: Approved.	
1373.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Gerolin-D Dispersible Tablet
	Composition	"Each Orodispersible Tablet Contains: Escitalopram (as oxalate)…10mg"
	Diary No. Date of R&I & fee	Dy.No 41587 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	10's, 14's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA(as film coated tablets)
	Me-too status	Citanew D 10mg Tablet of Hilton Karachi
	GMP status	Dated: 19-09-2018

		Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didont possess required machinery and equipments for said purpose.
	Remarks of Evaluator (VIII)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting, as it is not provided.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting, as provided evidence is not verifiable.	
1374.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Neostig 1ml Injection
	Composition	"Each 1ml Ampoule Contains: Neostigmine methyl sulphate…2.5mg Glycopyrrolate…0.5mg"
	Diary No. Date of R&I & fee	Dy.No 40175 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Anticholinesterases/anticholinergic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's (1ml),: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA(emc)
	Me-too status	Glycate-N Injection of Cirin Pharmaceuticals,
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	• Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.
	Decision: Deferred for the following: **al sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.** **of primary packaging material of applied formulation whether it is Type I, Type II & Type III r.**	
1375.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name+Dosage Form +Strength	Doset 225mg Oral Sachet
	Composition	"Each Sachet Contains: Erdosteine…225mg"
	Diary No. Date of R&I & fee	Dy.No 40202 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Mucolytic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	5's : As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved in MHRA(emc)
	Me-too status	Mucolec 225 mg Sachet of Wnsfeild Pharmaceutical,
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1376.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Mectal 3gm Oral Sachet
	Composition	"Each Sachet Contains: Dioctahedral Smectite…3g"
	Diary No. Date of R&I & fee	Dy.No 40205 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Intestinal Adsorbents
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	30's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Diosmectal 3g powder of Diosmectite for oral suspension by IPSEN S.P.A, approved by Italian Medicines Agency
	Me-too status	Mocta 3gm Sachet of High-Q, Karachi
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1377.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Lincomox 500mg Capsule
	Composition	"Each Capsule Contains: Lincomycin as hydrochloride…500mg"
	Diary No. Date of R&I & fee	Dy.No 41106 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	12's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM
	Me-too status	Loldin 500mg Capsule of Ardin Karachi
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.

	Remarks of Evaluator (VIII)	Reference product contains Lincomycin hydrochloride hydrate clarification regarding hydrate form of API is required.
	Decision: Deferred for the following: • **Clarification regarding hydrate form of API is required as reference product contains Lincomycin hydrochloride hydrate.** • **Confirmation of required equipment i.e. Raman spectroscopy**.	
1378.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Oxazolid 200mg/100ml Injection
	Composition	"Each 100ml Injection Contains: Linezolid…200mg"
	Diary No. Date of R&I & fee	Dy.No 40159 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	1's(100ml) : As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Unizolid 200mg /100ml Infusion of Uni-Tech Karachi
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	• Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.**	
1379.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Phenimide 20mg/2ml Injection
	Composition	"Each 2ml Ampoule Contains: Furosemide…20mg"
	Diary No. Date of R&I & fee	Dy.No 40154 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	50's(2ml) : As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Musem Injectable 20mg/2ml of Mission Pharma
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel

		unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.**	
1380.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Epilap 200mg/20ml Injection
	Composition	"Each 20ml Ampoule Contains: Lacosamide…200mg"
	Diary No. Date of R&I & fee	Dy. No. 40163 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	1's (20ml) : As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Lacolep 10mg/ml Injection (20ml) of Hilton Pharma
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Mention type of primary packaging material of applied formulation. • *USFDA: 200 mg/20 mL is a clear, colorless sterile solution supplied in 20 mL colorless single-dose glass vials.*
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.**	
1381.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Caelyx 4mg/2ml Injection
	Composition	"Each 2ml Ampoule Contains:

		Thiocolchicoside…4mg"
	Diary No. Date of R&I & fee	Dy.No 40200 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	6's (2ml) : As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM
	Me-too status	Muscoril Injection of Sanital Pharmaceutical
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.**	
1382.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Setoride 5mg/5ml Injection
	Composition	"Each 5ml Ampoule Contains: Tropisetron as hydrochloride…5mg"
	Diary No. Date of R&I & fee	Dy.No 41097 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	1's (5ml) : As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Tropiset Injection of M/s. C.C.L Pharmaceuticals
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of Evaluator (VIII)	Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.

	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.**	
1383.	Name and address of Manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form +Strength	Valsa H Tablet 10/320/25mg
	Composition	"Each Film Coated Tablet Contains: Amlodipine (as besylate)…10mg Valsartan…320mg Hydrochlorothiazide…25mg"
	Diary No. Date of R&I & fee	Dy.No 41507 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Calcium channel blocker /angiotensin receptor blockers (ARBs)/diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Aldric-H 10/320/25mg Tablet of Martin Dow
	GMP status Dated: 06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).	
	Remarks of Evaluator (VIII)	
	Decision: Approved.	
1384.	Name and address of Manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form +Strength	Valsa H Tablet 10/160/25mg
	Composition	"Each Film Coated Tablet Contains: Amlodipine (as besylate)…10mg Valsartan…160mg Hydrochlorothiazide…25mg"
	Diary No. Date of R&I & fee	Dy.No 41506 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Calcium channel blocker /angiotensin receptor blockers (ARBs)/diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	As per SRO
	Approval status of product in	Approved in USFDA

	Reference Regulatory Authorities	
	Me-too status	Aldric-H 10/160/25mg Tablet of Martin Dow
	GMP status	Same as recorded for above Application
	Remarks of Evaluator (VIII)	
	Decision: Approved.	
1385.	Name and address of Manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form +Strength	Valsa H Tablet 10/160/25mg
	Composition	"Each Film Coated Tablet Contains: Amlodipine (as besylate)…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R&I & fee	Dy.No 41505 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Calcium channel blocker /angiotensin receptor blockers (ARBs)/diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Aldric-H 5/160/12.5mg Tablet of Martin Dow
	GMP status	Same as recorded for above Application
	Remarks of Evaluator (VIII)	
	Decision: Approved.	
1386.	Name and address of Manufacturer / Applicant	"M/s Gillman Pharmaceuticals. 41/2-A, Phase I & II, Industrial Estate, Hattar, Pakistan By M/s Aulton Pharmaceuticals.Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K"
	Brand Name +Dosage Form +Strength	Keto 30mg/1ml Injection
	Composition	"Each 1ml Amber Glass Ampoule Contains: Ketorolac tromethamine…30mg"
	Diary No. Date of R&I & fee	Dy.No 41506 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	5's (1ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	
	GMP status	Panel Inspection conducted on 12-08-2017 recommended renewal of DML.
	Remarks of Evaluator (VIII)	Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. • Justification on scientific grounds for addition of 5% overage in master formulation.
	Decision: Deferred for the following: • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.** • **Mention type of primary packaging material of applied formulation whether it is Type**	

	I, Type II & Type III glass container. • **Justification on scientific grounds for addition of 5% overage in master formulation.** • **Remaining fee for contract manufacturing** • **Updated GMP status of the applicant firm from QA&LT Division.**	
1387.	Name and address of Manufacturer / Applicant	"M/s Gillman Pharmaceuticals. 41/2-A, Phase I & II, Industrial Estate, Hattar, Pakistan By M/s Aulton Pharmaceuticals.Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K"
	Brand Name +Dosage Form +Strength	Summer-D 1ml Liquid Injection
	Composition	"Each 1ml Amber Glass Ampoule Contains: Cholecalciferol…5mg"
	Diary No. Date of R&I & fee	Dy.No 41703 dated 07-12-2018 Rs.50,000/-
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	5's (1ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Saf-D injection 5mg of Saaaf Pharmaceuticals,
	GMP status	Panel Inspection conducted on 12-08-2017 recommended renewal of DML.
	Remarks of Evaluator (VIII)	• Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. • Justification on scientific grounds for addition of 30% overage in master formulation.
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Justification on scientific grounds for addition of 30% overage in master formulation.** • **Updated GMP status of the applicant firm from QA&LT Division.**	
1388.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Doxin 100mg Capsule
	Composition	"Each Capsule Contains: Doxycycline hyclate Eq. to Doxycycline…100mg"
	Diary No. Date of R&I & fee	Dy.No 41069 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	1's, 6's, 10's, 12,s, 14's, 20's, 30's, 50's, 60's, 80's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Mafmycin 100 mg Capsule of Mafins Karachi
	GMP status	Panel Inspection conducted on 12-08-2017 recommended renewal of DML.
	Remarks of Evaluator (VIII)	
	Decision: Approved.	
1389.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Muscorex 4mg Injection
	Composition	"Each Injection Contains:

		Thiocolchicoside…4mg"
	Diary No. Date of R&I & fee	Dy. No. 41705 dated 07-12-2018 Rs.50,000/-
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form-5
	Finished Product Specification	As per innovator's Specifications
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM (4mg/2ml)
	Me-too status	Could not be confirmed
	GMP status	Panel Inspection conducted on 12-08-2017 recommended renewal of DML.
	Remarks of Evaluator (VIII)	• Evidence of intravenous use of applied formulation. • Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Mention volume of applied formulation. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision: Deferred for the following: • **Evidence of intravenous use of applied formulation.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.** • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container& also mention volume of applied formulation.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.**	
1390.	Name and address of Manufacturer / Applicant	"M/s Gillman Pharmaceuticals. 41/2-A, Phase I & II, Industrial Estate, Hattar, Pakistan By M/s Aulton Pharmaceuticals.Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K"
	Brand Name +Dosage Form +Strength	Linza 100mg/5ml Suspension
	Composition	"Each 5ml Contains: Linezolid…100mg"
	Diary No. Date of R&I & fee	Dy. No. 41704 dated 07-12-2018 Rs.50,000/-
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Manufacturers Specifications
	Pack Size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Dinoza Dry Powder Suspension of Cibex Pharmaceuticals
	GMP status	**Gillman Pharma:** 24-03-2017, Panel recommended the renewal of DML **Aulton Pharma:** The firm was last inspected on 13.02.2018, the firm was operating at good level of compliance with cGMP guidelines

	Remarks of Evaluator (VIII)	
	Decision: Deferred for updated GMP status of the applicant firm from QA&LT Division.	
1391.	Name and address of Manufacturer / Applicant	"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form +Strength	Alkire 150mg Tablet
	Composition	"Each Film Coated Tablet Contains: Aliskiren (as hemifumarate)…150mg"
	Diary No. Date of R&I & fee	Dy.No 43747 dated 24-12-2018 Rs.20,000/-
	Pharmacological Group	Renin-inhibitors
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications
	Pack Size & Demanded Price	7's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Stay Tablet 150mg of Wilson's Pharmaceuticals
	GMP status	GMP Inspection conducted on 07-06-2018 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1392.	Name and address of Manufacturer / Applicant	"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form +Strength	Alkire 300mg Tablet
	Composition	"Each Film Coated Tablet Contains: Aliskiren (as hemifumarate)…300mg"
	Diary No. Date of R&I & fee	Dy.No 43748 dated 24-12-2018 Rs.20,000/-
	Pharmacological Group	Renin-inhibitors
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications
	Pack Size & Demanded Price	7's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Stay Tablet 300mg of Wilson's Pharmaceuticals
	GMP status	GMP Inspection conducted on 07-06-2018 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1393.	Name and address of Manufacturer / Applicant	"M/s Bosch Pharmaceuticals (Pvt.) Ltd.Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form +Strength	Nebivas 5mg/80mg
	Composition	"Each Film Coated Tablet Contains: Nebivolol (as hydrochloride)…5mg Valsartan…80mg"
	Diary No. Date of R&I & fee	Dy.No 43746 dated 24-12-2018 Rs.20,000/-
	Pharmacological Group	Antihypertensive beta blocker, Angiotensin II receptor blocker
	Type of Form	Form-5D
	Finished Product Specification	Innovator's Specifications
	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA

	Me-too status	Stay Tablet 300mg of Wilson's Pharmaceuticals
	GMP status	GMP Inspection conducted on 07-06-2018 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator (VIII)	Please submit stability studies for applied formulation as per guidelines approved in 251st & later amended in 278th meeting of Registration Board.
	Decision: Deferred for submission of stability studies for applied formulation as per guidelines approved in 251st & later amended in 278th meeting of Registration Board, as applied formulation is subsequent drug generic version.	
1394.	Name and address of Manufacturer / Applicant	"M/s Pharmevo Private Limited.Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Brand Name +Dosage Form +Strength	Cloniv 0.1mg Tablet
	Composition	"Each Tablet Contains: Clonidine hydrochloride…0.1mg"
	Diary No. Date of R&I & fee	Dy.No 43244 dated 19-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	30's: Rs.225/- or As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Inspection conducted on 23-02-2018 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of the Evaluator (VIII)	Please submit either the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise stability studies for applied formulation as per guideline approved in 251st & later amended in 278th meeting of Registration Board.
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise stability studies for applied formulation as per guideline approved in 251st & later amended in 278th meeting of Registration Board alongwith submission of differential fee Rupee 30,000/-.	
1395.	Name and address of Manufacturer / Applicant	"M/s Pharmevo Private Limited.Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Brand Name +Dosage Form +Strength	Cloniv 0.2mg Tablet
	Composition	"Each Tablet Contains: Clonidine hydrochloride…0.2mg"
	Diary No. Date of R&I & fee	Dy.No 43246 dated 19-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	30's: Rs.275/- or As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Inspection conducted on 23-02-2018 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of the Evaluator (VIII)	Please submit either the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise stability studies for applied

		formulation as per guideline approved in 251st & later amended in 278th meeting of Registration Board.
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise stability studies for applied formulation as per guideline approved in 251st & later amended in 278th meeting of Registration Board alongwith submission of differential fee Rupee 30,000/-.	
1396.	Name and address of Manufacturer / Applicant	"M/s Pharmevo Private Limited.Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Brand Name +Dosage Form +Strength	Cloniv 0.3mg Tablet
	Composition	"Each Tablet Contains: Clonidine hydrochloride…0.3mg"
	Diary No. Date of R&I & fee	Dy.No 43245 dated 19-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	30's: Rs.315/- or As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Could not be confirmed
	GMP status	GMP Inspection conducted on 23-02-2018 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of the Evaluator (VIII)	Please submit either the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise stability studies for applied formulation as per guideline approved in 251st & later amended in 278th meeting of Registration Board.
	Decision: Deferred for submission of either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise stability studies for applied formulation as per guideline approved in 251st & later amended in 278th meeting of Registration Board alongwith submission of differential fee Rupee 30,000/-.	
1397.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Procit-K XR 10Meq Tablet
	Composition	"Each Extended Release Tablet Contains: Potassium Citrate…10meq"
	Diary No. Date of R&I & fee	Dy.No 41560 dated 07-12-2018 Rs.20,000/
	Pharmacological Group	Alkalinizing Agent
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Urocit-K 10meq Tablets Of Universal Enterprises
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.

	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1398.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Mulac 200mg Oral Sachet
	Composition	"Each Sachet Contains: Acetylcysteine…200mg"
	Diary No. Date of R&I & fee	Dy. No. 40232 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Mucolytic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	30's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Bulgus Sachet of M/s Searle IV Solutions
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1399.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Remin 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Galantamine (as hydrobromide)…4mg"
	Diary No. Date of R&I & fee	Dy.No 41588 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Anticholinesterase
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, 20's, 30's, 14's,: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Reminyl 4mg Tablets of JOHNSON & JOHNSON
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1400.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Laxiz 10gm/15ml Liquid Syrup
	Composition	"Each 15ml Contains: Lactitol…10gm"

	Diary No. Date of R&I & fee	Dy.No 41124 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Osmotic Laxative
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lactitol Monohydrate by M/s Zambon Schweiz AG (Swiss Medica) Switzerland Approved
	Me-too status	Lactowin Syrup of Winthrox Lab
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of the Evaluator (VIII)	• Submit Evidence of availability of HPLC with RI detector. • Reference product is a solution but applied formulation is syrup, Clarify. • Mention type of primary packaging material of applied formulation.
	Decision: Deferred for the following: • **Submit Evidence of availability of HPLC with RI detector.** • **Reference product is a solution but applied formulation is syrup, Clarify.** • **Mention type of primary packaging material of applied formulation.**	
1401.	Name and address of Manufacturer / Applicant	"M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Torivas-E 10/10 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ezetimibe…10mg Atorvastatin (as calcium trihydrate)…10mg"
	Diary No. Date of R&I & fee	Dy.No 41584 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Osmotic Laxative
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, 20's, 30's,: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Z-Tin 10/10mg of Genix Pharma
	GMP status	Dated: 19-09-2018 Recommendations: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didn't possess required machinery and equipment for said purpose.
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1402.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Losta 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin (as calcium) …5mg"

	Diary No. Date of R&I & fee	Dy.No 39634 dated 03-12-2018 Rs.20,000/
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Save-R Tablets 5mg of Wilson's Pharmaceuticals
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification	
1403.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Amlovar 10/160 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Valsartan…160mg"
	Diary No. Date of R&I & fee	Dy.No 39633 dated 03-12-2018 Rs.20,000/
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Co-Valzaar 10mg/160mg Tablet of Vision Pharmaceuticals.
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1404.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Amlovar 5/160 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…160mg"
	Diary No. Date of R&I & fee	Dy.No 39632 dated 03-12-2018 Rs.20,000/-
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished Product Specification	USP Specifications

	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Co-Valzaar 5mg/160mg Tablet of Vision Pharmaceuticals.
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1405.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Amlovar 5/80 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…80mg"
	Diary No. Date of R&I & fee	Dy.No. 39631 dated 03-12-2018 Rs.20,000/-
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Amlodine Tablet 5/80 mg of M/s Jupiter Pharma
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1406.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Fixamin 550mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rifaximin…550mg"
	Diary No. Date of R&I & fee	Dy.No 39630 dated 03-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Rixago 550mg Tablet OBS Pharma Karachi
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow:

		Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1407.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Wincet 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Escitalopram (as oxalate)…10mg"
	Diary No. Date of R&I & fee	Dy.No 39620 dated 03-12-2018 Rs.20,000/
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Citanew 10 mg tablet of Hilton Pharma
	GMP status	Panel Inspection for grant of DML conducted on 12-10-2017 & 12-12-2017 decided as follow: Keeping in view the above improvements made by the firm the members of the panel are of the opinion to recommend the grant of DML for the following sections by the way of formulation: 1. General Tablet Section 2. General Capsule Section 3. Oral Dry Powder Suspension Section(General) 4. Liquid Syrup(General)
	Remarks of the Evaluator (VIII)	
	Decision: Approved	
1408.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Lodisar 10/12.5/160 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine…10mg Hydrochlorothiazide…12.5mg Valsartan…160mg"
	Diary No. Date of R&I & fee	Dy.No 39619 dated 03-12-2018 Rs.20,000/
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Valtec AMH 10/160/12.5 Tablet of Tabros Pharma
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1409.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Lifen 5mg Tablet

	Composition	"Each Film Coated Tablet Contains: Solifenacin Succinate…5mg"
	Diary No. Date of R&I & fee	Dy.No 39625 dated 03-12-2018 Rs.20,000/-
	Pharmacological Group	Antimuscrinic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's, 20's, 40's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Fenaso 5mg of M/s Highnoon
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1410.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Dulet 30mg Capsule
	Composition	"Each Capsule Contains: Duloxetine as hydrochloride…30mg (Delayed Release Pellets) Source of pellets; Vision Pharmaceuticals
	Diary No. Date of R&I & fee	Dy.No 40898 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Serotonin and norepinephrine reuptake inhibitor (SNRI)
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Zenbar capsule 30mg byM/s. Searle, Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1411.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Co-Rize 50/12.5 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Losartan Potassium…50mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R&I & fee	Dy.No 40922 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Angiotensin II receptor blockers /Thiazide Diuretic Anti-hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Lotass Plus 50mg/12.5mg of Getz Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1412.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Diclowin 75mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Diclofenac sodium…75mg" (core than enteric coating)
	Diary No. Date of R&I & fee	Dy.No 40928 dated 06-12-2018 Rs.20,000/-

	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Fedgesic Tablets 75mg of Fedro Pharmaceutical
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	• Evidence of approval of applied formulation as enteric coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation as enteric coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1413.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Acefen 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Aceclofenac…100mg"
	Diary No. Date of R&I & fee	Dy.No 40923 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anti-inflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Rumanac 100mg Tablet OF Noahemis Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1414.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Loret 5mg/5ml Syrup
	Composition	"Each 5ml Syrup Contains: Loratadine…5mg"
	Diary No. Date of R&I & fee	Dy.No 40914 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished Product Specification	USP Specifications (as oral solution)
	Pack Size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA (as solution)(amber glass bottle)
	Me-too status	Loradine Syrup 5mg/5ml of Global Pharmaceuticals
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	Mention type of primary packaging material of applied formulation. Reference product is approved as solution while applied formulation is syrup please clarify.
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation.** • **Submit clarification regarding physical form of applied drug product as reference product is approved as solution while applied formulation is syrup.**	

1415.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Respiez 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Montelukast (as sodium)…10mg"
	Diary No. Date of R&I & fee	Dy.No 40917 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	MonteNovex 10mg Tablet of M/s Herbion Pakistan.
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1416.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Fenoset 200mg Capsule
	Composition	"Each Capsule Contains: Fenofibrate…200mg" (Micronized)
	Diary No. Date of R&I & fee	Dy.No 40901 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Lipid Modifying Agents
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	Corfibrate 200mg Capsule of OBS Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1417.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Antilept 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…500mg"
	Diary No. Date of R&I & fee	Dy.No 40921 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Vetrawin Tablets 500mg tablet of M/s Shrooq Pharmaceuticals (Pvt) Ltd.
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1418.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Zolmy 2.5mg Tablet
	Composition	"Each Film Coated Tablet Contains:

		Zolmitriptan…2.5mg"
	Diary No. Date of R&I & fee	Dy.No 40936 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antimigraine preparations
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	3's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Mitprix 2.5mg Tablets Of Alliance Pharmaceuticals
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1419.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Traxa 250mg Capsule
	Composition	"Each Capsule Contains: Tranexamic Acid…250mg"
	Diary No. Date of R&I & fee	Dy.No 40907 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antifibrinolytic
	Type of Form	Form-5
	Finished Product Specification	Japanese Pharmacopoeia Specifications
	Pack Size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in AIFA
	Me-too status	Haemic 250mg Capsule of Genix Pharma
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1420.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Nebilet 5mg Tablet
	Composition	"Each Tablet Contains: Nebivolol as hydrochloride…5mg"
	Diary No. Date of R&I & fee	Dy.No 40930 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Beta Blocker
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Nebil 5mg Tablet of Getz Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1421.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Smartin 40mg Capsule
	Composition	"Each Capsule Contains: Fluvastatin (as sodium)…40mg"
	Diary No. Date of R&I & fee	Dy.No 40904 dated 06-12-2018 Rs.20,000/
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's,14's,28's: As per SRO
	Approval status of product in	Approved in MHRA

	Reference Regulatory Authorities	
	Me-too status	Liproscot-F Capsule 40mg of Scotmann Pharmaceuticals
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1422.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Irovit 50mg/5ml Syrup
	Composition	"Each 5ml Syrup Contains: Iron III Hydroxide Polymaltose Complex Eq. to Elemental Iron…50mg"
	Diary No. Date of R&I & fee	Dy. No. 40913 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antianeamic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Addfer Syrup 50mg/5ml of Acto Labs, Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1423.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Itowin 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Itopride hydrochloride…50mg"
	Diary No. Date of R&I & fee	Dy.No 40919 dated 06-12-2018 Rs.20,000/
	Pharmacological Group	Propulsive
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in PMDA
	Me-too status	Ganaton by M/s Abbott Pakistan
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1424.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Retina 25mg Capsule
	Composition	"Each Capsule Contains: Acitretin…25mg"
	Diary No. Date of R&I & fee	Dy.No 40902 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Retinoids
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved In US-FDA
	Me-too status	Neotigason Capsule 25mg Of Muller &Phipps
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	

1425.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Hapilet 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Paroxetine (as hydrochloride)…20mg"
	Diary No. Date of R&I & fee	Dy.No 40931 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	antidepressant
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Proxetol tablet 20mg by Linear Pharma.
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1426.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Albawin 200mg Tablet
	Composition	"Each Chewable Tablet Contains: Albendazole…200mg"
	Diary No. Date of R&I & fee	Dy.No 40924 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	2's, 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Not verifiable
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	• Evidence of applied formulation/drug i.e. Albendazole 200mg chewable tablet already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Please submit justification for carrying out film coating of a chewable tablet.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug i.e. Albendazole 200mg chewable tablet already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Submit justification for carrying out film coating of a chewable tablet.**	
1427.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Bilet 500mg Capsule
	Composition	Each Capsule Contains: Ursodeoxycholic Acid…500mg
	Diary No. Date of R&I & fee	Dy.No 40909 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Bile acid
	Type of Form	Form-5
	Finished Product Specification	BP Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ursochol 500 mg capsule, hard By Orifarm Generics A/S (Sweden Approved).
	Me-too status	Triptor Capsule 500mg of M/s CCL Pharmaceuticals
	GMP status	Same as recorded for above application

	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1428.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Clarit 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clarithromycin…250mg"
	Diary No. Date of R&I & fee	Dy.No 40925 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10'S: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Claramet -250 Tablets of M/s Metro Pharmaceuticals.
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1429.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Cardilet 150mg Tablet
	Composition	"Each Film Coated Tablet Contains: Irbesartan…150mg"
	Diary No. Date of R&I & fee	Dy.No 40918 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antihypertensive/Angiotensin II receptor blockers
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Aproval 150mg Tablets Of Aventis Limited, Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1430.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Bilet 250mg Capsule
	Composition	"Each Capsule Contains: Ursodeoxycholic Acid…250mg"
	Diary No. Date of R&I & fee	Dy.No 40908 dated 06-12-2018 Rs.20,000/
	Pharmacological Group	Bil acid
	Type of Form	Form-5
	Finished Product Specification	BP Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Triptor Capsule 250mg of M/s CCL Pharmaceuticals
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1431.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Itrazol 100mg Capsule
	Composition	"Each Capsule Contains: Itraconazole …100mg" (as IR Pellets)

	Diary No. Date of R&I & fee	Dy.No 40905 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	4's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Itrax Capsule 100mg of Ferozsons Labs.
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	• COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred for submission of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	
1432.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Valet 50mg Tablet
	Composition	"Each Tablet Contains: Voriconazole…50mg"
	Diary No. Date of R&I & fee	Dy.No 40933 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Japanese Pharmacopoeia Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA (emc) (film coated)
	Me-too status	Vorinaz 200mg Tablet of Atco Lab. Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	Please submit either evidence of reference product approved as uncoated tablet or otherwise convert it to film coated tablet alongwith submission of requisite fee.
	Decision: Deferred for submission of either evidence of reference product approved as uncoated tablet or otherwise change it to film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
1433.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Fenoset 134mg Capsule
	Composition	"Each Capsule Contains: Fenofibrate…134mg"
	Diary No. Date of R&I & fee	Dy.No 40900 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Lipid Modifying Agents
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	Fenoget 134mg Capsule of Getz Pharma, Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1434.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Antilept 250mg Tablet
	Composition	"Each Film Coated Tablet Contains:

		Levetiracetam…250mg"
	Diary No. Date of R&I & fee	Dy.No 40910 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Vetrawin Tablets 250mg tablet of M/s Shrooq Pharmaceuticals (Pvt) Ltd.
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1435.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Dulet 60mg Capsule
	Composition	"Each Capsule Contains: Duloxetine as hydrochloride…60mg" (Delayed Release Pellets) Source of pellets; Vision Pharmaceuticals
	Diary No. Date of R&I & fee	Dy.No 40899 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Serotonin and norepinephrine reuptake inhibitor (SNRI)
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, 14's;: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Zenbar capsule 60mg by Searle, Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1436.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Valet 200mg Tablet
	Composition	"Each Tablet Contains: Voriconazole…200mg"
	Diary No. Date of R&I & fee	Dy.No 40934 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Japanese Pharmacopoeia Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA (emc) (film coated)
	Me-too status	Vorinaz 200mg Tablet of Atco Lab. Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	Please submit either evidence of reference product approved as uncoated tablet or otherwise convert it to film coated tablet alongwith submission of requisite fee.
	Decision: Deferred for submission of either evidence of reference product approved as uncoated tablet or otherwise change it to film coated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
1437.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Smartin 20mg Capsule
	Composition	"Each Capsule Contains:

		Fluvastatin (as sodium)…20mg"
	Diary No. Date of R&I & fee	Dy.No 40903 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, 14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Farmastin Capsules 20mg of Farmaceutics Int. Karachi
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1438.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Fluxet 20mg Capsule
	Composition	"Each Capsule Contains: Fluoxetine as hydrochloride…20mg"
	Diary No. Date of R&I & fee	Dy.No 40902 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Fluxyan 20mg Capsules of Nenza Pharmaceuticals,
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1439.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Diclowin 50mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Diclofenac Sodium…50mg"
	Diary No. Date of R&I & fee	Dy. No .40927 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Fedgesic Tablets 50mg of Fedro Pharmaceutical,
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1440.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore"
	Brand Name +Dosage Form +Strength	Clarit 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clarithromycin…500mg"
	Diary No. Date of R&I & fee	Dy.No 40926 dated 06-12-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA

	Me-too status	Claramet -500 Tablets of M/s Metro Pharmaceuticals.
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1441.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore BY M/S Bio Labs Pvt Ltd Plot.no.145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form +Strength	Mecowin 500mcg Ampoule
	Composition	"Each ampoule contains: Mecobalamin…500mcg"
	Diary No. Date of R&I & fee	Dy.No 40954 dated 06-12-2018 Rs.50,000/-
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished Product Specification	Specifications
	Pack Size & Demanded Price	: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in PMDA (as provided by the firm)
	Me-too status	Nervpower of 500mcg of Swiss Pharmaceuticals
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1442.	Name and address of Manufacturer / Applicant	"M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form +Strength	Fenoset 67mg Capsule
	Composition	"Each Capsule Contains: Fenofibrate…67mg" (micronized)
	Diary No. Date of R&I & fee	Dy.No 41785 dated 07-12-2018 Rs.20,000/-
	Pharmacological Group	Lipid Modifying Agents
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	Corfibrate 67mg Capsule of OBS Karachi
	GMP status	Same as recorded for above application.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1443.	Name and address of manufacturer / Applicant	"M/s Ciba pharmaceuticals (pvt) Ltd.Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi"
	Brand Name +Dosage Form + Strength	Cibval-A 5/160 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as besylate…5mg " Valsartan… 160mg
	Diary No. Date of R& I & fee	Dy.No 38941 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	7's, 14's, 28's, 30's, 56's, 90's, 98: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and	Co-Valzaar 5mg/160mg Tablet of Vision Pharmaceuticals.

	dosage form)	
	GMP status	Dated: 20-08-2019 Certificate of GMP issued on 20-08-2019.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1444.	Name and address of manufacturer / Applicant	"M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi"
	Brand Name +Dosage Form + Strength	Cibval-A 10/160 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as besylate…10mg" Valsartan…160mg
	Diary No. Date of R& I & fee	Dy.No 38942 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	7's, 14's, 28's, 30's, 56's, 90's, 98: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Co-Valzaar 10mg/160mg Tablet of Vision Pharmaceuticals.
	GMP status	Dated: 20-08-2019 Certificate of GMP issued on 20-08-2019.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1445.	Name and address of manufacturer / Applicant	"M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi"
	Brand Name +Dosage Form + Strength	Cibval-A 5/80 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as besylate…5mg" Valsartan…80mg
	Diary No. Date of R& I & fee	Dy.No 38940 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	7's, 14's, 28's, 30's, 56's, 90's, 98: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Amlodine Tablet 5/80 mg of M/s Jupiter Pharma
	GMP status	Dated: 20-08-2019 Certificate of GMP issued on 20-08-2019.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1446.	Name and address of manufacturer / Applicant	"M/s Ciba pharmaceuticals (pvt) Ltd.Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi"
	Brand Name +Dosage Form + Strength	Cibval-H 160/25 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Valsartan…160mg Hydrochlorothiazide…25mg"
	Diary No. Date of R& I & fee	Dy.No 38939 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	USP Specifications

	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status (with strength and dosage form)	Co-Sartan Tablets of Werrick Pharmaceuticals,
	GMP status	Dated: 20-08-2019 Certificate of GMP issued on 20-08-2019.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1447.	Name and address of manufacturer / Applicant	"M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrail Area, superhighway, Karachi"
	Brand Name +Dosage Form + Strength	Cibval-H 160/12.5 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Valsartan…160mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 38938 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status (with strength and dosage form)	CO-DIOVAN Tablets Of NOVARTIS PHARMA,
	GMP status	Dated: 20-08-2019 Certificate of GMP issued on 20-08-2019.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1448.	Name and address of manufacturer / Applicant	"M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad"
	Brand Name +Dosage Form + Strength	Linzopearl 100mg/5ml Oral Suspension
	Composition	"Each 5ml Contains: Linezolid…100mg"
	Diary No. Date of R& I & fee	Dy.No 38921 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	(60ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Linzol 100mg /5ml oral dry suspension of M/s Regal Pharmaceuticals
	GMP status	GMP inspection conducted on 23-07-2018 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator (VIII)	Mention type of primary packaging material of applied formulation. Mention polymeric form of Linezolid
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation.** • **Mention polymeric form of Linezolid.**	

1449.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Ltd.Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Rebosta 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rebamipide…100mg"
	Diary No. Date of R& I & fee	Dy.No 37119 dated 09-11-2018 Rs.20,000/-
	Pharmacological Group	Drugs for peptic ulcer and gastro-esophageal reflux disease (GORD)
	Type of Form	Form-5
	Finished product Specifications	JP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	Mucosta tablet 100mg of M/s Regal Pharmaceuticals(uncoated)
	GMP status	Dated: 29-01-2019 The firm is overall GMP compliant.
	Remarks of the Evaluator (VIII)	
	Decision: Deferred for evidence of Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1450.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad"
	Brand Name +Dosage Form + Strength	Pizo 0.5mg Tablet
	Composition	"Each Sugar Coated Tablet Contains: Pizotifen (as maleate)…0.5mg"
	Diary No. Date of R& I & fee	Dy. No. 37116/4 dated 09-11-2018 Rs.20,000/-
	Pharmacological Group	Antimigraine)
	Type of Form	Form-5
	Finished product Specifications	JP Specifications(not found)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Mosegor 0.5mg sugar coated tablet of M/s Novartis
	GMP status	Dated: 10-10-2018 & 17-10-2018 Recommendations: Firm has been adhering to GMP guidelines and showing good compliance with quality policy completely implemented. Guidelines, SOP's and written instructions for each and every step in manufacturing testing, and storage ensuring quality products are intact and implemented. Keeping in view the above, the panel unanimously recommends for grant of GMP certificate.
	Remarks of the Evaluator (VIII)	• Evidence of approval of applied formulation as sugar coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting & also submit master formulation &manufacturing in line with reference product.
	Decision: Deferred for evidence of approval of applied formulation as sugar coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting & also submit master formulation & manufacturing in line with reference product.	

1451.	Name and address of manufacturer / Applicant	"M/s Medicon Pharmaceuticals Pvt Ltd. Industrial Estate, Jamrud Road, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Medilate 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Montelukast sodium…10mg"
	Diary No. Date of R& I & fee	Dy.No 37102 dated 08-11-2018 Rs.20,000/-
	Pharmacological Group	Antiasthematic
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Moutimak Tablets 10 mg of Makson Pharmaceuticals
	GMP status	GMP inspection conducted on Nov 22, 2018 concluded that firm is directed to prepare a plan for the rectification of all deficienceies noted by them at the earliest. Directions to firm: • Caliberation of all equipment • Preparation & upgradation of all SOPs production & QC • Preparation & upgradation of testing method according to latest pharmacopoeia • Purchase of potentiometer, karl fischer, FTIR & upgradation of HPLC • Adaptation of official testing method • Validation of stability chamber & drafting of SOPs • Training of staff • Appointment of QA staff as per rules
	Remarks of the Evaluator (VIII)	Reference product is approved as Montelukast as sodium 10mg tablet which is different from applied formulation. Submit master formulation & manufacturing method after correction.
	Decision: Deferred for the following: • **Reference product is approved as Montelukast as sodium 10mg tablet which is different from applied formulation. Submit master formulation & manufacturing method after correction.** • **Submit latest GMP inspection report.**	
1452.	Name and address of manufacturer / Applicant	"M/s Medicon Pharmaceuticals Pvt Ltd. Industrial Estate, Jamrud Road, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Moxicon 400mg Tablet
	Composition	"Each Tablet Contains: Moxifloxacin as hydrochloride…400mg"
	Diary No. Date of R& I & fee	Dy.No 37104 dated 08-11-2018 Rs.20,000/-
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	5's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA Avelox 400mg film-coated tablets byM/s Bayerplc,
	Me-too status (with strength and dosage form)	Molinza tablet 400mg M/S Zafa

	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)[VIII]	Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision: Deferred for the following: • **Clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.** • **Submit latest GMP inspection report.**	
1453.	Name and address of manufacturer / Applicant	"M/s Medicon Pharmaceuticals Pvt Ltd. Industrial Estate, Jamrud Road, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Pantomed 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pantoprazole Sodium…40mg"
	Diary No. Date of R& I & fee	Dy.No 37105 dated 08-11-2018 Rs.20,000/-
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Flexura 50mg Tablets of Fassgen Pharmaceuticals
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	Reference product is approved as enteric coated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet.
	Decision: Deferred for the following: • **Either evidence of reference product approved as film coated tablet or otherwise revision of formulation in line with reference product i.e. enteric coated tablet alongwith submission of requisite fee.** • **Submit latest GMP inspection report**	
1454.	Name and address of manufacturer / Applicant	"M/s OBS Pakistan Private Limited. C-14, S.I.T.E, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Pepcidine 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Famotidine…10mg"
	Diary No. Date of R& I & fee	Dy. No. 37194 dated 09-11-2018 Rs.20,000/-
	Pharmacological Group	H2-receptor antagonists
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	6's, 12's, 24's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA(but label is not available so film coating is not confirmed)
	Me-too status (with strength and dosage form)	Famoscot Tablets 10mg of Scotmann Pharmaceuticals,
	GMP status	GMP inspection conducted at 28-05-18 concluded current level of compliance as good.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	

1455.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Ivanic 7.5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ivabradine (as hydrochloride)…7.5mg"
	Diary No. Date of R& I & fee	Dy.No 38720 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	C01EB: Other cardiac preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Iva Tablet 7.5 mg of CSH, Pharmaceuticals-North (Pvt.) Ltd.
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	Please clarify whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision: Deferred for clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing does not contain step of coating.	
1456.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Ivanic 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Ivabradine (as hydrochloride)…5mg"
	Diary No. Date of R& I & fee	Dy.No 38719 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	C01EB: Other cardiac preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Iva Tablet 5 mg of CSH, Pharmaceuticals-North (Pvt.) Ltd.
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	Please clarify whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision: Deferred for clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing does not contain step of coating.	
1457.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Rexira 2mg Tablets
	Composition	"Each Film Coated Tablet Contains: Brexpiprazole…2mg"
	Diary No. Date of R& I & fee	Dy.No 38722 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1458.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Rexira 1mg Tablets
	Composition	"Each Film Coated Tablet Contains: Brexpiprazole…1mg"
	Diary No. Date of R& I & fee	Dy.No 38721 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

1459.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Vilazo 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Vilazodone hydrochloride…10mg"
	Diary No. Date of R& I & fee	Dy.No 38726 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 15's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA(film coated)
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Please clarify whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.**	
1460.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Vilazo 20mg Tablets
	Composition	"Each Film Coated Tablet Contains: Vilazodone hydrochloride…20mg"
	Diary No. Date of R& I & fee	Dy.No 38727 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 15's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA(film coated)
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of**	

	manufacturing do not contain step of coating.	
1461.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Vilazo 40mg Tablets
	Composition	"Each Film Coated Tablet Contains: Vilazodone hydrochloride…40mg"
	Diary No. Date of R& I & fee	Dy.No 38728 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 15's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA(film coated)
	Me-too status (with strength and dosage form)	Not Provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.**	
1462.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Bivolol 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Nebivolol as hydrochloride…10mg"
	Diary No. Date of R& I & fee	Dy.No 38718 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 10mg of "M/s. Dyson Research Laboratories.
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet.
	Decision: Deferred for either submission of evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	

1463.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Bivolol 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Nebivolol as hydrochloride…5mg"
	Diary No. Date of R& I & fee	Dy.No 38717 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's: 14's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nibovo Tablets 10mg of "M/s. Dyson Research Laboratories.
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet.
	Decision: Deferred for either submission of evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
1464.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Caberlin 0.5mg Tablets
	Composition	"Each Tablet Contains: Cabergoline…0.5mg"
	Diary No. Date of R& I & fee	Dy.No 38716 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	Dopamine agonists
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	30's: 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA 0.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status (with strength and dosage form)	Not provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
1465.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Methimax 5mg Tablets
	Composition	"Each Tablet Contains: Methimazole…5mg"
	Diary No. Date of R& I & fee	Dy.No 39118 dated 28-11-2018 Rs.20,000/-
	Pharmacological Group	anti-hyperthyroidism
	Type of Form	Form-5

	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 50,s: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA 0.5MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status (with strength and dosage form)	Not provided
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.**	
1466.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Loxo 60mg Tablets
	Composition	"Each Tablet Contains: Loxoprofen sodium as dihydrate…60mg"
	Diary No. Date of R& I & fee	Dy. No. 39119 dated 28-11-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	30's, 100,s: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in PMDA(uncoated tablet)
	Me-too status (with strength and dosage form)	Qizta Tablets of M/s Wilshire Laboratories,
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision: Deferred for clarification for applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.	
1467.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Telista 10/40 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy. No. 39130 dated 28-11-2018 Rs.20,000/-
	Pharmacological Group	Calcium Channel blocker/ Angiotensin II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications

	Pack size & Demanded Price	4's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Telam 40mg/10mg of Macter Intr.Karachi
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product is multilayer uncoated tablet but you have applied for single layer coated tablet you are required to submit master formulation & manufacturing method either in line with reference product or evidence of approval of reference product as coated single layer tablet.
	Decision: Deferred for submission of either evidenceof approval of reference product as coated single layer tablet or otherwise revision of applied formulation in line with reference product i.e. multilayer uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
1468.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Telista 5/80 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Telmisartan…80mg"
	Diary No. Date of R& I & fee	Dy.No 39131 dated 28-11-2018 Rs.20,000/-
	Pharmacological Group	Calcium Channel blocker/ Angiotensin II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Telam 80mg/5mg of Macter Intr.Karachi
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.
	Remarks of the Evaluator (VIII)	• Reference product is multilayer uncoated tablet but you have applied for single layer coated tablet you are required to submit master formulation & manufacturing method either in line with reference product or evidence of approval of reference product as coated single layer tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as coated single layer tablet or otherwise revision of applied formulation in line with reference product i.e. multilayer uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
1469.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Seromet 500/85 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Naproxen sodium…500mg Sumatriptan as succinate…85mg"
	Diary No. Date of R& I & fee	Dy. No. 38715 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	NSAID/ Selective serotonin (5HT1) agonists
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	6's, 10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA(film coated)
	Me-too status (with strength and dosage form)	Migrot Plus Tablet of Genix Karachi
	GMP status	Dated: 11-03-2017 GMP was Satisfactory.

	Remarks of the Evaluator (VIII)	• Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision: Deferred for clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.	
1470.	Name and address of manufacturer / Applicant	"M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Loxit 20mg Capsule
	Composition	"Each Capsule Contains: Duloxetine HCl Eq. to Duloxetine…20mg" (enteric coated pellets)
	Diary No. Date of R& I & fee	Dy.No 38955 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	antidepressants
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Swenta 20mg Capsule of Martin Dow, Karachi.
	GMP status	GMP inspection report conducted on 12-03-2018 concluded that firm is operating at satisfactory level of GMP compliance on the day of inspection.
	Remarks of the Evaluator (VIII)	• COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred for submission of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	
1471.	Name and address of manufacturer / Applicant	"M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Loxit 30mg Capsule
	Composition	"Each Capsule Contains: Duloxetine HCl Eq. to Duloxetine…30mg" (enteric coated pellets)
	Diary No. Date of R& I & fee	Dy.No 38956 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	antidepressants
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Swenta 30mg Capsule of Martin Dow, Karachi.
	GMP status	GMP inspection report conducted on 12-03-2018 concluded that firm is operating at satisfactory level of GMP compliance on the day of inspection.
	Remarks of the Evaluator (VIII)	• COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred for submission of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	
1472.	Name and address of manufacturer / Applicant	"M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad"
	Brand Name +Dosage Form + Strength	Terbipearl 1% Cream

	Composition	"Each Gram Contains: Terbinafine as HCL…1% w/w"
	Diary No. Date of R& I & fee	Dy. No. 38920 dated 27-11-2018 Rs.20,000/-
	Pharmacological Group	Fungal-Anti
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Exinofin Cream of Brookes Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 23-07-2018 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator (VIII)	• Reference product is approved as Terbinafine hydrochloride 1.0% w/w cream which is different from applied formulation i.e. Terbinafine as HCL 1% w/w"& also submit label claim of applied formulation in line with innovator product. • Mention primary packaging material for applied formulation.
	Decision: Deferred for the following: • **Reference product is approved as Terbinafine hydrochloride 1.0% w/w cream which is different from applied formulation i.e. Terbinafine as HCL 1% w/w"& also submit label claim of applied formulation in line with innovator product.** • **Mention primary packaging material for applied formulation.**	
1473.	Name and address of manufacturer / Applicant	"M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Ebacon 5mg/5ml Liquid
	Composition	"Each 5ml Contains: Ebastine…5mg"
	Diary No. Date of R& I & fee	Dy. No. 37185 dated 09-11-2018 Rs.20,000/-
	Pharmacological Group	allergic-Anti
	Type of Form	Form-5
	Finished product Specifications	Innovator's Specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Exinofin Cream of Brookes Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 23-07-2018 concluded that firm is operating at fair level of GMP compliance.
	Remarks of the Evaluator (VIII)	Mention primary packaging material for applied formulation.
	Decision: Deferred for the following: • **Mention primary packaging material for applied formulation.**	
1474.	Name and address of manufacturer / Applicant	"M/s Otsuka Pakistan Ltd,F/4-9, Hub Industrial Tradin Estate, Distt Lasbella, Balochistan"
	Brand Name +Dosage Form + Strength	Totsunil 10mg/ml Injection
	Composition	"Each ml Contains: Nalbuphine hydrochloride…10mg"
	Diary No. Date of R& I & fee	Dy.No 38595 dated 23-11-2018 Rs.20,000/-
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications

	Pack size & Demanded Price	8's (1ml) (LDPE ampoule) :Rupee 100/- per 1 ampoule
	Approval status of product in Reference Regulatory Authorities	Approved in Health Canada (10mg/ml), 10MG/ML **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status (with strength and dosage form)	Nalfy Injection 10mg of M/s Vision Pharmaceuticals,
	GMP status	Dated: 13-12-2017 Conclusion: Based on the areas visited people met and documentation reviewed and found good and compliant as per GMP requirement."
	Remarks of the Evaluator (VIII)	Please submit evidence of reference product packed in LDPE ampoule. Please submit clarification/justification on scientific basis for not performing terminal sterilization of applied formulation
	Decision: Deferred for the following: • **Submit evidence of reference product packed in LDPE ampoule.** • **Submit clarification/justification on scientific basis for not performing terminal sterilization of applied formulation.**	
1475.	Name and address of manufacturer / Applicant	"M/s Otsuka Pakistan Ltd, F/4-9, Hub Industrial Tradin Estate, Distt Lasbell, Balochistan"
	Brand Name +Dosage Form + Strength	Totsunil 20mg/ml Injection
	Composition	"Each ml Contains: Nalbuphine hydrochloride…20mg"
	Diary No. Date of R& I & fee	Dy.No 38596 dated 23-11-2018 Rs.20,000/-
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	1's (LDPE ampoule) :Rupee 150/-
	Approval status of product in Reference Regulatory Authorities	Approved in Health Canada (as provided by firm), it is for 10mg/ml 20MG/ML **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status (with strength and dosage form)	Nalbin Injection Of Global Pharmaceutical
	GMP status	Dated: 13-12-2017 Conclusion: Based on the areas visited people met and documentation reviewed and found good and compliant as per GMP requirement."
	Remarks of the Evaluator (VIII)	Please submit evidence of reference product packed in LDPE ampoule. Please submit clarification/justification on scientific basis for not performing terminal sterilization of applied formulation
	Decision: Deferred for the following: • **Submit evidence of reference product packed in LDPE ampoule.** • **Submit clarification/justification on scientific basis for not performing terminal sterilization of applied formulation.**	

1476.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Loxic 15mg Tablets
	Composition	"Each Tablet Contains: Meloxicam…15mg"
	Diary No. Date of R& I & fee	Dy.No 38734 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Orthicam Tablet 15mg of M/s Linear Parma,
	GMP status	Date: 29-03-2019. Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnels, Quality control/QA and production operations. Keeping in view the abservations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1477.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind, Lahore"
	Brand Name +Dosage Form + Strength	Loxic 7.5mg Tablets
	Composition	"Each Tablet Contains: Meloxicam…7.5mg"
	Diary No. Date of R& I & fee	Dy.No 38733 dated 26-11-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Orthicam Tablet 15mg of M/s Linear Parma,
	GMP status	Date: 29-03-2019. Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnels, Quality control/QA and production operations. Keeping in view the abservations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	

1478.	Name and address of manufacturer / Applicant	"M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt."
	Brand Name +Dosage Form + Strength	Clofiride 0.9% Injection
	Composition	"Each 5ml Contains: Sodium Chloride…45mg"
	Diary No. Date of R& I & fee	Dy. No. 34321 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Diluent
	Type of Form	Form-5
	Finished Product Specifications	USP Specifications
	Pack size & Demanded Price	1's (5ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	N90 Injection IV of Aulton Pharmaceuticals
	GMP status	GMP Inspection conducted on 20th of December 2017 stated following: "Reference to previous inspection it was found that the firm rectified most of the shortcomings pointed out during last inspection. Panel advised the firm to continue the up gradation of building and system to maintain the GMP, which is a continuous process. Firm undertook to further upgrade the manufacturing & QC facility and documentation in the light of advices given by inspecting panels of experts. The panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest."
	Remarks of the Evaluator (VIII)	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.
	Decision: Deferred for the following: • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.** • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same**	
1479.	Name and address of manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Etoraim 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib…60mg"
	Diary No. Date of R& I & fee	Dy. No. 34338 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA

	Me-too status (with strength and dosage form)	Starcox 60 mg tab by Getz Pharma
	GMP status	Dated: 31-05-2018 "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	Monograph for test/analysis of applied formulation is not present in available USP & B.P.
	Decision: Approved as per innovator's specification.	
1480.	Name and address of manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Terbiaim 250mg Tablet
	Diary No. Date of R& I & fee	Dy.No 34340 dated 16-10-2018 Rs.20,000/-
	Composition	Each film coated tablet contains: Terbinafine (as hydrochloride)…250mg
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack size & Demanded Price	10's: Rs.474.00
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(uncoated tablet)
	Me-too status	Logirid Tablet 250mg of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	Dated: 31-05-2018 "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	• Reference product is approved as uncoated tablet but you have applied for coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as film coated tablet.
	Decision: Deferred for clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.	
1481.	Name and address of Manufacturer / Applicant	"M/s Surge Laboratories Pvt Ltd. 10 km, Faisalabad Road, Bikhi, District Sheikhupura"
	Brand Name+Dosage Form+Strength	Surgidex 25% Injection
	Composition	"Each ml Contains: Dextrose…250mg"
	Diary No. Date of R&I & fee	Dy. No. 34293 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Glucose Elevating Agent
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's: 20ml
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Pladex-25 Infusion of Otsuka Baluchistan. Each 1000ml contains:- Dextrose Anhydrous…250 gm(1000ml)
	GMP status	Date: 22-02-2018 & 04-05-2018 **Recommendations:** Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Surge Labs Sheikhupura has maintained a

		fair level of GMP compliance as per Schedule B-II of Drug (Lic, Reg & Adv) Rules 1976 on the day of inspection.
	Remarks of the Evaluator (VIII)	• Evidence of reference product packed in polypropylene ampoule.
	Decision: Deferred for the following: • **Evidence of reference product packed in polypropylene ampoule.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
1482.	Name and address of Manufacturer / Applicant	"M/s Surge Laboratories Pvt Ltd. 10 km, Faisalabad Road, Bikhi, District Sheikhupura"
	Brand Name+Dosage Form+Strength	Kolite 7.46% Injection
	Composition	"Each ml Contains: Potassium Chloride…74.6mg"
	Diary No. Date of R&I & fee	Dy. No. 34292 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications
	Pack Size & Demanded Price	20ml
	Approval status of product in Reference Regulatory Authorities.	could not be confirmed
	Me-too status	Potassium Chloride Injection of Otsuka Pakistan, Balochistan Each 100ml contains: Potassium Chloride …..7.46 g (25ml)
	GMP status	Date: 22-02-2018 & 04-05-2018 Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Surge Labs Sheikhupura has maintained a fair level of GMP compliance as per Schedule B-II of Drug (Lic, Reg & Adv) Rules 1976 on the day of inspection
	Remarks of the Evaluator (VIII)	• Evidence of reference product packed in polypropylene ampoule.
	Decision: Deferred for the following: • **Evidence of reference product packed in polypropylene ampoule.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
1483.	Name and address of Manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name+Dosage Form+Strength	Rostin 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin (as calcium trihydrate)…5mg"
	Diary No. Date of R&I & fee	Dy.No 34342 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Save-R Tablets 5mg of Wilson's Pharmaceuticals
	GMP status	Date: 31-05-2018 Comments: "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	

1484.	Name and address of Manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name+Dosage Form+Strength	Prasuaim 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Prasugrel (as hydrochloride)…10mg"
	Diary No. Date of R&I & fee	Dy.No 34347 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Platelet aggregation inhibitors
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	PRASUGREL Tablet 10mg of Opal Laboratory
	GMP status	Date: 31-05-2018 Comments: "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1485.	Name and address of Manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name+Dosage Form+Strength	Aimpride 2mg Tablet
	Composition	"Each Film Coated Tablet Contains: Glimepiride…2mg"
	Diary No. Date of R&I & fee	Dy.No 34348 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Glimera 2mg Tablet of PPP, Karachi
	GMP status	Date: 31-05-2018 Comments: "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with submission of requisite fee or evidence of approval of applied drug product as film coated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise for revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
1486.	Name and address of Manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name+Dosage Form+Strength	Aimpride 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Glimepiride…4mg"
	Diary No. Date of R&I & fee	Dy.No 34349 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Glimera 4mg Tablet of PPP, Karachi
	GMP status	Date: 31-05-2018 Comments: "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	• Reference product in approved as uncoated tablet but you have applied for film coated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with submission of requisite fee or evidence of approval of applied drug product as film coated coated tablet.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise for revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
1487.	Name and address of Manufacturer / Applicant	"M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore,
	Brand Name+ Dosage Form +Strength	Obtor 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib…60mg"
	Diary No. Date of R&I & fee	Dy.No 34726 dated 18-10-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Etoricox 60mg Tablet of Kaizen Pharma
	GMP status	GMP Inspection conducted on 12-07-2018 stated that most of the shortcomings pointed out during last inspection had been rectified by the firm. Some advices were also given for further improvements & up-gradations & management showed positive approach towards compliance.
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1488.	Name and address of Manufacturer / Applicant	"M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore,
	Brand Name+ Dosage Form +Strength	Obiva 7.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ivabradine as hydrochloride…7.5mg"
	Diary No. Date of R&I & fee	Dy. No. 34725 dated 18-10-2018 Rs.20,000/-
	Pharmacological Group	Heart-rate-lowering agent
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	14's: Rs 280/-
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Iva Tablet 7.5 mg of CSH, Pharmaceuticals-North (Pvt.) Ltd.
	GMP status	GMP Inspection conducted on 12-07-2018 stated that most of the shortcomings pointed out during last inspection had been rectified by the firm. Some advices were also given for further improvements & up-gradations & management showed positive approach towards compliance.

	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1489.	Name and address of Manufacturer / Applicant	"M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore,
	Brand Name+ Dosage Form +Strength	Obpride 1mg Tablet
	Composition	"Each film coated Tablet Contains: Cinitapride (as hydrogen tartrate)…1mg"
	Diary No. Date of R&I & fee	Dy.No 34723 dated 18-10-2018 Rs.20,000/-
	Pharmacological Group	anti-emetic Propulsives
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's: Rs 190/-
	Approval status of product in Reference Regulatory Authorities	Approved in sweeden
	Me-too status	Sitip 1mg Tablet of Sami Pharma.
	GMP status	GMP Inspection conducted on 12-07-2018 stated that most of the shortcomings pointed out during last inspection had been rectified by the firm. Some advices were also given for further improvements & up-gradations & management showed positive approach towards compliance.
	Remarks of the Evaluator (VIII)	
	Decision: Referred to QA Division for updated GMP status.	
1490.	Name and address of Manufacturer / Applicant	"M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan"
	Brand Name+ Dosage Form +Strength	Obiva 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ivabradine as hydrochloride …5mg"
	Diary No. Date of R&I & fee	Dy. No. 34724 dated 18-10-2018 Rs.20,000/-
	Pharmacological Group	Heart-rate-lowering agent
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	14's: Rs 280/-
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Iva Tablet 5 mg of CSH, Pharmaceuticals-North (Pvt.) Ltd.
	GMP status	GMP Inspection conducted on 12-07-2018 stated that most of the shortcomings pointed out during last inspection had been rectified by the firm. Some advices were also given for further improvements & up-gradations & management showed positive approach towards compliance.
	Remarks of the Evaluator (VIII)	
	Decision: Referred to QA Division for updated GMP status.	
1491.	Name and address of Manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name+ Dosage Form +Strength	Ferowim 150/0.5 mg Tablet
	Composition	"Each Tablet Contains: Ferrous Fumarate…150mg Folic Acid…0.5mg"
	Diary No. Date of R&I & fee	Dy.No 34701 dated 18-10-2018 Rs.20,000/-
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in	Approved in US-FDA(not confirmed)

	Reference Regulatory Authorities	
	Me-too status	Lowrate Tablets of Lowitt Pharmaceutical
	GMP status	GMP Inspection conducted on 03-11-17 concluded that firm is operating at good level of GMP Compliance
	Remarks of the Evaluator (VIII)	Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation does not contains ingredients of coating but Outline of method of manufacturing contains step of coating.
	Decision: Deferred for following: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation does not contain ingredients of coating but Outline of method of manufacturing contains step of coating.**	
1492.	Name and address of Manufacturer / Applicant	"M/s Shazal's Pharmaceuticals. Plot No.41/1-A, Phase-I, Industrial Estate, Hattar By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar"
	Brand Name+ Dosage Form +Strength	Ozam 40mg Injection
	Composition	"Each Vial Contains: Omeprazole sodium…40mg"
	Diary No. Date of R&I & fee	Dy.No 34451 dated 17-10-2018 Rs.50,000/-
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Lowrate Tablets of Lowitt Pharmaceutical
	GMP status	GMP Inspection conducted on 03-11-17 concluded that firm is operating at good level of GMP Compliance.
	Remarks of the Evaluator (VIII)	• All undertakings attached in the dossier are not signed. Submit signed undertakings & also application on Form is not signed. • Mention type of primary packaging material of applied formulation. • Submit composition & label claim of applied formulation in line with reference product.
	Decision: Deferred for the following: • **Submit signed application alongwith singed undertakings.** • **Mention type of primary packaging material of applied formulation.** • **Submit composition & label claim of applied formulation in line with reference product i.e. Omeprazole (as sodium)… 40mg injection.**	
1493.	Name and address of Manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name+ Dosage Form +Strength	Episaf 500mg/5ml Injection
	Composition	"Each 5ml Contains: Levetiracetam…500mg"
	Diary No. Date of R&I & fee	Dy.No 34294 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	1's: Rs.1000/-
	Approval status of product in	Approved in US-FDA

	Reference Regulatory Authorities	
	Me-too status	Lerace 100mg Oral Solution of Hilton Pharma Karachi
	GMP status	Dated: 08-10-2019 **Recommendations:** Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Saffron Pvt Ltd was considered to be operating at Good level of compliance with GMP guidelines as per Drugs Act 1976, and rules framed there under, The panel recommends considering the firm for grant of CGMP certificate, un respect of all approved sections.
	Remarks of the Evaluator (VIII)	• Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container. • Clarification/justification for not performing terminal sterilization of applied formulation. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as provided me too is of another formulation. Reference product is in usfda is packed in single use vial.
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.** • **Clarification/justification for not performing terminal sterilization of applied formulation.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as provided me too is of another formulation.**	
1494.	Name and address of Manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name + Dosage Form +Strength	Cinisaf 1mg/5ml Syrup
	Composition	"Each 5ml Contains: Cinitapride as acid tartrate…1mg"
	Diary No. Date of R&I & fee	Dy. No. 34296 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Propulsive
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	60ml, 120ml: Rs.500/-, Rs.1000/-,
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Cidine syrup of M/s. Highnoon Laboratories,
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	~~Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.~~ • Clarification is required whether applied formulation is solution or suspension. • Clarification/justification is required for use of amber glass bottle for packaging of applied formulation as reference product is packed in topaz glass bottle. reference product is solution

	Decision: Deferred for the following: • **Clarification regarding applied formulation is solution or suspension is required.** • **Clarification/justification for use of amber glass bottle for packaging of applied formulation as reference product is packed in topaz glass bottle.**	
1495.	Name and address of Manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name+ Dosage Form +Strength	Cinisaf 1mg Tablet
	Composition	"Each Tablet Contains: Cinitapride as acid tartrate…1mg"
	Diary No. Date of R&I & fee	Dy.No 34295 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Propulsive
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's, 50's: Rs.500/-, Rs.2000/-,
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Sitip 1mg Tablet of Sami Pharma.
	GMP status	Same as recorded for above application
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1496.	Name and address of Manufacturer / Applicant	"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name+ Dosage Form +Strength	Boschofen 200mg Effervescent Granules
	Composition	"Each Sachet Contains: Ibuprofen (effervescent granules)…200mg"
	Diary No. Date of R&I & fee	Dy.No 34115 dated 15-10-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Anti-inflammatory, anti-rheumatic.
	Finished Product Specification	Innovator's Specification
	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	not verifiable
	GMP status	GMP Inspection conducted on 07-06-2018 concluded that firm is operating at an acceptable level of compliance with GMP guidelines at the time of inspection.
	Remarks of the Evaluator (VIII)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.	
1497.	Name and address of Manufacturer / Applicant	"M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name+ Dosage Form +Strength	Boschofen 600mg Effervescent Granules
	Composition	"Each Sachet Contains: Ibuprofen (effervescent granules)…600mg"
	Diary No. Date of R&I & fee	Dy.No 34114 dated 15-10-2018 Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specification
	Pack Size & Demanded Price	14's: As per SRO
	Approval status of product in	Approved in MHRA

	Reference Regulatory Authorities	
	Me-too status	Hibufen 600mg Sachet of Indus Pharma Each sachet contains: Ibuprofen ……..600 mg
	GMP status	GMP Inspection conducted on 07-06-2018 concluded that firm is operating at an acceptable level of compliance with GMP guidelines at the time of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1498.	Name and address of Manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name+ Dosage Form +Strength	Vagistat 20mg Cream
	Composition	"Each Gram Contains: Butoconazole…20mg"
	Diary No. Date of R&I & fee	Dy.No 34332 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Anti-fungal
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	15gm, 30gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in Israel (as provided by the firm)
	Me-too status	Could not be confirmed
	GMP status	Date: 31-05-2018 Comments: "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.**	
1499.	Name and address of Manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name+ Dosage Form +Strength	Dermera Cream 40mg/0.5mg/0.1mg Cream
	Composition	"Each Gram Contains: Hydroquinone…40mg Tretinoin…0.5mg Fluocinolone Acetonide…0.1mg"
	Diary No. Date of R&I & fee	Dy.No 34335 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	Anti-fungal
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	15gm, 30gm: As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Tricuma Cream Topical of Ciba Pharmaceuticals
	GMP status	Date: 31-05-2018 Comments: "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for approval of section/manufacturing facility by the Central Licensing Board.	
1500.	Name and address of Manufacturer / Applicant	"M/s Aims Pharmaceuticals. Plot # 291, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name+ Dosage Form +Strength	Azeskin 200mg Cream
	Composition	"Each Gram Contains: Azelaic Acid…200mg"
	Diary No. Date of R&I & fee	Dy.No 34333 dated 16-10-2018 Rs.20,000/-
	Pharmacological Group	anti-acne preparations for topical use
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	15gm, 30gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA(emc)
	Me-too status	Not verifiable.
	GMP status	Date: 31-05-2018 Comments: "The panel unanimously recommended the grant of renewal of DML after thorough and detailed evaluation/inspection."
	Remarks of the Evaluator (VIII)	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.** • **Approval of section/manufacturing facility by the Central Licensing Board**	
1501.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi,
	Brand Name +Dosage Form + Strength	Vastarel MR 35mg Tablet
	Composition	Each film coated modified release tablet contains: Trimetazidine dihydrochloride …35mg
	Diary No. Date of R& I & fee	Dy No. 5727: 16-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-ischemic (anti-anginal)
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	10's,14's,20's 28's :As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Trikat MR Tablets of M/s. Novamed Pharmaceuticals.

	GMP status	Last inspection conducted on 15-09-2017 and report concludes that firm is found complying GMP as of today.
	Remarks of the Evaluator (VIII).	Mention type of primary packaging material of applied formulation. Applied formulation is modified release tablet but master formulation does not contain any modified release ingredient , Clarify.
	Decision: Deferred for the following: • **Mention type of primary packaging material of applied formulation.** • **Mention name of modified release polymer for applied formulation & submit master formulation accordingly.**	
1502.	Name and address of manufacturer / Applicant	M/s Spencer & Company Pvt Ltd. D-105, S.I.T.E Karachi
	Brand Name +Dosage Form + Strength	Carvetek 3.125mg Tablet
	Composition	Each film coated tablet contains: Carvedilol…3.125mg
	Diary No. Date of R& I & fee	Dy No. 5139: 16-02-18 ; Rs. 20,000
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Hidilol 3.125mg Tablets of Helix Pharma (Pvt.) Ltd; Karachi.
	GMP status	GMP Inspection conducted on 29-01-2019: Penicillin, Topical products and veterinary products registered in the name of the firm should be de-registered forthwith as no dedicated sections exist for them. Renewal of DML no 000272 may be deferred till rectification of observations/ improvements as identified by the panel Renewal not recommended. & The CLB considered the case and decided to issue Show cause notice.
	Remarks of the Evaluator (VIII)	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for submission of updated status of DML (valid or invalid) & GMP of the firm alongwith evidence of section approval.	
1503.	Name and address of manufacturer / Applicant	M/s Spencer & Company Pvt Ltd. D-105, S.I.T.E Karachi
	Brand Name +Dosage Form + Strength	Carvetek 6.25mg Tablet
	Composition	Each film coated tablet contains: Carvedilol…6.25mg
	Diary No. Date of R& I & fee	Dy No. 5736: 16-02-18 ; Rs. 20,000
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Hidilol 6.25mg Tablets of Helix Pharma (Pvt.) Ltd; Karachi.

	GMP status	GMP Inspection conducted on 29-01-2019: Penicillin, Topical products and veterinary products registered in the name of the firm should be de-registered forthwith as no dedicated sections exist for them. Renewal of DML no 000272 may be deferred till rectification of observations/ improvements as identified by the panel Renewal not recommended. & The CLB considered the case and decided to issue Show cause notice.
	Remarks of the Evaluator (VIII)	
	Decision: Deferred for submission of updated status of DML (valid or invalid) & GMP of the firm alongwith evidence of section approval.	
1504.	Name and address of manufacturer / Applicant	M/s Spencer & Company Pvt Ltd. D-105, S.I.T.E Karachi
	Brand Name +Dosage Form + Strength	Carvetek 12.5mg Tablet
	Composition	Each film coated tablet contains: Carvedilol…12.5mg
	Diary No. Date of R& I & fee	Dy No. 5737: 16-02-18 ; Rs. 20,000
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Cavidol 12.5mg Tablet of Indus Pharma, Karachi
	GMP status	GMP Inspection conducted on 29-01-2019: Penicillin, Topical products and veterinary products registered in the name of the firm should be de-registered forthwith as no dedicated sections exist for them. Renewal of DML no 000272 may be deferred till rectification of observations/ improvements as identified by the panel Renewal not recommended. & The CLB considered the case and decided to issue Show cause notice.
	Remarks of the Evaluator (VIII)	
	Decision: Deferred for submission of updated status of DML (valid or invalid) & GMP of the firm alongwith evidence of section approval.	
1505.	Name and address of manufacturer / Applicant	M/s Spencer & Company Pvt Ltd. D-105, S.I.T.E Karachi
	Brand Name +Dosage Form + Strength	Carvetek 25mg Tablet
	Composition	Each film coated tablet contains: Carvedilol…25mg
	Diary No. Date of R& I & fee	Dy No. 5738: 16-02-18 ; Rs. 20,000
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Cavidol 25mg Tablet of Indus Pharma, Karachi
	GMP status	GMP Inspection conducted on 29-01-2019: Penicillin, Topical products and veterinary products registered in the name of the firm should be de-registered forthwith as no dedicated sections exist for them.

		Renewal of DML no 000272 may be deferred till rectification of observations/ improvements as identified by the panel Renewal not recommended. & The CLB considered the case and decided to issue Show cause notice.
	Remarks of the Evaluator (VIII)	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for submission of updated status of DML (valid or invalid) & GMP of the firm alongwith evidence of section approval.	
1506.	Name and address of manufacturer / Applicant	Nabi Qasim Industries 17/24, Korangi Industrial Area Karachi contract manufactured by Surge laboratories 10 Km, Faisalabad Road, Dist. Sheikhupura.
	Brand Name +Dosage Form + Strength	Transic Injection 250mg
	Composition	Each 5ml ampoule contains: Tranexamic acid …250mg
	Diary No. Date of R& I & fee	Dy No. 11087: 04-08-17 ; Rs. 20,000
	Pharmacological Group	Haemostatic/Fibrinolytic
	Type of Form	Form-5
	Finished product Specification	As per innovator's Specifications
	Pack size & Demanded Price	10's (5ml): As per SRO
	Approval status of product in Reference Regulatory Authorities.	could not be confirmed
	Me-too status	Traxacid 250mg/ml Injection of Asian Continental
	GMP status	Dated: 05-08-2019 Conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of GMP requirements.
	Remarks of the Evaluator (VIII)	Scientific justification for addition of 2% overage in master formulation. Mention type of primary packaging material of applied formulation.
	Decision: Deferred for the following: • **Scientific justification for addition of 2% overage in master formulation.** • **Mention type of primary packaging material of applied formulation.**	
1507.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Sofen Tablets 5mg
	Composition	"Each Film Coated Tablet Contains: Solifenacin Succinate…5mg"
	Diary No. Date of R& I & fee	Dy. No. 39903 dated 04-12-2018 Rs.20,000/-
	Pharmacological Group	Antidepressants – selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Fenaso 5mg of M/s Highnoon
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.

	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1508.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Sofen Tablets 10mg
	Composition	"Each Film Coated Tablet Contains: Solifenacin Succinate…10mg"
	Diary No. Date of R& I & fee	Dy. No. 40293 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Antidepressants – selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	As per Innovator's Specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Fenaso 10mg of M/s Highnoon
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1509.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name+ Dosage Form + Strength	Voxacin 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levofloxacin as hemihydrate…500mg"
	Diary No. Date of R&I & Fee	Dy.No 2949 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's : Rs. 48/tablet
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Pelromet Tablet 500mg of Wisdom Pharmaceuticals
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1510.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name + Dosage Form + Strength	Voxacin 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levofloxacin as hemihydrate…250mg"
	Diary No. Date of R&I & Fee	Dy.No 2948 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	Rs. 29/tablet
	Me-too status	Pelromet Tablet 250mg of Wisdom Pharmaceuticals
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in

		the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1511.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name + Dosage Form + Strength	Tinabin Lotion
	Composition	Terbinafine hydrochloride… 1.0% w/w
	Diary No. Date of R&I & Fee	Dy.No 2947 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Me-too status	Could not be confirmed
	Approval status of product in reference regulatory authorities	Could not be confirmed
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	Evidence of approval of applied formulation in reference agencies is required.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1512.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name + Dosage Form + Strength	Tinabin Cream
	Composition	Each gram contains: Terbinafine as hydrochloride.. 1.0%w/w
	Diary No. Date of R&I & Fee	Dy.No 2946 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	Rs. 322/20ml
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Bina cream 1% of Linta Pharma
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
1513.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name + Dosage Form + Strength	Piroxiderm S Liquid
	Composition	Ciclopirox as Olamine…1.5% w/v Salicylic Acid…3.0% w/v
	Diary No. Date of R&I & Fee	Dy.No 2939 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic

	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml: Rs 184/-
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	Evidence of approval of applied formulation in reference agencies is required. Evidence of approval of Me Too is required.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1514.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name + Dosage Form + Strength	Zemitech 500mg Capsule
	Composition	Each Capsule Contains: Azithromycin as dihydrate…500mg
	Diary No. Date of R&I & Fee	Dy.No 2937 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	Rs./55- Rupees/Capsule
	Approval status of product in reference regulatory authorities	Could not be confirmed
	Me-too status	Zelide capsule 500mg of Navegal Laboratories
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	Evidence of approval of applied formulation in reference agencies is required. (500 mg tablets are available)
	Decision: Deferred foreEvidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1515.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name + Dosage Form + Strength	Zemitech 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin as dihydrate…250mg
	Diary No. Date of R&I & Fee	Dy.No 2938 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	Rs./32- Rupees/Capsule
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Pilvazith capsule 250mg of Pilva Balochistan
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18

		concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1516.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name + Dosage Form + Strength	Klithrocin 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clarithromycin…500mg"
	Diary No. Date of R&I & Fee	Dy.No 2935 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's: Rs 61/tablet
	Me-too status	SN Clar 500 mg Tablets of SNB Pharma (Pvt) Ltd
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1517.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name+ Dosage Form + Strength	Klithrocin 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clarithromycin…250mg"
	Diary No. Date of R&I & Fee	Dy.No 2936 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's: Rs 32/tablet
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Klarinor 250 mg Tablets of M/S Nortech Pharmaceuticals
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1518.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name+ Dosage Form+ Strength	FSID Cream
	Composition	Each gram contains: Fusidic acid ……2.0% w/w
	Diary No. Date of R&I & Fee	Dy.No 2941 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	5gm, 15gm: Rs. 75/5gm, Rs. 190/15gm

	Approval status of product in reference regulatory authorities	Approved in MHRA (20mg/gram cream)
	Me-too status	Hifuzin Cream of Hiranis Karachi
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1519.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name+ Dosage Form+ Strength	Kriprox 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ciprofloxacin as HCL…250mg"
	Diary No. Date of R&I & Fee	Dy.No 2944 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	Rs. 21.60/tablet
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Vift 250mg Tablet of Sigma Karachi
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1520.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name + Dosage Form + Strength	Kriprox 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ciprofloxacin as HCL……500mg"
	Diary No. Date of R&I & Fee	Dy.No 2945 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	Rs. 32/tablet
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Vift 500mg Tablet of Sigma Karachi
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1521.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name+Dosage Form + Strength	Elimite Lotion 5.0%
	Composition	Each gram contains: Permethrin……50mg
	Diary No. Date of R&I & Fee	Dy.No 2943 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019

	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, 120ml: Rs.106/-, Rs. 175/-
	Me-too status	Plaveo Lotion of Hiranis Karachi Each ml contains:- Permethrin ……...50 mg Permatrin Cream of Noa Hemis Karachi Each gram contains: Permethrin…….5 %
	Approval status of product in reference regulatory authorities	Could not be confirmed(5 % w/w cream is available)
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	Evidence of approval of applied formulation in reference regulatory/authorities is required.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submit composition/label claim of applied formulation in line with reference product.**	
1522.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name+Dosage Form + Strength	Elimite Cream 5.0%
	Composition	Each gram contains: Permethrin……50mg
	Diary No. Date of R&I & Fee	Dy.No 2943 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA(emc)
	Me-too status	Permatrin Cream of Noa Hemis Karachi Each gram contains: Permethrin…….5 %
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18 concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	
	Decision: Approved as per innovator's specification.	
1523.	Name and address of manufacturer / Applicant	M/s Derma Techno Pakistan, Plot No. 528 Sundar Industrial Estate Raiwind Road Lahore
	Brand Name+Dosage Form + Strength	Piroxiderm 1.5% Liquid
	Composition	Ciclopirox Olamine…. 1.5% w/v
	Diary No. Date of R&I & Fee	Dy.No 2940 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5A
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Could not confirmed
	Me-too status	Could not confirmed
	GMP status	GMP inspection conducted on 21-05-18 & 05-07-18

		concluded that firm has maintained conformance to GMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of the Evaluator (VIII)	Evidence of approval of applied formulation in reference regulatory/authorities is required.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submit composition/label claim of applied formulation in line with reference product.**	
1524.	Name and address of manufacturer / Applicant	"M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatabad"
	Brand Name + Dosage Form + Strength	Rostonate 35mg Tablets
	Composition	"Each Film Coated Tablet Contains: Risedronate Sodium…35mg"
	Diary No. Date of R&I & Fee	Dy.No 16534 dated 04-05-2018 Rs.20,000/- Dated 04-05-2018
	Pharmacological Group	Bisphosphonates
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Rizidro 35 mg Tablets of Gray's Pharmaceuticals
	GMP status	Dated: 26-07-2018 Recommendations: Keeping in view the above, the panel unanimously recommends the grant of renewal of DML by way of formulation of M/s Hicon Pharma Peshawar for following sections: i- Tablet Section (General) ii- Tablet section (General Antibiotic) iii- Liquid Syrup section (General)
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1525.	Name and address of manufacturer / Applicant	"M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatabad"
	Brand Name+Dosage Form + Strength	Osteonate 70mg Tablets
	Composition	"Each Film Coated Tablet Contains: Alendronate sodium eq to Alendronic acid…70mg"
	Diary No. Date of R&I & Fee	Dy.No 16533 dated 04-05-2018 Rs.20,000/- Dated 04-05-2018
	Pharmacological Group	Anti-osteoporotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	:As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA (uncoated tablet)
	Me-too status	Deonate Tablets 70mg of Cirin Pharmaceuticals,
	GMP status	Dated: 26-07-2018 Recommendations: Keeping in view the above, the panel unanimously recommends the grant of renewal of DML by way of formulation of M/s Hicon Pharma Peshawar for following sections: i- Tablet Section (Gen)

		ii- Tablet section (Gen Antibiotic) iii- Liquid Syrup section (Gen)
	Remarks of the Evaluator (VIII)	~~• Reference Product is approved as uncoated tablet which is different from applied formulation submit either composition & master formulation after correction alongwith submission of requisite fee or evidence of reference product approved as film coated tablet.~~
	Decision: Deferred for either submission of evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
1526.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name+Dosage Form + Strength	Bensol Bacteriostatic Water
	Composition	Each ml of sterile water Contains: Sterile Water Benzyl Alcohol…….9mg
	Diary No. Date of R& I & fee	Dy. No 16527 dated 04-05-2018 Rs.20,000/- Dated 03-05-2018
	Pharmacological Group	Diluent
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	
	GMP status	Dated; 08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1527.	Name and address of manufacturer / Applicant	"M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Axitrim Injection 2gm
	Composition	"Each vial contains: Ceftriaxone as sodium…2000mg"
	Diary No. Date of R& I & fee	Dy. No. 23501 dated 06-07-2018 Rs.20,000/- Dated 06-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA(emc)
	Me-too status (with strength and dosage form)	Wintax 2 g Injection of Wnsfeild Pharmaceutical,
	GMP status	The firm has maintained conformance to GMP compliance as per inspection report dated 01/04/2019

	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1528.	Name and address of Manufacturer / Applicant	M/s Hiranis Pharmaceuticals, Plot No., E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi,
	Brand Name +Dosage Form +Strength	Infexo DS 250mg Dry Suspension 250mg/5ml
	Composition	Each 5ml of Reconstituted Suspension Contains: Ciprofloxacin …250mg
	Diary No. Date of R&I & fee	DyNo.30785; 12-09-2018; Rs. 20,000/-(fee challan is duplicate)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cinoxin 250mg Dry Suspension of M/s Searle IV Solutions (Pvt.) Ltd.
	GMP status	Dated: 29-01-2019 The firm is overall GMP compliant.
	Remarks of the Evaluator (VIII)	COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions is required.
	Decision: Deferred for COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions is required.	
1529.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Jenprox SR Tablets 25mg
	Composition	Each SR Tablet Contains: Paroxetine (as hydrochloride)… 25mg
	Diary No. Date of R& I & fee	Dy. No. 40294 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Antidepressants – selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Deroxat CR tablet 12.5 mg by global Pharma
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	Submit composition master formulation & manufacturing method of applied formulation in line with reference product.
	Decision: Deferred for submission of master formulation & manufacturing method of applied formulation in line with reference product.	
1530.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd. 26- km Lahore Sharaqpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Tramajen 100mg Tablets SR
	Composition	Each SR Tablet Contains: Tramadol Hydrochloride …. 100mg
	Diary No. Date of R& I & fee	Dy.No 40292 dated 05-12-2018 Rs.20,000/-
	Pharmacological Group	Analgesics, other opioids
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA RYZOLT™ tablet

	Me-too status	Allay SR Tablet of Tabros Karachi
	GMP status	Last GMP inspection conducted on 15.02.2019 concluded satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII).	RYZOLT™ (tramadol hydrochloride extended-release tablets) is a centrally acting analgesic composed of a dual-matrix delivery system with both immediate-release and extended-release characteristics. Please submit your master formulation & manufacturing method in line with reference product.
	Decision: Deferred for submission of master formulation & manufacturing method of applied formulation in line with reference product which is composed of a dual-matrix delivery system with both immediate-release and extended-release characteristics.	
1531.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Vanlodip 10mg/160mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Valsartan…160mg
	Diary No. Date of R&I & Fee	Dy.No 4884 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Amlodine Tablet 10/160mg of M/s Jupiter Pharma
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications	
1532.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name + Dosage Form + Strength	Vanlodip 5mg/80mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…80mg"
	Diary No. Date of R&I & Fee	Dy.No 4882 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Amlodine Tablet 5/80 mg of M/s Jupiter Pharma
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1533.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Vanlodip 5mg/160mg Tablet

	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…160mg
	Diary No. Date of R&I & Fee	Dy.No 4883 dated 02-02-2019 Rs.20,000/- 04-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Co-Valzaar 10mg/160mg Tablet of Vision Pharmaceuticals.
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1534.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Vanlodip S 10mg/160mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 4879 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Me-too status	Valtec AMH 10/160/12.5 Tablet of Tabros Pharma Karachi
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1535.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Vanlodip S 5mg/160mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R&I & Fee	Dy.No 4877 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 5/160/12.5mg Tablet of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.

	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1536.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Vanlodip S 10mg/320mg/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Valsartan…320mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy.No 4881 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 10/320/25mg Tablet of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	
1537.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850,
	Brand Name + Dosage Form + Strength	Vanlodip S 10mg/160mg/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…10mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R&I & Fee	Dy.No 4880 dated 02-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Aldric-H 10/160/25mg Tablet of Martin Dow
	GMP status	Dated:04-07-2018 Conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator (VIII)	
	Decision: Approved with USP Specifications.	

b. Deferred cases

1538.	Name and address of Manufacturer / Applicant	"M/s Atco Laboratories Limited. B-18, S.I.T.E, Karachi"
	Brand Name +Dosage Form +Strength	Eskazole 100mg/5ml Suspension
	Composition	"Each 5ml Contains: Albendazole…100mg"
	Diary No. Date of R&I & fee	Dy.No 6118 dated 19-02-2018 Rs. 20,000/-
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10ml, 15ml, 20ml, 30ml, 60ml,120ml: Rs.500/-, Rs.750/-,

		Rs.1000/-, Rs.1500/-, Rs.3000/-, Rs.6000/-.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Nenzole Suspension of "Nenza Pharmaceuticals (Pvt) Ltd.,
	GMP status	Panel inspection conducted on 28-02-2017 concludes recommended grant of renewal of DML by the way of Formulation.
	Remarks of the Evaluator (VIII)	
	Decision(M-290): Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Evaluation by PEC: Applicant has submitted that h applied is approved in EMA. Approval authority name: EMA Product Name: Zentel 100mg/5mlperorrainasuspenzia Generic : albendazole National Authorization Number: 10/0173/85-C/S MAH of Product in member state: GSK	
	Decision: Approved with USP Specifications.	

	Name and address of manufacturer / Applicant	**Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification**	**Type of Form Initial date, diary Fee including differential fee Demanded Price / Pack size**	**Remarks on the formulation (if any) including International status in stringent drug regulatory agencies / authorities Me-too status GMP status as depicted in latest inspection report (with date) by the Evaluator**	**Decision**
1539.	M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, Rawalpindi (New Section)	Hycort 100 injection Each vial contains lyophilized powder: Hydrocortisone as sodium succinate (USP)….100mg Glucocorticoid-Minerolcorticoid (Manufacturer's specs)	Form 5 Dy.No.773 02-09-2016 Rs.20,000/- 1's Rs.400/-	Hydrocortisone as sodium succinate Injection-USFDA Solu-cortef by Pfizer Pharma Inspection report dated 17-08-2016 recommended for the grant of additional sections	263rd Meeting Registration Board held on 29-30th November, 2016. Deferred for confirmation of section
	Evaluation By PEC • Firm has submitted copy of letter issued by Secretary CLB, dated 27th Sep, 2016, stating the grant of additional section for "Lyophilized Injection Ampoule (Hormone). • Firm has stated that Hydrocortisone is a steroid & according to the classification of Hormone, steroids fall under the subclass of Hormone. Decision: Registration Board deferred for clarification of product pharmacological classification with respect to manufacturing facility.				
	Previous Decision: Registration Board in its 267th meeting deferred the case for the clarification of product pharmacological classification with respect to manufacturing facility.				

	Evaluation By PEC. **a.** According to WHO ATC classification system Hydrocortisone is classified as under: H Systemic Hormonal Preparations, Excl. Sex Hormones And Insulin H02 Corticosteroids For Systemic Use H02A Corticosteroids For Systemic Use, Plain H02AB Glucocorticoids H02AB09 Hydrocortisone **b.** Now the firm has submitted the letter of Licensing Division bearing a number "No.F. 1-18/92-Lic (Vol-II)" dated 6th July, 2018 for modification of section from "Lyophilized Injection Ampoule (Hormone)" to "Lyophilized Injection vials(steroids)".				
	Previous Decision: Registration Board in its 284th meeting deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Evaluation by PEC: Applicant has submitted letter of CLB having No. F-18/92-Lic(Vol-II) dated 7th of November, 2019 grant of lyophilized Injection Vials Steroidal (Hormone).				
	Decision(M-293): Registration Board deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Registration Board deliberated the matter in detail and discussed that aplicant has steroidal hormone section & applied formulation is a corticosteroid which can not be manufactured with hormones like estrogen, progesterone & testosterone etc due to the risk of cross contamination. However, firm don't have any approved or registered formulation in the said section neither hormone nor steroid. **Decision: Keeping in view the above discussion, the Board decided as follows:** • **Approve registration of applied drug product in the above said section & advised firm to change the title of section from "Steroidal (Hormone)" to "Steroids" so to avoid any future registration of hormonal preparation in the said section.** • **The Board further decided that letter of registration will be issued to the firm after change of name of section.**				
1540.	M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, Rawalpindi (New Section)	Hycort 250 injection Each vial contains lyophilized powder: Hydrocortisone as sodium succinate (USP).....250mg Glucocorticoid-Minerolcorticoid (Manufacturer's specs) Glucocorticoid-Minerolcorticoid (Manufacturer's specs)	Form 5 Dy.No.774 02-09-2016 Rs.20,000/ 1's Rs.550/-	Hydrocortisone as sodium succinate Injection-USFDA, Solu-cortef by Pfizer Pharma Inspection report dated 17-08-2016 recommended for the grant of additional sections	263rd Meeting Registration Board held on 29-30th November, 2016 Deferred for confirmation of section
	Evaluation By PEC • Firm has submitted copy of letter issued by Secretary CLB, dated 27th Sep, 2016, stating the grant of additional section for "Lyophilized Injection Ampoule (Hormone). • Firm has stated that Hydrocortisone is a steroid & according to the classification of Hormone, steroids fall under the subclass of Hormone. Decision: Registration Board deferred for clarification of product pharmacological classification with respect to manufacturing facility.				
	Previous Decision: Registration Board in its 267th meeting deferred the case for the clarification of product pharmacological classification with respect to manufacturing facility.				
	Evaluation By PEC. **a.** According to WHO ATC classification system Hydrocortisone is classified as under: H Systemic Hormonal Preparations, Excl. Sex Hormones And Insulin H02 Corticosteroids For Systemic Use H02A Corticosteroids For Systemic Use, Plain				

	H02AB Glucocorticoids H02AB09 Hydrocortisone **b.** Now the firm has submitted the letter of Licensing Division bearing a number "No.F. 1-18/92-Lic (Vol-II)" dated 6th July, 2018 for modification of section from "Lyophilized Injection Ampoule (Hormone)" to "Lyophilized Injection vials(steroids)".				
	Previous Decision: Registration Board in its 284th meeting deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Evaluation by PEC: Applicant has submitted letter of CLB having No. F-18/92-Lic(Vol-II) dated 7th of November, 2019 grant of lyophilized Injection Vials Steroidal (Hormone).				
	Decision(M-293): Registration Board deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Registration Board deliberated the matter in detail and discussed that aplicant has steroidal hormone section & applied formulation is a corticosteroid which can not be manufactured with hormones like estrogen, progesterone & testosterone etc due to the risk of cross contamination. However, firm don't have any approved or registered formulation in the said section neither hormone nor steroid. **Decision: Keeping in view the above discussion, the Board decided as follows:** • **Approve registration of applied drug product in the above said section & advised firm to change the title of section from "Steroidal (Hormone)" to "Steroids" so to avoid any future registration of hormonal preparation in the said section.** • **The Board further decided that letter of registration will be issued to the firm after change of name of section.**				
1541.	M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, Rawalpindi	Hycort 500 Injection Each vial contains lyophilized powder: Hydrocortisone as sodium succinate (USP) …….500mg Glucocorticoid-Minralocorticoid (Manufacturer's specs)	Form 5 Dy.No.777 02-09-2016 Rs.20,000/- 1's vial 1's x4ml ampoule Rs.600/-	Solu-cortef by Pfizer Pharma (EU/USA), Solu-cortef by Pfizer Pharma Inspection report dated 17-08-2016 recommended for the grant of additional sections	263rd Meeting Registration Board held on 29-30th November, 2016 Deferred for approval of steroidal section
	Evaluation By PEC • Firm has submitted copy of letter issued by Secretary CLB, dated 27th Sep, 2016, stating the grant of additional section for "Lyophilized Injection Ampoule (Hormone). • Firm has stated that Hydrocortisone is a steroid & according to the classification of Hormone, steroids fall under the subclass of Hormone. Decision: Registration Board deferred for clarification of product pharmacological classification with respect to manufacturing facility.				
	Previous Decision: Registration Board in its 267th meeting deferred the case for the clarification of product pharmacological classification with respect to manufacturing facility.				
	Evaluation By PEC. **a.** According to WHO ATC classification system Hydrocortisone is classified as under: H Systemic Hormonal Preparations, Excl. Sex Hormones And Insulin H02 Corticosteroids For Systemic Use H02A Corticosteroids For Systemic Use, Plain H02AB Glucocorticoids H02AB09 Hydrocortisone **b.** Now the firm has submitted the letter of Licensing Division bearing a number "No.F. 1-18/92-Lic (Vol-II)" dated 6th July, 2018 for modification of section from "Lyophilized Injection Ampoule (Hormone)" to "Lyophilized Injection vials(steroids)".				

	Previous Decision: Registration Board in its 284th meeting deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Evaluation by PEC: Applicant has submitted letter of CLB having No. F-18/92-Lic(Vol-II) dated 7th of November, 2019 grant of lyophilized Injection Vials Steroidal (Hormone).				
	Decision(M-293): Registration Board deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Registration Board deliberated the matter in detail and discussed that aplicant has steroidal hormone section & applied formulation is a corticosteroid which can not be manufactured with hormones like estrogen, progesterone & testosterone etc due to the risk of cross contamination. However, firm don't have any approved or registered formulation in the said section neither hormone nor steroid. **Decision: Keeping in view the above discussion, the Board decided as follows:** • **Approve registration of applied drug product in the above said section & advised firm to change the title of section from "Steroidal (Hormone)" to "Steroids" so to avoid any future registration of hormonal preparation in the said section.** • **The Board further decided that letter of registration will be issued to the firm after change of name of section.**				
1542.	M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road,	Medrone 500 Injection Each vial contains: Methylprednisolne as sodium succinate (USP) ……500mg Glucocorticoids (USP Specs)	Form 5 Dy.No.771 02-09-2016 Rs.20,000/- 1's x8ml Rs.1150/-	International availability not provided, Solu –Medrol by Pfizer Pharma, Inspection report dated 17-08-2016 recommended for the grant of additional sections	263rd Meeting Registration Board held on 29-30th November, 2016. Deferred for approval of section
	Evaluation By PEC • Firm has submitted copy of letter issued by Secretary CLB, dated 27th Sep, 2016, stating the grant of additional section for "Lyophilized Injection Ampoule (Hormone). • Firm has stated that Methylprednisolone is a steroid & according to the classification of Hormone, steroids fall under the subclass of Hormone. Decision: Registration Board deferred for clarification of product pharmacological classification with respect to manufacturing facility.				
	Previous Decision: Registration Board in its 267th meeting deferred the case for the clarification of product pharmacological classification with respect to manufacturing facility.				
	Evaluation By PEC. **a.** According to WHO ATC classification system Hydrocortisone is classified as under: H Systemic Hormonal Preparations, Excl. Sex Hormones And Insulin H02 Corticosteroids For Systemic Use H02A Corticosteroids For Systemic Use, Plain H02AB Glucocorticoids H02AB09 Hydrocortisone **b.** Now the firm has submitted the letter of Licensing Division bearing a number "No.F. 1-18/92-Lic (Vol-II)" dated 6th July, 2018 for modification of section from "Lyophilized Injection Ampoule (Hormone)" to "Lyophilized Injection vials(steroids)".				
	Previous Decision: Registration Board in its 284th meeting deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Evaluation by PEC: Applicant has submitted letter of CLB having No. F-18/92-Lic(Vol-II) dated 7th of November, 2019 grant of lyophilized Injection Vials Steroidal (Hormone).				

	Decision(M-293): Registration Board deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Registration Board deliberated the matter in detail and discussed that aplicant has steroidal hormone section & applied formulation is a corticosteroid which can not be manufactured with hormones like estrogen, progesterone & testosterone etc due to the risk of cross contamination. However, firm don't have any approved or registered formulation in the said section neither hormone nor steroid. **Decision: Keeping in view the above discussion, the Board decided as follows:** • **Approve registration of applied drug product in the above said section & advised firm to change the title of section from "Steroidal (Hormone)" to "Steroids" so to avoid any future registration of hormonal preparation in the said section.** • **The Board further decided that letter of registration will be issued to the firm after change of name of section.**				
1543.	M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road,	Medrone 1000 Injection Methylprenisole as Sodium succinate USP…….1000mg Glucocorticoid (USP Specs)	Form 5 Dy.No.769 02-09-2016 Rs.20,000/-1's 1'sx16ml ampoule Of WFI Rs.2150/-	International availability not provided, Solu –Medrol by Pfizer Pharma, Inspection report dated 17-08-2016 recommended for the grant of additional	263rd Meeting Registration Board held on 29-30th November Deferred for approval of section
	Evaluation By PEC • Firm has submitted copy of letter issued by Secretary CLB, dated 27th Sep, 2016, stating the grant of additional section for "Lyophilized Injection Ampoule (Hormone). • Firm has stated that Methylprednisolone is a steroid & according to the classification of Hormone, steroids fall under the subclass of Hormone. Decision: Registration Board deferred for clarification of product pharmacological classification with respect to manufacturing facility.				
	Previous Decision: Registration Board in its 267th meeting deferred the case for the clarification of product pharmacological classification with respect to manufacturing facility.				
	Evaluation By PEC. **a.** According to WHO ATC classification system Hydrocortisone is classified as under: H Systemic Hormonal Preparations, Excl. Sex Hormones And Insulin H02 Corticosteroids For Systemic Use H02A Corticosteroids For Systemic Use, Plain H02AB Glucocorticoids H02AB09 Hydrocortisone **b.** Now the firm has submitted the letter of Licensing Division bearing a number "No.F. 1-18/92-Lic (Vol-II)" dated 6th July, 2018 for modification of section from "Lyophilized Injection Ampoule (Hormone)" to "Lyophilized Injection vials(steroids)".				
	Previous Decision: Registration Board in its 284th meeting deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Evaluation by PEC: Applicant has submitted letter of CLB having No. F-18/92-Lic (Vol-II) dated 7th of November, 2019 grant of lyophilized Injection Vials Steroidal (Hormone).				
	Decision(M-293): Registration Board deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Registration Board deliberated the matter in detail and discussed that aplicant has steroidal hormone section & applied formulation is a corticosteroid which can not be manufactured with hormones like estrogen, progesterone & testosterone etc due to the risk of cross contamination. However, firm don't have any approved or registered formulation in the said section neither hormone nor steroid.				

	Decision: Keeping in view the above discussion, the Board decided as follows: • **Approve registration of applied drug product in the above said section & advised firm to change the title of section from "Steroidal (Hormone)" to "Steroids" so to avoid any future registration of hormonal preparation in the said section.** • **The Board further decided that letter of registration will be issued to the firm after change of name of section.**				
1544.	M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road,	Medrone 125 Injection Each vial contains: Methylprednisolne as sodium succinate (USP) ……125mg Glucocorticoids (USP Specs)	Form 5 Dy.No.770 02-09-2016 Rs.20,000/- 1's x2ml Rs.255/-	International availability not provided, Solu –Medrol by Pfizer Pharma, Inspection report dated 17-08-2016 recommended for the grant of additional sections	263rd Meeting Registration Board held on 29-30th November, 2016. Deferred for approval of section
	Evaluation By PEC • Firm has submitted copy of letter issued by Secretary CLB, dated 27th Sep, 2016, stating the grant of additional section for "Lyophilized Injection Ampoule (Hormone). • Firm has stated that Methylprednisolone is a steroid & according to the classification of Hormone, steroids fall under the subclass of Hormone. Decision: Registration Board deferred for clarification of product pharmacological classification with respect to manufacturing facility.				
	Previous Decision: Registration Board in its 267th meeting deferred the case for the clarification of product pharmacological classification with respect to manufacturing facility.				
	Evaluation By PEC. **a.** According to WHO ATC classification system Hydrocortisone is classified as under: H Systemic Hormonal Preparations, Excl. Sex Hormones And Insulin H02 Corticosteroids For Systemic Use H02A Corticosteroids For Systemic Use, Plain H02AB Glucocorticoids H02AB09 Hydrocortisone **b.** Now the firm has submitted the letter of Licensing Division bearing a number "No.F. 1-18/92-Lic (Vol-II)" dated 6th July, 2018 for modification of section from "Lyophilized Injection Ampoule (Hormone)" to "Lyophilized Injection vials(steroids)".				
	Previous Decision: Registration Board in its 284th meeting deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Evaluation by PEC: Applicant has submitted letter of CLB having No. F-18/92-Lic (Vol-II) dated 7th of November, 2019 grant of lyophilized Injection Vials Steroidal (Hormone).				
	Decision(M-293): Registration Board deferred the case for further deliberation upon facility required for manufacturing of applied formulation.				
	Registration Board deliberated the matter in detail and discussed that aplicant has steroidal hormone section & applied formulation is a corticosteroid which can not be manufactured with hormones like estrogen, progesterone & testosterone etc due to the risk of cross contamination. However, firm don't have any approved or registered formulation in the said section neither hormone nor steroid. **Decision: Keeping in view the above discussion, the Board decided as follows:** • **Approve registration of applied drug product in the above said section & advised firm to change the title of section from "Steroidal (Hormone)" to "Steroids" so to avoid any future registration of hormonal preparation in the said section.** • **The Board further decided that letter of registration will be issued to the firm after change of name of section.**				

Case no. 02 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

1545.	Name and address of Manufacturer / Applicant	M/s Farm Aid Group Plot No. 3/2 Phase I & II Hattar, Industrial Estate, Haripur.
	Brand Name + Dosage Form + Strength	Zinco B Powder
	Composition	Each kg Contains: Streptomycin Sulphate…36gm Penicillin Penicillin…12gm Zinc Bacitracin 10%…52gm
	Diary No. Date of R&I & fee	DyNo.3737; 30-01-2018; Rs. 20,000/-
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications
	Pack Size & Demanded Price	10g, 20g, 30g, 50g, 100g,250g,500g, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg: Decontrolled
	Me-too status	Penstrep Powder of Anima Nutrition Products Islamabad.
	GMP status	GMP inspection conducted on 11-02-16 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	What does this Zinc Bacitracin 10%...52gm mean? Clarify. Applied formulation is Powder but outline of manufacturing method is for capsule, Clarify.
	Decision: Deferred for the following: • **Clarification of formulation with reference to innovator/generic drug product** • **Correct outline of manufacturing method of applied formulation**	
1546.	Name and address of Manufacturer / Applicant	M/s Farm Aid Group Plot No. 3/2 Phase I & II Hattar, Industrial Estate, Haripur.
	Brand Name + Dosage Form + Strength	Mycopen Powder 72gm/24gm/104gm
	Composition	Each kg Contains: Streptomycin Sulphate…72gm Procaine Penicillin…24gm Zinc Bacitracin …104gm
	Diary No. Date of R&I & fee	DyNo.3732; 30-01-2018; Rs. 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications
	Pack Size & Demanded Price	10g, 20g, 30g, 50g, 100g,250g,500g, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg: Decontrolled
	Me-too status	S.P.Z.200 Water Soluble Powder of Islamabad Pharmaceutical Products
	GMP status	GMP inspection conducted on 11-02-16 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	Applied formulation is Powder but outline of manufacturing method is for capsule, Clarify.
	Decision: Deferred for submission of correct outline of manufacturing method of applied formulation	
1547.	Name and address of Manufacturer / Applicant	M/s Farm Aid Group Plot No. 3/2 Phase I & II Hattar, Industrial Estate, Haripur.
	Brand Name + Dosage Form + Strength	Septo can Powder 72gm/24gm/104gm
	Composition	Each kg Contains: Streptomycin Sulphate…36gm Procaine Penicillin…12gm Zinc Bacitracin …52gm
	Diary No. Date of R&I & fee	DyNo.3733; 30-01-2018; Rs. 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications

	Pack Size & Demanded Price	10g, 20g, 30g, 50g, 100g,250g,500g, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg: Decontrolled
	Me-too status	Pro Sb Powder of Medicure Laboratories, Karachi.
	GMP status	GMP inspection conducted on 11-02-16 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (VIII)	Approval of section/manufacturing facility (Penicillin dedicated facility) by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for clarification of formulation with reference to innovator/generic drug product.	
1548.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"
	Brand Name +Dosage Form + Strength	Amantacin 10gm Powder
	Composition	Each 100gm Contains: Amantadine HCL…10gm
	Diary No. Date of R& I & fee	Dy.No 34438 dated 17-10-2018 Rs.20,000/- Dated 16-10-2018
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	decontrolled
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	----
	Remarks of the Evaluator (VIII)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Submit latest GMP inspection report.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.** • **Approval of section/manufacturing facility by the Central Licensing Board.** • **Latest GMP inspection report.**	
1549.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"
	Brand Name +Dosage Form + Strength	NFO Powder
	Composition	Each 1000gm Contains: Florfenicol…100gm Oxytetracycline HCL…300gm Neomycin Sulphate…150gm
	Diary No. Date of R& I & fee	Dy.No 34440 dated 17-10-2018 Rs.20,000/- Dated 16-10-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	decontrolled
	Me-too status (with strength and dosage form)	Could not be confirmed

	GMP status	----
	Remarks of the Evaluator (VIII)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable. • Submit latest GMP inspection report.
	Decision: **Decision: Deferred for the following:** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.** • **Submit latest GMP inspection report.**	
1550.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"
	Brand Name +Dosage Form + Strength	Interflor 250mg/ml Liquid
	Composition	Each ml Contains: Florfenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 34439 dated 17-10-2018 Rs.20,000/- Dated 16-10-2018
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	decontrolled
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	-----
	Remarks of the Evaluator (VIII)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.
	Decision: Deferre for thefollowing: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.**	
1551.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"
	Brand Name +Dosage Form + Strength	Doxyl-80 Powders
	Composition	Each gm Contains: Doxycycline Hyclate 918.23mg Eq. to Doxycycline Base…800mg
	Diary No. Date of R& I & fee	Dy. No. 34441 dated 17-10-2018 Rs.20,000/- Dated 16-10-2018
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	decontrolled
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	----
	Remarks of the Evaluator (VIII)	

	Decision: Deferre for thefollowing: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided Me Too is not verifiable.** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.**	
1552.	Name and address of manufacturer / Applicant	"M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi"
	Brand Name +Dosage Form + Strength	Encopol Liquid
	Composition	Each ml Contains: Enrofloxacin…20% Colistin Sulphate…3%
	Diary No. Date of R& I & fee	Dy.No 34443 dated 17-10-2018 Rs.20,000/- 16-10-2018
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	decontrolled
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	----
	Remarks of the Evaluator (VIII)	• Please clarify the following: Enrofloxacin… 20%/ml & Colistin Sulphate…3%"/ml. what does it mean? • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility
	Decision: Deferred for the following: • **Please clarify the following: Enrofloxacin… 20%/ml & Colistin Sulphate…3%"/ml. what does it mean?** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility**	

Case no. 03 Registration applications of newly granted DML or New section (Veterinary)

a. Deferred Cases

1553.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Grand TD Plus Oral Powder
	Composition	Each 100 gram contains: Tylosin Tartrate…….20 gm Doxycycline Hyclate……40 gm Colistin Sulphate…….10 gm Bromhexin HCl……..……....2 gm
	Diary No. Date of R&I & Fee	Dy. No. 21141 dated 18-10-2019 Rs. 20,000
	Pharmacological Group	Antibiotic/ Expectorant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	0.5kg, 1kg, 2.5kg, 5kg; Decontrolled
	Approval status of product in Reference Regulatory Authority	N/A
	Me-too status	Tydoxin-60 Powder of Aptly Reg. 093862 (not veriofiable)
	GMP status	Oral Powder section (general)(veterinary) Letter Issuance Date: 26th September, 2019..
	Remarks of the Evaluator (VIII)	Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration

		number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision (M-294): Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Evaluation by PEC: Now the Applicant has Submitted Evidence of Me Too: BROCOTYD POWDER of UNIVET PHARMACEUTICAL (Reg No.'058962) Each 100gm Contains: - Doxycycline Hyclate…Bp…40gm Tylosin Tartrate…Bp….20gm Colistin Sulphate….Bp…10gm Bromhexine Hcl….Bp…2gm (Antibiotic / Antibacterial)	
	Decision: Approved as per innovator's specification.	
1554.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Doxy-Hy 50 Oral Powder
	Composition	Each kg contains: Doxycycline Hyclate (BP)……..……500 gm
	Diary No. Date of R&I & Fee	Dy. No. 21140 dated 18-10-2019 Rs. 20,000
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	0.5kg, 1kg, 2.5kg, 5kg; Decontrolled
	Approval status of product in Reference Regulatory Authority	N/A
	Me-too status	Doxyvetz Oral Powder of M/s Vetz Pharma Reg. No.088059 (not verifiable)
	GMP status	Oral Powder section (general)(veterinary) Letter Issuance Date: 26th September, 2019.
	Remarks of the Evaluator (VIII)	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided evidence is not verifiable.
	Decision (M-294): Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Evaluation by PEC: Now the Applicant has Submitted Evidence of following Me Too: Seldox Powder Of Selmore Pharmaceuticals Each G Contains: - Doxycycline Hyclate…..500mg. *applied formulation is in kg but me too product is in grams.	
	Decision: Deferred for either evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise revision of formulation in line with provided Me Too alongwith submission of requisite fee as the provided evidence is in gram while applied formulation contains same quanity of ingredient per kg.	
1555.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Tylvotart Soluble Granules/Oral Dry Powder
	Composition	Each gm contains: Acetyl IsovalerylTylosin Tartrate……...850 mg
	Diary No. Date of R&I & Fee	Dy. No. 21146 dated 18-10-2019 Rs. 20,000
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification

	Pack size & Demanded Price	25gm, 50gm, 100gm 500gm, 1kg, 2.5kg, 5kg; Decontrolled
	Me-too status	Aivlosin Soluble Granules1gm of Hilton Pharma
	GMP status	Oral Powder section (general)(veterinary) Letter Issuance Date: 26th September, 2019.
	Remarks of the Evaluator (VIII)	
	Decision (M-294): Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Evaluation by PEC: Now the Applicant has Submitted Evidence of following Me Too: AIVLOSIN SOLUBLE GRANULES of HILTON PHARMA 1gm Contains: - Acetyl Isovaleryl Tylosin Tartrate 850mg	
	Decision: Approved as per innovator's specification.	
1556.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Neocin 72% Oral Powder
	Composition	Each gram contains: Neomycin (as Sulphate) (BP)…….720 mg
	Diary No. Date of R&I & Fee	Dy. No. 21144 dated 18-10-2019 Rs. 20,000
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	0.5kg, 1kg, 2.5kg, 5kg; Decontrolled
	Approval status of product in Reference Regulatory Authority	N/A
	Me-too status	Neovetz 72% Of Vetz Pharma Reg. 079295
	GMP status	Same as recorded for above application.
	Remarks of the Evaluator (VIII)	
	Decision (M-294): Deferred for scientific rational for neomycin 72% water soluble powder, since neomycin 70% water soluble powder is already approved.	
	Evaluation by PEC: Now the Applicant has Submitted Evidence of following Me Too: Neovetz 72% Of Vetz Pharma Reg. 079295 Each 1gm Contains:- Neomycin Sulphate……720mg	
	Decision: Approved as per innovator's specification.	

Case no. 04 Registration applications of categories to be considered on priority

c. Export facilitation

1557.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Amsart- H Tablets 10mg/160mg/25mg
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)…10mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 144730; 07-03-19: Rs. 20,000
	Pharmacological Group	Calcium Channel Blocker / Angiotensin receptor blocker/ diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Valtec AMH 10/160/25 Tablet of Tabros Pharma Karachi
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP

	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1558.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Amsart- H Tablets 10mg/160mg/12.5mg
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)…10mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 144729; 07-03-19: Rs. 20,000
	Pharmacological Group	Calcium Channel Blocker / Angiotensin receptor blocker/ Diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Valtec AMH 10/160/12.5 Tablet of Tabros Pharma Karachi
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1559.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Amsart- H Tablets 5mg/160mg/12.5mg
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 144728; 07-03-19: Rs. 20,000
	Pharmacological Group	Calcium Channel Blocker / Angiotensin receptor blocker/ Diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Valtec AMH 5/160/12.5 Tablet of Tabros Pharma Karachi
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1560.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Amsart- H Tablets 5mg/160mg/25mg
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)…5mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 144731; 07-03-19: Rs. 20,000
	Pharmacological Group	Calcium Channel Blocker / Angiotensin receptor blocker/ Diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications

	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Valtec AMH 5/160/25 Tablet of Tabros Pharma Karachi
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1561.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Amsart- H Tablets 10mg/320mg/25mg
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)…10mg Valsartan…320mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 144732; 07-03-19: Rs. 20,000
	Pharmacological Group	Calcium Channel Blocker / Angiotensin receptor blocker/ Diuretic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Valtec AMH 5/160/25 Tablet of Tabros Pharma Karachi
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1562.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Macban tablet 20mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban …. 20mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 14727; 07-03-19: Rs. 20,000
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	7's, 10's, 14's, 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Mabinat tablet 20mg of Martin Dow
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved with innovator's specification.	
1563.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Macban tablet 15mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…. 15mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 14726; 07-03-19: Rs. 20,000
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications

	Pack size & Demanded Price	7's, 10's, 14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	072549 "Xarelto 15mg Tablets "M/s. Bayer Pakistan (Private) Limited, S.I.T.E.,Karachi."
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved with innovator's specification.	
1564.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Macban tablet 10mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…. 10mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 14725; 07-03-19: Rs. 20,000
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	5's, 10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved with innovator's specification.	
1565.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Etrozole tablet 2.5mg
	Composition	Each Film Coated Tablet Contains: Letrozole…. 2.5mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 14735; 07-03-19: Rs. 20,000
	Pharmacological Group	Aromatase inhibitors
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA(film coated)
	Me-too status	LETARA TABLETS 2.5mg By AJ MIRZA PHARMA
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	Fee challan is for letrozole 2.5mg tablet but on Form 5 Letrozole 5mg is mentioned and undertakings are of anestrozole tablet. Submit the correct. Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing do not contain step of coating.
	Decision:Deferred for the following: • **Submit complete application for relevant formulation after correcting strength and name of API in entire application..** • **Clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but outline of method of manufacturing does not contain step of coating.**	

1566.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Antrozole tablet 1mg
	Composition	Each Film Coated Tablet Contains: Anastrozole…. 1mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 14736; 07-03-19: Rs. 20,000
	Pharmacological Group	Aromatase inhibitors
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA(film coated)
	Me-too status	ARMOTRAZ TABLETS 1mg Of AJ MIRZA PHARMA
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation contains ingredients of coating but Outline of method of manufacturing does not contain step of coating.
	Decision: **Deferred for clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation contains ingredients of coating but outline of method of manufacturing does not contain step of coating.**	
1567.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Napso tablet 550mg
	Composition	Each Film Coated Tablet Contains: Naproxen sodium…. 550mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 14734; 07-03-19: Rs. 20,000
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Freshnap tablet 550mg of Fresh Pharmaceuticals
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	
1568.	Name and address of manufacturer / Applicant	Macter International Limited, F-2016, S.I.T.E. Karachi,
	Brand Name +Dosage Form + Strength	Napso tablet 275mg
	Composition	Each Film Coated Tablet Contains: Naproxen sodium…. 275mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 14733; 07-03-19: Rs. 20,000
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Nextar 250mg tablet of Novamed
	GMP status	GMP Inspection conducted on 23-01-2019 concluded that

		firm is operating at good level of GMP
	Remarks of the Evaluator (VIII)	
	Decision: Approved.	

Case no. 06 Registration applications of import cases

a. New Cases (Human)

1569.	Name and address of Applicant	"M/s Bristol Mayer Biotech Pakistan. 73-B, Guldasht Town Lahore Cantt Pakistan
	Detail of Drug Sale License	Address: M/s Bristol Mayer Biotech73-B, Guldasht Town,Zarrar Shaheed Road, Lahore Validity: 7th April 2020 Status: Liense to sell drugs as a distributor.
	Name and address of manufacturer	M/s VEM ILAC San. Ve Tic.A.S. Sogutozo Mahallesi 2177 Cad.No 10 B/49 Cankaya Turkey"
	Name and address of marketing authorization holder	M/s VEM ILAC San. Ve Tic.A.S.Sogutozo Mahallesi 2177 Cad.No 10 B/49 Cankaya Turkey"
	Name of exporting country	Argentine
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy.No 18449 dated 21-05-2018
	Fee including differential fee	Rs.50,000/- Dated 21-05-2018
	Brand Name +Dosage Form + Strength	Ondaren 8mg/4ml Solution for Injection
	Composition	"Each 4ml Contains: Ondansetron as Hydrochloride Dihydrate…8mg"
	Finished Product Specification	Manufacturer Specifications
	Pharmacological Group	Antiemetic
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	As per SRO
	International availability	Approved in USFDA
	Me-too status	
	Detail of certificates attached	Applicant has submitted the following documents stating following information on it: **Certificate of Pharmaceutical Product.** **Certificate No. 2018/1900** **Certificate validity: 18/05/2020** **Issued by:** Republic of Turkey, Ministry of Health Turkish Medicine & Medical Devices Agency **Free sale in exporting country:** yes. **GMP:** Facilities & operations conform to GMP as recommended by WHO. **Letter of authorization: ---** M/s Bristol Mayer Biotech Pakistan & M/s VEM ILAC San. Ve Tic.A.S. **Dated:** 07-06-2018 **Validity**: 2 years.

Remarks of the Evaluator (VIII)

Sr. No.	Queries	Response
1	Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.	It is type I transparent glass, as submitted by applicant
2	Submit copy of valid DSL of the	Address: M/s Bristol Mayer Biotech73-B, Guldasht

		applicant.	Town,Zarrar Shaheed Road, Lahore Validity: 7th April 2020 Status: Liense to sell drugs as a distributor.
	3	Fee for imported product is one lac but you have submitted fifty thousand rupees. Submit differential fee.	Applicant has submitted fee challan of Rupee 50,000/- Slip No. 1914217 Endorsement date: 24-12-2019
	4	Submit either original legalized COPP or legalized free sale certificate & GMP certificate of manufacturer of applied drug product before further processing of case.	Applicant has submitted the following documents stating following information on it: **Certificate of Pharmaceutical Product.** **Certificate No. 2018/1900** **Certificate validity: 18/05/2020** **Issued by:** Republic of Turkey, Ministry of Health Turkish Medicine & Medical Devices Agency **Free sale in exporting country:** yes. **GMP:** Facilities & operations conform to GMP as recommended by WHO.
	Decision: Approved with USP specifications as per Policy for inspection of Manufacturer abroad.		
1570.	Name and address of Applicant	"M/s Bristol Mayer Biotech Pakistan. 73-B, Guldasht Town Lahore Cantt Pakistan	
	Detail of Drug Sale License	Address: M/s Bristol Mayer Biotech73-B, Guldasht Town,Zarrar Shaheed Road, Lahore Validity: 7th April 2020 Status: Liense to sell drugs as a distributor.	
	Name and address of manufacturer	M/s VEM ILAC San. Ve Tic.A.S. Sogutozo Mahallesi 2177 Cad.No 10 B/49 Cankaya Turkey"	
	Name and address of marketing authorization holder	M/s VEM ILAC San. Ve Tic.A.S.Sogutozo Mahallesi 2177 Cad.No 10 B/49 Cankaya Turkey"	
	Name of exporting country	Turkey"	
	Type of Form	Form 5A	
	Diary No. & Date of R& I	Dy.No 18448 dated 21-05-2018	
	Fee including differential fee	Rs.50,000/- Dated 21-05-2018	
	Brand Name +Dosage Form + Strength	Ondaren 4mg/2ml Solution for Injection	
	Composition	"Each 2ml Contains: Ondansetron as Hydrochloride Dihydrate…4mg"	
	Finished Product Specification	Manufacturer Specifications	
	Pharmacological Group	Antiemetic	
	Shelf life	24 months	
	Demanded Price	As per SRO	
	Pack size	As per SRO	
	International availability	Approved in USFDA	
	Me-too status		
	Detail of certificates attached	Applicant has submitted the following documents stating following information on it: **Certificate of Pharmaceutical Product.** **Certificate No. 2018/1903** **Certificate valid 18-05-2020** **Issued by:** Republic of Turkey, Ministry of Health Turkish Medicine & Medical Devices Agency **Free sale in exporting country:** yes. **GMP:** Facilities & operations conform to GMP as recommended by WHO. **Letter of authorization: ---** M/s Bristol Mayer Biotech Pakistan & M/s VEM ILAC San. Ve	

		Tic.A.S. **Dated:** 07-06-2018 **Validity**: 2 years.

Remarks of the Evaluator (VIII)

Sr. No.	Queries	Response
1	Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.	It is type I transparent glass, as submitted by applicant
2	Submit copy of valid DSL of the applicant.	Address: M/s Bristol Mayer Biotech73-B, Guldasht Town,Zarrar Shaheed Road, Lahore Validity: 7th April 2020 Status: Liense to sell drugs as a distributor.
3	Fee for imported product is one lac but you have submitted fifty thousand rupees. Submit differential fee.	Applicant has submitted fee challan of Rupee 50,000/- Slip No. 1914216 Endorsement date: 24-12-2019
4	Submit either original legalized COPP or legalized free sale certificate & GMP certificate of manufacturer of applied drug product before further processing of case.	Applicant has submitted the following documents stating following information on it: **Certificate of Pharmaceutical Product.** **Certificate No. 2018/1903** **Certificate valid 18-05-2020** **Issued by:** Republic of Turkey, Ministry of Health Turkish Medicine & Medical Devices Agency **Free sale in exporting country:** yes. **GMP:** Facilities & operations conform to GMP as recommended by WHO. **Letter of authorization: ---** M/s Bristol Mayer Biotech Pakistan & M/s VEM ILAC San. Ve Tic.A.S. **Dated:** 07-06-2018 **Validity**: 2 years.

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

b. New Cases (Veterinary)

1571.	Name and address of Applicant	"M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Detail of Drug Sale License	**Address:** **Validity:** up to 07-Apr-2020 **Status:** License to Sell Drug as Distributor
	Name and address of manufacturer	M/s Von Franken Saic. Gral Lavalle 2247 Florida PCIA BSAS (1602) Argentine"
	Name and address of marketing authorization holder	M/s Von Franken Saic. Gral Lavalle 2247 Florida PCIA BSAS (1602) Argentine"
	Name of exporting country	Argentine
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy. No. 20216, 04-06-2018,
	Fee including differential fee	Rs.50,000/- Dated 04-06-2018
	Brand Name +Dosage Form + Strength	Dispocel Max IVD
	Composition	" Each Device: Progesterone…1.20g Except…q. s., …34g" (Each device contains: Progesterone…1.20g

		Inert Supporting Insert… 10.80g Inert Silicon…. 34.00g)
	Finished Product Specification	Manufacturer Specifications
	Pharmacological Group	Hormones
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	As per SRO
	International availability	Could not be confirmed
1572.	Me-too status	Could not be confirmed
	Detail of certificates attached	Applicant has submitted the following documents stating following information on it: **Certificate of Registration of Veterinary Product.** **Registration No. 07-057** **Registration expiration date: 03/28/27** **Issued by:** National Directorate Agrochemicals, Veterinary Products & Food Direction of Veterinary Products & Food For Animals. **Free sale in exporting country:** could not be confirmed. **GMP:** **Letter of authorization: ---** **Validity**:
	Remarks of the Evaluator (VIII)	• Submit Sole agency agreement. • Submit copy of valid DSL of the applicant. • Please submit FPP Specifications. • Mention type of primary packaging material of applied formulation. • Submit accelerated stability studies for applied formulation.
	Decision: Deferred for the following: • **Submit Sole agency agreement.** • **Submit copy of valid DSL of the applicant.** • **Please submit FPP Specifications.** • **Mention type of primary packaging material of applied formulation.** • **Submit accelerated stability studies for applied formulation.**	
1573.	Name and address of Applicant	"M/s Prix Pharmaceutical Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Detail of Drug Sale License	**Address:** **Validity:** **Status:**
	Name and address of manufacturer	M/s Von Franken Saic. Gral Lavalle 2247 Florida PCIA BSAS (1602) Argentine"
	Name and address of marketing authorization holder	M/s Von Franken Saic. Gral Lavalle 2247 Florida PCIA BSAS (1602) Argentine"
	Name of exporting country	Argentina
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy.No 20215 dated 04-06-2018
	Fee including differential fee	Rs.50,000/- Dated 04-06-2018
	Brand Name +Dosage Form + Strength	Benzoato De Estradiol Von Franken Solution for Injection(i.m)
	Composition	"Complete Qualitative Quantitative Formula: Estradiol Benzoate…100mg Benzyl Alcohol…3000mg Sunflower Oil C.S.P…100ml"
	Finished Product Specification	Manufacturer Specifications
	Pharmacological Group	Hormones

	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	As per SRO
	International availability	Could not be confirmed
	Me-too status	Could not be confirmed
	Detail of certificates attached	Applicant has submitted the following documents stating following information on it: **Certificate of Registration of Veterinary Product.** **Registration No. 07-057** **Registration expiration date: 03/28/27** **Issued by:** National Directorate Agrochemicals, Veterinary Products & Food Direction of Veterinary Products & Food For Animals. **Free sale in exporting country:** could not be confirmed. **GMP:** **Letter of authorization: ---** **Validity**:
	Remarks of the Evaluator (VIII)	• Submit Sole agency agreement. • Submit copy of valid DSL of the applicant. • Please submit FPP Specifications. • Mention type of primary packaging material of applied formulation. • Submit accelerated stability studies for applied formulation.
	Decision: Deferred for the following: • **Submit Sole agency agreement.** • **Submit copy of valid DSL of the applicant.** • **Please submit FPP Specifications.** • **Mention type of primary packaging material of applied formulation.** **Submit accelerated stability studies for applied formulation.**	
1574.	Name and address of Applicant	"M/s Chappal Enterprises. G8, Muhammadi Trade Tower, Opposite Adam Chamber, Altaf Hussain Road, New Challi, Karachi
	Detail of Drug Sale License	**Address:** Suit No. 4/23 Arkay Square Extension New Challi Shahra e Liaqat, Karachi. **Validity:** valid till 08.06.2019 **Status:** License to sell drugs by way of wholesale
	Name and address of manufacturer	M/s Atco Pharma for Pharmaceutical Industries. Industrial Quisna Zone, Part No.1, Phase No. 3-Quisna-El Menofia, Egypt"
	Name and address of marketing authorization holder	M/s Atco Pharma for Pharmaceutical Industries. Industrial Quisna Zone, Part No.1, Phase No. 3-Quisna-El Menofia, Egypt"
	Name of exporting country	Egypt"
	Type of Form	Form 5A
	Diary No. & Date of R& I	Dy.No 8531 dated 07-03-2018
	Fee including differential fee	Rs. 100,000/- Dated 07-03-2018
	Brand Name +Dosage Form + Strength	Atco-Tylan Water Soluble Powder
	Composition	Each 100gm Contains: Tylosin Tartrate Eq. to 92 gm Tylosin Base…100gm
	Finished Product Specification	Manufacturer Specifications
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	As per SRO

	International availability	Could not be confirmed
	Me-too status	Tyloveto-S Soluble Powder of VMD PAKISTAN
	Detail of certificates attached	Applicant has submitted the following documents stating following information on it: Certificate of Pharmaceutical Product. Certificate No. Certificate valid till: Issued by: Free sale in exporting country: GMP: Letter of authorization: --- Dated: Validity:
	Remarks of the Evaluator (VIII)	
	Decision: Deferred for confirmation of approval status in reference regulatory authorities.	

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

a. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1575.	M/s. Macter International Limited, F-216, S.I.T.E, Karachi.	Vireof-N 25mg Tablets. Each film coated tablet contains: Tenofovir alafenamide (as fumarate)… 25mg	Duplicate dossier	Approved in US-FDA The firm was granted GMP certificate based on inspection conducted on 14-03-2017.

STABILITY STUDY DATA			
Drug	Vireof-N 25mg Tablets.		
Name of Manufacturer	M/s. Macter International Limited, F-216, S.I.T.E, Karachi		
Manufacturer of API	Shengai Desano Chemical Pharmaceuticals, No. 417, Binhai Road, Laogang Town, Pudong New Area, Shanghai.		
API Lot No.	DBH251-B15A-180802		
Description of Pack (Container closure system)	Alu/alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,1, 3,6 (month) Real Time: 0,1, 3,6 (month)		
Batch No.	001P	002P	003P
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	09-2018	09-2018	09-2018

Date of Initiation	Sep- 2018	Sep- 2018	Sep- 2018
No. of Batches	03		
Date of Submission	15-04-19 (Dy. No. 3603)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted the following: **Copy of COA** **From**:Shengai Desano Chemical Pharmaceuticals**Batch No**: DBH251-B15A-180802
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted the following: Copy of GMP Certificate: **Certificate No:** SH2017046 **Issued To**: Shengai Desano Chemical Pharmaceuticals, No. 417, Binhai Road, Laogang Town, Pudong New Area, Shanghai. **Issued ON**: 04-12-2017 **Valid Till**: 3-12-2022 **Issued By**: China Food & Drug Administration.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted Coy of Commercial invoice attested by ADC on 27-08-18 having following information on it: **Invoice Number**: DL-Y-2018-0208 **Manufacturer of API**: Desano Limited. No. 1479, Zhangheng Road, Zhangliang Hi- Tech Park, Shanghai 201203, China. Tenofovir Alafenamide Fumarate API: 1kg Tenofovir Alafenamide Fumarate API W/S: 4g Impurity 1: 100mg Fumaric acid: 100mg Impurity 2: 100mg
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Evaluation by PEC:

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Vireof-N Tablet 25mg (TenofovirAlafenamide Fumarate) Tablets by M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 14th Nov, 2019.
Investigation Date and Time: 18th December, 2019.

Investigation Site: M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Macter International Ltd., F-216, S.I.T.E, Karachi for registration of Vireof-N Tablet 25mg (Tenofovir Alafenamide Fumarate) Tablets. PE&R Division considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and also advised to verify:

"Confirmation of dissolution test results for all trial batches of applied formulation on US-FDA recommended dissolution parameters including RPM".

Composition of Panel:

1. Prof. Dr. Ghulam Sarwar, ex-member Registration Board, Dean faculty of Pharmacy, Jinnah University for Women, Karachi.
2. Dr. Affan Ali Qureshi, Assistant Director (CDL) DRAP, Karachi.
3. Dr. Kirshan Das, Assistant Director DRAP Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

S. No.	Question	Observation
1.	Do you have documents confirming the import of Tenofovir Alafenamide Fumarate API including approval from DRAP?	The firm has imported 1Kg Tenofovir Alafenamide Fumarate (API) from Shanghai Desano Chemical Pharmaceutical Co., Ltd.)vide invoice No. DL-Y-2018-0208 dated: 27.08. 2018. There is proper approval from DRAP Karachi Form 6 (2440-17).
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular manufacturer of API is the vendor evaluation process based on audit and other criteria like manufacturer GMP status, DMF source etc.
3.	Do you have documents confirming the import of Tenofovir Alafenamide Fumarate reference standard and impurity standards?	The firm has imported Tenofovir Alafenamide Fumarate working standard and two impurities standards from the API manufacturer.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has Certificate of Analysis of API, working standard of API and impurities standards.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificates for API manufacturer issued by China Food & Drugs Administration valid till 03/12/2022.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method of testing.
7.	Do you have stability studies reports on APIs?	The firm has stability studies report on API (Tenofovir Alafenamide Fumarate) conducted by API manufacturer.

8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The manufacturer of API has performed the stability studies as per SIM method. The process related impurities and degradation product ie. Impurity I have been observed.
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying impurities.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of API (Tenofovir Alafenamide Fumarate) working standard and impurity standard.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Microcrystalline cellulose, Lactose Monohydrate ,Croscarmellose sodium, Magnesium stearate
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records for the excipients used.
14.	Do you have written and authorized protocols for the development of Tenofovir Alafenamide Fumarate Tablets?	The firm has written and authorized protocol for the development Tenofovir Alafenamide Fumarate Vireof-N tablets 25mg.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug Excipient compatibility studies as composition of their product is similar to that of innovator product (VEMLIDY tablets 25mgfrom GILEAD Ontario Canada.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution profile of their product with VEMLIDY 25mg batch # CBNKMD of GILEAD and found comparable to the innovator product.
17.	Do you have product development (R&D) section	The firm has product development (R&D) section with requisite manufacturing, storage and analysis facilities.
18.	Do you have necessary equipments available in product development section for development Tenofovir Alafenamide Fumarate Tablets?	The firm has all the necessary equipment available in product development section for the development of Tenofovir Alafenamide Fumarate tablets now, however, the product in question was manufactured in routine production area.
19.	Are the equipment in product development section qualified?	The equipments in product development section and production area are qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff in PD section with proper knowledge and training in Product Development including 04 Pharmacists 05 MSc Chemistry and 01 M.Phil.

<table>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Tenofovir Alafenamide Fumarate Tablets required?</td><td>The firm has manufactured three stability batches as follows;
Tenofovir Alafenamide Fumarate 25mg tablets:
<table><tr><th>Sr. No.</th><th>B. No.</th><th>Batch size</th></tr><tr><td>1</td><td>001P</td><td>5000</td></tr><tr><td>2</td><td>002P</td><td>5000</td></tr><tr><td>3</td><td>003P</td><td>5000</td></tr></table>The tablets are packed in Alu Alu blisters with pack size 3 x 10’s.</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the number of tablets required per testing frequency and number of testing frequencies.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete records of production of stability batches. All log books are properly maintained.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocol for the stability testing of Tenofovir Alafenamide Fumarate tablets.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated method for testing of stability batches of finish product i.e. Tenofovir Alafenamide Fumarate tablets based on the API method of testing provided by the API manufacturer.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>The firm has developed and validated method based on API manufacturer for testing of finished product, so method transfer studies were required.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Tenofovir Alafenamide Fumarate and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the API (Tenofovir Alafenamide Fumarate) and the finished drug Vireof-N (Tenofovir Alafenamide Fumarate) tablets 25mg.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm’s method of analysis is stability indicating as evidence by forced degradation studies and spiking studies of the two major impurities.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21CFR Compliant?</td><td>The HPLC software is 21CFR compliant as per record available with the firm.</td></tr>
<tr><td>31.</td><td>Can you show Audit trail reports on Tenofovir Alafenamide Fumarate testing?</td><td>Audit Trail on the testing reports on Tenofovir Alafenamide Fumarate API and Vireof-N tablets 25mg is available.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm has only remaining quantities of stability batches kept on real-time stability testing.</td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>The firm has three lab scale batches kept on stability studies for real time stability testing. Currently 12 months studies have been completed with satisfactory results.</td></tr>
<tr><td>34.</td><td>Do you have valid calibration status for the equipment used in Tenofovir Alafenamide Fumarate Tablets production and analysis?</td><td>The firm has valid calibration status for the equipment used in Vireof-N (Tenofovir Alafenamide Fumarate) tablets 25mg production and analysis.</td></tr>
<tr><td>35.</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>The firm has adequate monitoring and control system for stability chambers.</td></tr>
</table>

36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipments, personnel and utilities are GMP compliant.
37.	Any other query raised by PE&R Division: Confirmation of dissolution test results for all trial batches of applied formulation on US-FDA recommended dissolution parameters including RPM.	As per firm they have adopted Dissolution method as recommended by US-FDA. The medium is 50 mM Sodium Acetate buffer pH 4.5, Apparatus is USP type II, RPM is 75 which are same as recommended by USFDA. The sampling time is 30 mins which is the maximum time point mentioned on the website of USFDA under dissolution data, however the NDA document of VEMLIDY shows the sampling time to be 15 mins. The firm states that F2 was calculated in CDP at 10 mins because the drug was dissolved more than 90% within 5 mins which shows the formulation complies with innovator as well as US-FDA recommendation. The firm has also performed dissolution testing on an additional time point of 15 month of stability studies and observed the result at 15 minutes and found more than 90% release, which complies with innovator and US-FDA recommendations.

Conclusions:

1. On the basis of risk based approach the genuineness / authenticity of stability data including dissolution method submitted by the firm for registration of Vireof-N (Tenofovir Alafenamide Fumarate) Tablets 25mg is verifiable satisfactory level.
2. The related manufacturing area, equipments, personnel and utilities are GMP compliant and well suited for the manufacturing of Vireof-N (Tenofovir Alafenamide Fumarate) Tablets 25mg.
3. The case is submitted before Registration Board for decision please.

Decision (M-293): Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:

Sr. No.	Deferred for :	Submitted following:
1.	Decision (M-293): Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.	Applicant has submitted stability studies data for following three batches at following time points: **Batches:** Batch No: P004, P005, P006 **Testing Frequency:** Initial: 1 month: real time plus accelerated. Sampling Time: 15 minutes Drug release at 15 minute sampling interval: Above 90% for all trials at Ist month, as per data submitted by the firm. However data submitted by the firm is in dates before the meeting was carried out & decision of the case was made.

Decision: Deferred for clarification since the dissolution testing at 15 minutes time point for 2 batches was carried out before the date of conduction of 293rd meeting of Registration Board.

c. Verification of stability study data

d. Exemption from onsite verification of stability data

1576.	Name and address of manufacturer / Applicant	M/s Getz Pharma, Karachi.
	Brand Name +Dosage Form + Strength	Siloget Capsule 4mg
	Composition	Each capsule contains: Silodosin.....……4mg
	Diary No. Date of R& I & fee	Dy. No.22676; Date 30-11-2017 Rs. 50,000/-,
	Pharmacological Group	Adrenoceptor antagonist
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's: Rs. 900/-
	Approval status of product in Reference Regulatory Authorities	Rapaflo by M/s Wastson USA, Approved in Us-FDA
	Me-too status (with strength and dosage form)	N/A
	GMP status	Date: 26-06-2018 "Conclusion: Based on the area inspected, the people met and the documents reviewed, the considering the findings of the inspection, including the observations listed in the inspection report, M/s Getz Pharma, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today."

STABILITY STUDY DATA

Drug	Siloget Capsule 4mg		
Name of Manufacturer	M/s Getz Pharma, Karachi.		
Manufacturer of API	M/s Zhejiang Tianyu Pharmaceutical Co., Ltd.		
API Lot No.			
Description of Pack (Container closure system)	10's: Alu/Alu blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 75% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated:06Months		
Frequency	Real Time: 0,3,6 Months(on going) Accelerated: 0,1,3,6 Months		
Batch No.	426DS01	426DS02	426DS03
Batch Size	7500 Capsules	7500 Capsules	7500 Capsules
Manufacturing Date	29-03-2018	30-04-2018	30-04-2018
Date of Initiation	07-05-2018	15-05-2018	15-05-2018
No. of Batches	03		
Date of Submission	Dy No.2277, 01-04-19		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted Copy of COA having following information on it. Batch No. L20160909

		Manufacturer: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd,
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted Copy of GMP certificate having following information on it: Issued On:13-09-2013 valid till: 12-09-2018
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Yes
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Data for Exemption from onsite investigation

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their Product "Siloget 8mg (Silodosin)", which was conducted on 16-02-2018, and was presented in 279th meeting of Registration Board held on 28th Feb -02nd March, 2018. Registration Board decided to approve registration of Siloget 8mg (Silodosin), of M/s. Getz Pharma (Pvt.) Ltd., Karachi. Following two points are reported inside the above stated inspection report: • The HPLC software is 21CFR complaint as per record available with the firm. • (Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well).
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Applicant has submitted the following: **For Silodosin:** License to import drug(s) for clinical trial examination, test or analysis having following information on it: Copy of commercial Invoice declaring following information on it: Attested by: ADC Karachi Attested on: 01-11-2016 Quantity: 0.45 Kg From: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td><u>For Silodosin:</u>
The firm has submitted copy of invoice declaring the submission of following reference standards.<table><tr><th>Particulars</th><th>Batch No.</th><th>Quantity</th><th>Supplier</th></tr><tr><td>Silodosin RS</td><td>WRS160101</td><td>0.1gm</td><td>M/s Zhejiang Tianyu Pharmaceutical</td></tr></table></td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Applicant has submitted the following:
<u>For Silodosin:</u>
GMP Certificate
Issued to:
Issued for:
Validity: Until 03-05-2019</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy for the following:
Getz Pharma (Private)Limited Vendor Certification Checklist</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COAs of Silodosin, working standard. Detail is as under :<table><tr><th>Particulars</th><th>Batch No</th></tr><tr><td>Silodosin</td><td>L20160909</td></tr><tr><td colspan="2">Working Standards</td></tr><tr><td>Silodosin RS</td><td>WRS160101</td></tr><tr><td colspan="2"></td></tr></table></td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Invoices for the procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development comprising of 21 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of protocol for stability study of three Primary batches of Silodosin (silodosin) 4mg Capsule.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of the following 03 Batches:<table><tr><td>BATCH NO</td><td>BATCH SIZE</td><td>MFG DATE</td></tr><tr><td>426DS01</td><td>7500 Capsules</td><td>29-03-2018</td></tr><tr><td>426DS01</td><td>7500 Capsules</td><td>30-04-2018</td></tr><tr><td>426DS01</td><td>7500 Capsules</td><td>30-04-2018</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted Record of remaining quantities of stability batches:</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
</table>

12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 01-07-2018 to 31-01-2019.
13.	Method used for analysis of API along with COA.	**For Silodosin:** The firm has submitted photocopy of method used for test analysis of API & Finished Product.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of method used for test analysis of API & Finished Product.
15.	Reports of stability studies of API from manufacturer.	**For Silodosin:** The firm has submitted photocopy of silodosin 06 Months Accelerated (40^oC+2^oC, RH 75+5%) & 18 month real time (30^oC+2^oC, RH 65+5%) stability study data of 03 batches from M/s Zhejiang Tianyu Pharmaceutical.
16.	Analysis reports for excipients used.	The firm has submitted photocopies of Analytical reports for excipients used in product development of Siloget Tablets by excipient's manufacturer & also its own.
17.	Drug-excipients compatibility studies.	The firm has stated that the composition of developed product is similar to the innovator's product formulation.
18.	Record of comparative dissolution data.	Comparative dissolution studies have been performed in following medium: i. pH 0.1N HCl buffer
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports of stability studies of applied formulation.

Evaluation by PEC :

Sr. No.	Queries	Response
01.	Please submit evidence of purchase of reference product for CDP & also submit justification for not performing Comparison Dissolution Profile in three dissolution media at three pH.	Now the Applicant has submitted following: 1. Invoice for purchase of Rapaflo Capsule 8mg. 2. Results of CDP for applied formulation with Rapaflo Capsule 8mg Batch No. 110179M at pH 1.2, pH 4.5, pH 6.8. & also stated following: Reference Product Silodosin Capsules 8mgis used for the Dissolution Profile Comparison, since the product is dose proportional. Further, product is BCS Class II and rapidly dissolving in all the three media therefore, F2 calculation is not applicable.
02.	Please submit clarification/ justification for selection of dissolution test criteria of applied drug product different from that of re erence product s according to USFDA Clinical & B o Pharmaceutics Review silodosin capsule is formulated as immediate release capsule with rapid dissolution ≥85% in 15 minutes.	We, Getz Pharma (Pvt.) Ltd., hereby inform your good office that during development and stability studies, we have kept General limits for the immediate release dosage form as per USP chapter (1092). However, we undertake that we will add additional sampling time i.e. 15 minutes for the initial 3 commercial batches that will be kept on stability. Upon completion of 6 months stability, we hereby commit to update our specifications and intimate DRAP accordingly.
03.	Submit valid GMP certificate of	Applicant has Copy of GMP Certificate having following

	API manufacturer.	information on it: "Certificate of GMP Compliance of a Manufacturer of Active Pharmaceutical Ingredients (APIs)" Certificate Number: MI-2016-CE-06202-1 Issued to: Zhejiang Tianyu Pharmaceutical Co Ltd Manufacturing Site Address: No 15 Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone Taizhou City Zhejiang Province P.R. China 317016 EXPIRY DATE: 15 March 2021 ISSUE DATE: 13 December 2017

Decision: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

1577.	Name and address of manufacturer / Applicant	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"
	Brand Name+Dosage Form + Strength	Dapawil 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin(as Propanediol monohydrate)…5mg"
	Diary No. Date of R& I & fee	Dy.No 41231 dated 07-12-2018 Rs.50,000/- Duplicate Dossier
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	N/A

STABILITY STUDY DATA

Drug	Dapawil 5mg Tablet		
Name of Manufacturer	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"		
Manufacturer of API	M/s. Jiangsu Yongan Pharmaceutical Co., Ltd.		
API Lot No.	Lot #: 201608001		
Description of Pack (Container closure system)	Alu/Alu foil		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/75%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 1, 2, 3, 4, 6 (Months) Real Time: 3,6 (Months)		
Batch No.	Trial # 001	Trial # 002	Trial # 003
Batch Size	0.350kg	0.350kg	0.350kg
Manufacturing Date	05-18	05-18	05-18
Date of Initiation	16-05-18	16-05-18	16-05-18
No. of Batches	03		
Date of Submission	Dy No. 25994, 04-12-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	Applicant has submitted following COAs: **For API:** Copy of COA (batch No.201608001, Exp Date: July, 2018) from M/s Jiangsu Yongan Pharmaceutical is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate declaring following information: Certificate No. JS20160548 Issued to: M/s. Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. Issued by: China Food & Drugs Administration, Validity: Valid Till 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. Manufacturer of API as per submitted invoice: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF THE EVALUATOR (VIII)

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided following documents as per checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 04-12-2019 vide diary No.25994.

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir 400mg/100mg (Sofosbuvir/Velpatasvir 400mg/100mg) Tablets", which was conducted on 23rd of May, 2019 and was presented in --- meeting of Registration board. Registration Board decided to approve registration Velbuvir 400mg/100mg Tablets" by M/s. Wilshire Laboratories. According to the report following points were confirmed.

<table>
<tr><td></td><td></td><td>• The firm has 21 CFR compliant HPLC software
• The firm has audit trail reports on Sofosbuvir testing.
• The firm possesses stability chambers with digital data loggers.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard.
Manufacturer of API as per submitted invoice:
Jiangsu Yongan Pharmaceutical Co., Ltd.
Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard.
For Working Standard & Impurities A, B, C, D, E.
Dated: 10-September-2017</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP certificate declaring following information:
Certificate No. JS20160548
Issued to: M/s. Jiangsu Yongan Pharmaceutical Co., Ltd.
Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus.
Issued by: China Food & Drugs Administration, Validity: Valid Till 03-03-2021.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td>Applicant has submitted following COAs:
<u>For API:</u>
• Copy of COA (batch No.201608001, Exp Date: July, 2018) from M/s Jiangsu Yongan Pharmaceutical is submitted.
<u>For reference/working standard:</u>
Not Submitted.
<u>For Impurities:</u>
• Copy of COA of impurity Standards A, B, has been submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices of the excipients used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff comprising of 06 members as per list involved in R&D</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>Yes</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Order of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial # 001</td><td>0.350kg/
83 packs</td><td>05-2018</td></tr>
<tr><td>Trial # 002</td><td>0.350kg/
83 packs</td><td>05-2018</td></tr>
</table>
</td></tr>
</table>

		Trial # 003 | 0.350kg/ 83 packs | 05-2018
11.	Record of remaining quantities of stability batches.	The firm has submitted reconciliation sheet mentioning followin details: **Batch No.** | **Dapawil 5mg Table Remaining Quantity** Trial # 001 | 58 packs Trial # 002 | 58 packs Trial # 003 | 58 packs
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-03-2018 to 30-09-2018.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopies of following: • Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house). • Method for analysis of API (Supplier/Manufacturer of FPP) & COA for Dapagliflozin Propanediol Monohydrate (Supplier).
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopies of following: • FPP Test/Analysis Method & FPP Specifications (In-house) for Dapawil 5mg Tablet.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Dapagliflozin Propanediol Monohydrate from M/s Jiangsu Yongan Pharmaceutical at Zone II.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	Excipients of applied drug product are similar to that of innovator product (Farxiga tablet 5mg) as submitted by firm.
18.	Record of comparative dissolution data.	The firm has submitted reports for comparative dissolution in three media including (0.1 N HCl) pH 1.2, Buffer pH 4.5 and Buffer pH 6.8.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted declaration of software quality & audit trail reports

Remarks of the Evaluator (VIII):

Sr. No.	Queries	Response
1.	Justification/Clarification for Use of Dissolution Method Different from That of US-FDA Recommended Dissolution Parameters in terms of sampling time (30min).	Applicant has submitted following: 1. Dissolution of Depawil is performed on 15 minutes in stability studies. 2. During 0 month testing and CDP, it has been performed in 30minutes, that's why test method was made according to FDA guidelines i.e. 30minutes. 3. But in stability studies the tablet dissolved within 15 minutes, as per innovator product release profile. 4. Moreover as evident by our CDP more than 85% drug was being released within 15 minutes.

2.	Please submit evidence of purchase of reference product for CDP.	Applicant has submitted invoice dated September 16, 2018 for purchase of Farxiga 5mg & 10mg tablet.
3.	Provide documents including chromatograms for initial testing of all three trial batches.	Applicant has submitted chromatograms of initial testing.
4.	Please submit copy of COA of reference/working standard for Dapagliflozin.	Applicant has submitted COA of Dapagliflozin Propanediol monohydrate working standard.
5.	Please explain why the content uniformity test is not performed for applied formulation at initial stage.	Now the applicant has submitted documents for content uniformity.
6.	Please explain why the invoice for purchase of API is not ADC attested & also mention quantity of API imported, before further processing of the case.	Commercial invoice is not ADC attested.

Decision: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

1578.	Name and address of manufacturer / Applicant	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Dapawil 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin (as prpanediol monohydrate)…10mg"
	Diary No. Date of R& I & fee	Dy.No 41232 dated 07-12-2018 Rs.50,000/-
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 18's, 20's, 28's, 30's, 40's, 50's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	N/A

STABILITY STUDY DATA

Drug	Dapawil 10mg Tablet		
Name of Manufacturer	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"		
Manufacturer of API	M/s. Jiangsu Yongan Pharmaceutical Co., Ltd.		
API Lot No.	Lot #: 201608001		
Description of Pack (Container closure system)	Alu/Alu foil		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 1, 2, 3, 4, 6(Months) Real Time: (Months)		
Batch No.	Trial # 001	Trial # 002	Trial # 003
Batch Size	0.350kg	0.350kg	0.350kg
Manufacturing Date	05-18	05-18	05-18

Date of Initiation	16-05-18	16-05-18	16-05-18
No. of Batches	03		
Date of Submission	Dy No. 25994, 04-12-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	Applicant has submitted following COAs: **For API:** Copy of COA (batch No.201608001, Exp Date: July, 2018) from M/s Jiangsu Yongan Pharmaceutical is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate declaring following information: Certificate No. JS20160548 Issued to: M/s. Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. Issued by: China Food & Drugs Administration, Validity: Valid Till 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. Manufacturer of API as per submitted invoice: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF THE EVALUATOR (VIII)

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided following documents as per checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 04-12-2019 vide diary No.25995.

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir 400mg/100mg (Sofosbuvir/Velpatasvir 400mg/100mg) Tablets", which was conducted on 23rd of May, 2019 and was presented in --- meeting of Registration board.

		Registration Board decided to approve registration Velbuvir 400mg/100mg Tablets" by M/s. Wilshire Laboratories. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports on Sofosbuvir testing. • The firm possesses stability chambers with digital data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. Manufacturer of API as per submitted invoice: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. For Working Standard & Impurities A, B, C, D, E. Dated: 10-September-2017
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. JS20160548 **Issued to**: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **Issued by**: China Food & Drugs Administration, **Validity**: Valid Till 03-03-2021.
5.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for Evaluation of Vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	Applicant has submitted following COAs: **For API:** • Copy of COA (batch No.201608001, Exp Date: July, 2018) from M/s Jiangsu Yongan Pharmaceutical is submitted. **For reference/working standard:** ***Not Submitted.*** **For Impurities:** • Copy of COA of impurity Standards A, B, has been submitted.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices of the excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff comprising of 06 members as per list involved in R&D
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Yes
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Batch Manufacturing Orders o following 03 Batches: **Batch No.** | **Batch Size** | **Mfg. Date**

		Trial # 001 | 0.350kg/83 packs | 05-2018 Trial # 002 | 0.350kg/83 packs | 05-2018 Trial # 003 | 0.350kg/83 packs | 05-2018
11.	Record of remaining quantities of stability batches.	The firm has submitted reconciliation sheet mentioning followin details: **Batch No.** | **Dapawil 5mg Table Remaining Quantity** Trial # 001 | 58 packs Trial # 002 | 58 packs Trial # 003 | 58 packs
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-03-2018 to 30-09-2018.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopies of following: • Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house). • Method for analysis of API (Supplier/Manufacturer of FPP) & COA for Dapagliflozin Propanediol Monohydrate (Supplier).
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopies of following: • FPP Test/Analysis Method & FPP Specifications (In-house) for Dapawil 5mg Tablet.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Dapagliflozin Propanediol Monohydrate from M/s Jiangsu Yongan Pharmaceutical at Zone II.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	Excipients of applied drug product are similar to that of innovator product (Farxiga tablet 5mg) as submitted by firm.
18.	Record of comparative dissolution data.	The firm has submitted reports for comparative dissolution in three media including (0.1 N HCl) pH 1.2, Buffer pH 4.5 and Buffer pH 6.8.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted declaration of software quality & audit trail reports

Remarks of the Evaluator (VIII):

Sr. No.	Queries	Response
1	Justification/Clarification for Use of Dissolution Method Different from That of US-FDA Recommended Dissolution Parameters in terms of sampling time (30min).	Applicant has submitted following: 1. Dissolution of Depawil is performed on 15 minutes in stability studies. 2. During 0 month testing and CDP, it has been performed in 30minutes, that's why test method was made according to FDA guidelines i.e. 30minutes. 3. But in stability studies the tablet dissolved within 15 minutes, as per innovator product release profile.

		4. Moreover as evident by our CDP more than 85% drug was being released within 15 minutes.
2	Please submit evidence of purchase of reference product for CDP.	Applicant has submitted invoice dated September 16, 2018 for purchase of Farxiga 5mg & 10mg tablet.
3	Provide documents including chromatograms for initial testing of all three trial batches.	Applicant has submitted chromatograms of initial testing.
4	Please submit copy of COA of reference/working standard for Dapagliflozin.	Applicant has submitted COA of Dapagliflozin Propanediol monohydrate working standard.
5	Please explain why the content uniformity test is not performed for applied formulation at initial stage.	Now the applicant has submitted documents for content uniformity.
6	Please explain why the invoice for purchase of API is not ADC attested & also mention quantity of API imported, before further processing of the case.	Commercial invoice is not ADC attested.

Decision: Registration Board decided to defer the case and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

1579.	Name and address of manufacturer / Applicant	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Dapawil 5/850mg Tablet
	Composition	"Each extended release tablet contains: Dapagliflozin (as Propanediol monohydrate) …5mg Metformin hydrochloride …850mg"
	Diary No. Date of R& I & fee	Dy.No 41233 dated 07-12-2018 Rs.50,000/-
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors/Biguanides
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 18's, 20's, 28's, 30's, 40's, 50's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in EMA
	Me-too status	N/A
	GMP status	

STABILITY STUDY DATA

Drug	Dapawil 5/850mg Tablet
Name of Manufacturer	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"
Manufacturer of API	**For Dapagliflozin (as Propanediol):** M/s. Jiangsu Yongan Pharmaceutical Co., Ltd. **For Metformin hydrochloride:** IPCA Laboratories Limited
API Lot No.	**For Dapagliflozin (as Propanediol):** Lot #: 201608001
Description of Pack (Container closure system)	Alu/Alu foil
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/75%±5% RH
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)

Frequency	Accelerated: 1,2,3,4,6 (Months) Real Time: 0, 3, 6, 9,12,18, 24 (Months)		
Batch No.	Trial # 001	Trial # 002	Trial # 003
Batch Size	3.25kg	3.25kg	3.25kg
Manufacturing Date	05-18	05-18	05-18
Date of Initiation	16-05-18	16-05-18	16-05-18
No. of Batches	03		
Date of Submission	Dy No. 27855, 23-12-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
9.	COA of API.	**For Dapagliflozin (as Propanediol):** Applicant has submitted following COAs: **For API:** • Copy of COA (batch No.201608001, Exp Date: July, 2018) from M/s Jiangsu Yongan Pharmaceutical is submitted. **For Metformin hydrochloride:** Applicant has submitted following COAs: **For API:** • Copy of COA (batch No.6417ML2RMI, Exp Date: NOV, 2021) from IPCA Laboratories Limited is submitted.
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**For Dapagliflozin (as Propanediol):** The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. JS20160548 **Issued to**: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **Issued by**: China Food & Drugs Administration, **Validity**: Valid Till 03-03-2021. **For Metformin hydrochloride:** The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. RTMGMP201703180 **Issued to**: IPCA Laboratories Limited. Address: Sejavta, Dit. Ratlam Madhya Pradesh, Ratlam. **Issued by**: Food & Drugs Administration, Madya Pradesh. **Validity**: Valid Till 31-12-2021.
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	**For Dapagliflozin (as Propanediol):** The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. Manufacturer of API as per submitted invoice: Jiangsu Yongan Pharmaceutical Co., Ltd.

		Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **For Metformin hydrochloride:** The firm has submitted copy of invoice dated 21-12-2016 not attested by ADC, DRAP declaring 2000kg APIMetformin hydrochloride. Manufacturer of API as per submitted invoice: IPCA Laboratories Limited. Address: Internation Division, International House, 48 Kandivili Industrial Estate, Kandivli (West) Mumbai, India.
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided following documents as per checklist approved by the Registration Board in its 278th Meeting: Date of submission: 04-12-2019 vide diary No.27855.		
Administrative Portion		
20.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir 400mg/100mg (Sofosbuvir/Velpatasvir 400mg/100mg) Tablets", which was conducted on 23rd of May, 2019 and was presented in --- meeting of Registration board. Registration Board decided to approve registration Velbuvir 400mg/100mg Tablets" by M/s. Wilshire Laboratories. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports on Sofosbuvir testing. • The firm possesses stability chambers with digital data loggers.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	**For Dapagliflozin (as Propanediol):** The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. Manufacturer of API as per submitted invoice: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **For Metformin hydrochloride:** The firm has submitted copy of invoice dated 21-12-2016 not attested by ADC, DRAP declaring 2000kg APIMetformin hydrochloride. Manufacturer of API as per submitted invoice: IPCA Laboratories Limited. Address: Internation Division, International House, 48 Kandivili Industrial Estate, Kandivli (West) Mumbai, India.
22.	Documents for the procurement of reference standard and impurity standards.	**For Dapagliflozin (as Propanediol):** The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP stating 0.5412kg API Dapagliflozin powder

		alongwith working reference standard & all impurities standard. For Working Standard & Impurities A, B, C, D, E. Dated: 10-September-2017. **For Metformin hydrochloride:** The firm has submitted copy of packing list dated 21-12-2016 stating 2000kg API Metformin hydrochloride alongwith working reference standard & all impurities standard as per packing list.
23.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**For Dapagliflozin (as Propanediol):** The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. JS20160548 **Issued to**: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **Issued by**: China Food & Drugs Administration, **Validity**: Valid Till 03-03-2021. **For Metformin hydrochloride:** The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. RTMGMP201703180 **Issued to**: IPCA Laboratories Limited. Address: Sejavta, Dit. Ratlam Madhya Pradesh, Ratlam. **Issued by**: Food & Drugs Administration, Madya Pradesh. **Validity**: Valid Till 31-12-2021.
24.	Mechanism for Vendor pre-qualification	The firm has submitted vendor Prequalification assessment form for only IPCA Laboratories Limited.
25.	Certificate of analysis of the API, reference standards and impurity standards	**For Dapagliflozin (as Propanediol):** Applicant has submitted following COAs: **For API:** • Copy of COA (batch No.201608001, Exp Date: July, 2018) from M/s Jiangsu Yongan Pharmaceutical is submitted. **For reference/working standard:** ***Not Submitted.*** **For Impurities:** • Copy of COA of impurity Standards A, B, has been submitted. **For Metformin hydrochloride:** Applicant has submitted following COAs: **For API:** • Copy of COA (batch No.6417ML2RMI, Exp Date: NOV, 2021) from IPCA Laboratories Limited is submitted. **For reference/working standard:** • Copy of COA (batch No. 4002ML2RII (A), Exp Date: June, 2019) from IPCA Laboratories Limited is submitted. **For Impurities:** • ***Not submitted***
26.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices of the excipients used in the formulation of applied product.
27.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff comprising of 06 members as per list involved in R&D
Production Data		

<table>
<tr><td>28.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>Yes</td></tr>
<tr><td>29.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Orders of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial # 001</td><td>3.25kg/
83 packs</td><td>05-2018</td></tr>
<tr><td>Trial # 002</td><td>3.25kg/
83 packs</td><td>05-2018</td></tr>
<tr><td>Trial # 003</td><td>3.25kg/
83 packs</td><td>05-2018</td></tr>
</table></td></tr>
<tr><td>30.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><th>Batch No.</th><th>Dapawil 5mg Table Remaining Quantity</th></tr>
<tr><td></td><td></td></tr>
<tr><td>Trial # 001</td><td>58 packs</td></tr>
<tr><td>Trial # 002</td><td>58 packs</td></tr>
<tr><td>Trial # 003</td><td>58 packs</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>31.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-03-2018 to 30-09-2018.</td></tr>
<tr><td>32.</td><td>Method used for analysis of API along with COA.</td><td><u>For Dapagliflozin (as Propanediol):</u>
The firm has submitted photocopies of following:
• Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house).
• Method for analysis of API (Supplier/Manufacturer of FPP) & COA for Dapagliflozin Propanediol Monohydrate (Supplier).
<u>For Metformin hydrochloride:</u>
• Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house).
• Method for analysis of API (Supplier/Manufacturer of FPP) & COA for Metformin hydrochloride (Supplier).</td></tr>
<tr><td>33.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopies of following:
• FPP Test/Analysis Method & FPP Specifications (In-house) for Dapawil-M 5mg/850 Tablet.</td></tr>
<tr><td>34.</td><td>Reports of stability studies of API from manufacturer.</td><td><u>For Dapagliflozin (as Propanediol):</u>
The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Dapagliflozin Propanediol Monohydrate from M/s Jiangsu Yongan Pharmaceutical at Zone II.
<u>For Metformin hydrochloride:</u>
The firm has submitted photocopy of 06 Months Accelerated and 60 Months Real Time Stability Study Data of 03 Batches of Metformin hydrochloride from M/s IPCA Laboratories Limited at Zone IV A.</td></tr>
<tr><td>35.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of Analytical reports of excipients used.</td></tr>
</table>

36.	Drug-excipients compatibility studies.	Excipients of applied drug product are similar to that of innovator product (xigduo 5/850mg tablet) as submitted by firm.
37.	Record of comparative dissolution data.	The firm has submitted reports for comparative dissolution in three media including (0.1 N HCl) pH 1.2, Buffer pH 4.5 and Buffer pH 6.8 innovator Xigdou 5/850mg tablets.
38.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted declaration of software quality & audit trail reports

Remarks of the Evaluator (VIII):

Sr. No.	Queries	Response
1.	Please clarify whether applied formulation is extended release or film coated tablet as in submitted dossier under heading of brand name & composition extended release is written & in clinical data & justification film coated is mentioned.	Applicant has clarified that applied formulation is film coated tablet.
2.	Please explain why the invoices for both APIs are not ADC attested.	Applicant has submitted the following: Dapagliflozin: Commercial invoice is not ADC attested. Metformin hydrochloride: ADC attested commercial invoice is submitted.
3.	Mention lot No. of API Metformin hydrochloride, as it is not mentioned on invoice.	--------
4.	Method for test/analysis of API is in-house or supplier? Moreover submit interpretation for using titration method for assay of Metformin hydrochloride.	Applicant has submitted Suppliers method test/analysis of API.
5.	Submit master formulation of applied formulation.	Not submitted.
6.	Please submit clarification for difference in the address of the manufacturer of metformin hydrochloride on invoice & on GMP certificate, moreover submit the GMP Certificate of relevant site & also provide list of drugs for which GMP certificate is issued to M/s. IPCA.	Applicant has submitted following: Address mentioned on commercial invoice is of office while the address on GMP is of manufacturing site. Applicant has submitted GMP certificate of another site of IPCA Laboratories Limited having address H4, MIDC, Waluj, Aurangabad, Maharastra state India. Issued by: Food & Drug Administration, Mahashtra, india.
7.	Submit evidence of purchase of reference product for CDP.	Applicant has submitted invoice dated October 1st 2018 for purchase of Xigduo 5/850mg & 5/1000mg tablet.
8.	Please explain why the content uniformity test is not performed for applied formulation.	Now the applicant has submitted documents for content uniformity.
9.	Please provide reference for selection of dissolution parameters for applied formulation before further processing of the case.	Dissolution parameters for applied formulation are following: Apparatus I, Basket 20mesh Rotation: 100rpm Time: 45 minutes Volume 1000ml

Decision: Deferred for following submissions:

- **Clarification of applied formulation, whether extended release or film coated**
- **Lot number of metformin hydrochloride API used in the stability studies along with evidence of its import**

- **Master formulation for the applied product**
- **Revised finished product specifications in the light of specifications of the innovator product and decision of 293rd meeting of Registration Board.**
- **Specify the exact site address of API manufacturer of metformin hydrochloride along with submission of its GMP certificate.**

1580.	Name and address of manufacturer / Applicant	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Dapawil-M XR 5/1000mg Tablet
	Composition	"Each extended release tablet contains: Dapagliflozin(as propanediol monohydrate)…5mg Metformin hydrochloride …1000mg"
	Diary No. Date of R& I & fee	Dy.No 41234 dated 07-12-2018 Rs.50,000/-
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 18's, 20's, 28's, 30's, 40's, 50's:As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in EMA
	Me-too status	N/A
	GMP status	

STABILITY STUDY DATA

Drug	Dapawil-M XR 5/1000mg Tablet		
Name of Manufacturer	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"		
Manufacturer of API	**For Dapagliflozin (as Propanediol):** M/s. Jiangsu Yongan Pharmaceutical Co., Ltd. **For Metformin hydrochloride:** IPCA Laboratories Limited		
API Lot No.	**For Dapagliflozin (as Propanediol):** Lot #: 201608001		
Description of Pack (Container closure system)	Alu/Alu foil		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/75%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 1,2,3,4,6 (Months) Real Time: 0, 3, 6, 9,12,18, 24 (Months)		
Batch No.	Trial # 001	Trial # 002	Trial # 003
Batch Size	0.350kg	0.350kg	0.350kg
Manufacturing Date	05-18	05-18	05-18
Date of Initiation	16-05-18	16-05-18	16-05-18
No. of Batches	03		
Date of Submission	Dy No. 25994, 04-12-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	**For Dapagliflozin (as Propanediol):** Applicant has submitted following COAs:

		For API: • Copy of COA (batch No.201608001, Exp Date: July, 2018) from M/s Jiangsu Yongan Pharmaceutical is submitted. **<u>For Metformin hydrochloride:</u>** Applicant has submitted following COAs: **For API<u>:</u>** • Copy of COA (batch No.6417ML2RMI, Exp Date: NOV, 2021) from IPCA Laboratories Limited is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**<u>For Dapagliflozin (as Propanediol):</u>** The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. JS20160548 **Issued to**: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **Issued by**: China Food & Drugs Administration, **Validity**: Valid Till 03-03-2021. **<u>For Metformin hydrochloride:</u>** The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. RTMGMP201703180 **Issued to**: IPCA Laboratories Limited. Address: Sejavta, Dit. Ratlam Madhya Pradesh, Ratlam. **Issued by**: Food & Drugs Administration, Madya Pradesh. **Validity**: Valid Till 31-12-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**<u>For Dapagliflozin (as Propanediol):</u>** The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. Manufacturer of API as per submitted invoice: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **<u>For Metformin hydrochloride:</u>** The firm has submitted copy of invoice dated 21-12-2016 not attested by ADC, DRAP declaring 2000kg APIMetformin hydrochloride. Manufacturer of API as per submitted invoice: IPCA Laboratories Limited. Address: Internation Division, International House, 48 Kandivili Industrial Estate, Kandivli (West) Mumbai, India.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life	

	of the product.	
8.	Commitment to follow Drug Specification Rules, 1978.	

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided following documents as per checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 04-12-2019 vide diary No.25995.

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Velbuvir 400mg/100mg (Sofosbuvir/Velpatasvir 400mg/100mg) Tablets", which was conducted on 23rd of May, 2019 and was presented in --- meeting of Registration board. Registration Board decided to approve registration Velbuvir 400mg/100mg Tablets" by M/s. Wilshire Laboratories. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports on Sofosbuvir testing. • The firm possesses stability chambers with digital data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**For Dapagliflozin (as Propanediol):** The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP declaring 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. Manufacturer of API as per submitted invoice: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **For Metformin hydrochloride:** The firm has submitted copy of invoice dated 21-12-2016 not attested by ADC, DRAP declaring 2000kg APIMetformin hydrochloride. Manufacturer of API as per submitted invoice: IPCA Laboratories Limited. Address: Internation Division, International House, 48 Kandivili Industrial Estate, Kandivli (West) Mumbai, India.
3.	Documents for the procurement of reference standard and impurity standards.	**For Dapagliflozin (as Propanediol):** The firm has submitted copy of invoice dated 10-09-2017 not attested by ADC, DRAP stating 0.5412kg API Dapagliflozin powder alongwith working reference standard & all impurities standard. For Working Standard & Impurities A, B, C, D, E. Dated: 10-September-2017. **For Metformin hydrochloride:** The firm has submitted copy of packing list dated 21-12-2016 stating 2000kg API Metformin hydrochloride alongwith working reference standard & all impurities standard as per packing list.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**For Dapagliflozin (as Propanediol):** The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. JS20160548 **Issued to**: Jiangsu Yongan Pharmaceutical Co., Ltd. Address: No. 18, 237 Provincial Road, Economic Development Zone, Huian Jiangus. **Issued by**: China Food & Drugs Administration, **Validity**: Valid Till 03-03-2021. **For Metformin hydrochloride:**

<table>
<tr><td></td><td></td><td>The firm has submitted copy of GMP certificate declaring following information:
Certificate No. RTMGMP201703180
Issued to: IPCA Laboratories Limited.
Address: Sejavta, Dit. Ratlam Madhya Pradesh, Ratlam.
Issued by: Food & Drugs Administration, Madya Pradesh.
Validity: Valid Till 31-12-2021.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted vendor Prequalification assessment form for only IPCA Laboratories Limited.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td><u>For Dapagliflozin (as Propanediol):</u>
Applicant has submitted following COAs:
For API:
• Copy of COA (batch No.201608001, Exp Date: July, 2018) from M/s Jiangsu Yongan Pharmaceutical is submitted.
For reference/working standard:
Not Submitted.
For Impurities<u>:</u>
• Copy of COA of impurity Standards A, B, has been submitted.
<u>For Metformin hydrochloride:</u>
Applicant has submitted following COAs:
For API<u>:</u>
• Copy of COA (batch No.6417ML2RMI, Exp Date: NOV, 2021) from IPCA Laboratories Limited is submitted.
For reference/working standard:
• Copy of COA (batch No. 4002ML2RII (A), Exp Date: June, 2019) from IPCA Laboratories Limited is submitted.
For Impurities:
• Not submitted</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices of the excipients used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff comprising of 06 members as per list involved in R&D</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>Yes</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Orders of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial # 001</td><td>3.25kg/
83 packs</td><td>05-2018</td></tr>
<tr><td>Trial # 002</td><td>3.25kg/
83 packs</td><td>05-2018</td></tr>
<tr><td>Trial # 003</td><td>3.25kg/
83 packs</td><td>05-2018</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:<table><tr><th>Batch No.</th><th>Dapawil 5mg Table
Remaining Quantity</th></tr><tr><td></td><td></td></tr><tr><td>Trial # 001</td><td>58 packs</td></tr><tr><td>Trial # 002</td><td>58 packs</td></tr><tr><td>Trial # 003</td><td>58 packs</td></tr></table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-03-2018 to 30-09-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td><u>For Dapagliflozin (as Propanediol):</u>
The firm has submitted photocopies of following:
Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house).
Method for analysis of API (Supplier/Manufacturer of FPP) & COA for Dapagliflozin Propanediol Monohydrate (Supplier).
<u>For Metformin hydrochloride:</u>
Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house).
Method for analysis of API (Supplier/Manufacturer of FPP) & COA for Metformin hydrochloride (Supplier).</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopies of following:
FPP Test/Analysis Method & FPP Specifications (In-house) for Dapawil-M 5mg/850 Tablet.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td><u>For Dapagliflozin (as Propanediol):</u>
The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Dapagliflozin Propanediol Monohydrate from M/s Jiangsu Yongan Pharmaceutical at Zone II.
<u>For Metformin hydrochloride:</u>
The firm has submitted photocopy of 06 Months Accelerated and 60 Months Real Time Stability Study Data of 03 Batches of Metformin hydrochloride from M/s IPCA Laboratories Limited at Zone IV A.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>Excipients of applied drug product are similar to that of innovator product (xigduo 5/1000mg tablet) as submitted by firm.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has submitted reports for comparative dissolution in three media including (0.1 N HCl) pH 1.2, Buffer pH 4.5 and Buffer pH 6.8 innovator Xigdou 5/1000mg tablets.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted declaration of software quality but not audit trail reports.</td></tr>
<tr><td colspan="3"><u>Remarks of the Evaluator (VIII):</u><table><tr><th>Sr. No.</th><th>Queries</th><th>Response</th></tr><tr><td>1</td><td>Please clarify whether applied formulation is extended release or film coated tablet as in</td><td>Applicant has clarified that applied formulation is film coated tablet.</td></tr></table></td></tr>
</table>

	submitted dossier under heading of brand name & composition extended release is written & in clinical data & justification film coated is mentioned.	
2	Please explain why the invoices for both APIs are not ADC attested.	Applicant has submitted the following: Dapagliflozin: Commercial invoice is not ADC attested. Metformin hydrochloride: ADC attested commercial invoice is submitted.
3	Mention lot No. of API Metformin hydrochloride, as it is not mentioned on invoice.	--------
4	Method for test/analysis of API is in-house or supplier? Moreover submit interpretation for using titration method for assay of Metformin hydrochloride.	Applicant has submitted Suppliers method test/analysis of API.
5	Submit master formulation of applied formulation.	Not submitted.
6	Please submit clarification for difference in the address of the manufacturer of metformin hydrochloride on invoice & on GMP certificate, moreover submit the GMP Certificate of relevant site & also provide list of drugs for which GMP certificate is issued to M/s. IPCA.	Applicant has submitted following: Address mentioned on commercial invoice is of office while the address on GMP is of manufacturing site. applicant has submitted GMP certificate of another site of IPCA Laboratories Limited having address H4, MIDC, Waluj, Aurangabad, Maharastra state India. Issued by: Food & Drug Administration, Mahashtra, india.
7	Submit evidence of purchase of reference product for CDP.	Applicant has submitted invoice dated October 1st 2018 for purchase of Xigduo 5/850mg & 5/1000mg tablet.
8	Please explain why the content uniformity test is not performed for applied formulation.	Now the applicant has submitted documents for content uniformity.
9	Please provide reference for selection of dissolution parameters for applied formulation before further processing of the case.	dissolution parameters for applied formulation are following: Apparatus I, Basket 20mesh Rotation: 100rpm Time: 45 minutes Volume 1000ml

Decision: Deferred for following submissions:

- **Clarification of applied formulation, whether extended release or film coated**
- **Lot number of metformin hydrochloride API used in the stability studies along with evidence of its import**
- **Master formulation for the applied product**
- **Revised finished product specifications in the light of specifications of the innovator product and decision of 293rd meeting of Registration Board.**
- **Specify the exact site address of API manufacturer of metformin hydrochloride along with submission of its GMP certificate.**

1581.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharma, Lahore**
	Brand Name +Dosage Form + Strength	Plexodol Tablets 75mg
	Composition	Each film coated tablet contains: Tapentadol (as hydrochloride)……75mg
	Diary No. Date of R& I & fee	Dairy No. 913dated 30.09.15 Rs:50,000 dated 29.09.2015
	Pharmacological Group	Analgesic, Opioids

	Type of Form	Form 5D
	Finished product Specifications	In house specifications/Manufacturer's specifications
	Pack size & Demanded Price	As per SRO Alu foil, PVC 10's
	Approval status of product in Reference Regulatory Authorities	Palexia Tablets by Grunenthal Ltd. UK Approved in USFDA
	Me-too status (with strength and dosage form)	N/A
	Previous Decision	Registration Board in its 254th meeting decided as follow: Deferred for Stability Data as per guidelines approved by the Board in 251st meeting.
	Evaluation by PEC	Now the firm has submitted stability studies data details of which are given below:

STABILITY STUDY DATA

Drug	Plexodol Tablets 75mg		
Name of Manufacturer	M/s Jenner Pharma, Lahore		
Manufacturer of API	M/s. Precise Chemipharm Pvt. Ltd.		
API Lot No.	Batch No. 6010032019		
Description of Pack (Container closure system)	alu/alu blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real Time: 12 Months Accelerated:06Months		
Frequency	Real Time: 0,3,6,9,12 Months(on going) Accelerated: 0,1,2,3,4,6 Months		
Batch No.	PLX-PB-013001	PLX-PB-013002	PLX-PB-013003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation			
No. of Batches	03		
Date of Submission	Dy No.27741 , 20/12/2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted following COAs: **For API:** • Copy of COA for Tapentadol hydrochloride Batch No. 6010032019.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. 6090300 **Issued to**: M/s. Precise Chemipharm Pvt. Ltd. Address: C-384, T.T.C. Industrial Area M.I.D.C Village PAWNE, Navi Mumbai 400703, India. **Issued by**: Food & Drugs Administration, KonKan Division, Maharashtra State. **Validity**: Valid Till 21-09-2020.

3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of invoice dated 01-04-2019 attested by ADC, DRAP on 08-04-2019 declaring 0.6kg API Tapentadol hydrochloride (Batch No. 6010032019). Manufacturer of API as per submitted invoice: M/s. Precise Chemipharm Pvt. Ltd. Address: C-384, T.T.C. Industrial Area M.I.D.C Village PAWNE, Navi Mumbai 400703, India.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided following documents as per checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 20-12-2019 vide diary No.27741.

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Sofpas tablet 400mg/100mg (Sofosbuvir/Velpatasvir 400mg/100mg) Tablets", which was conducted on 10th of December, 2018 and was presented in 287th meeting of Registration board. Registration Board decided to approve registration of Sofpas tablet 400mg/100mg Tablets" by M/s. Wilshire Laboratories. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm demonstrated audit trail reports of data submitted for Sofpas testing. • The firm has two separate Memmert (Germany) stability chambers for Real Time and Accelerated stability studies which are equipped with data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice dated 01-04-2019 attested by ADC, DRAP on 08-04-2019 declaring 0.6kg API Tapentadol hydrochloride (Batch No. 6010032019). Manufacturer of API as per submitted invoice: M/s. Precise Chemipharm Pvt. Ltd. Address: C-384, T.T.C. Industrial Area M.I.D.C Village PAWNE, Navi Mumbai 400703, India.
3.	Documents for the procurement of reference standard and impurity	The firm has submitted Following: **For Working Standard:** Firm has stated that Tapentadol hydrochloride working standard was

<table>
<tr><td></td><td>standards.</td><td>received alongwith shipment of API.
Copy of COA for Tapentadol hydrochloride Batch No. 6010032019.
<u>For Impurity Standards:</u>
Firm has stated that working standard is received through indenter M/s. Synapse Chemicals.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP certificate declaring following information:
Certificate No. 6090300
Issued to: M/s. Precise Chemipharm Pvt. Ltd.
Address: C-384, T.T.C. Industrial Area M.I.D.C Village PAWNE, Navi Mumbai 400703, India.
Issued by: Food & Drugs Administration, KonKan Division, Maharashtra State.
Validity: Valid Till 21-09-2020.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted a document with the name rational for selection of manufacturer of API.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td>Applicant has submitted following COAs:
<u>For API:</u>
• Copy of COA for Tapentadol hydrochloride Batch No. 6010032019.
<u>For reference/working standard:</u>
Copy of COA for Tapentadol hydrochloride working standard Batch No. 6001012017.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices of the excipients used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff comprising of 03 members as per list involved in R&D</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>Yes</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Orders of following 03 Batches:
<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>PLX-PB-013001</td><td>1000 tablets</td><td>05-2019</td></tr><tr><td>PLX-PB-013002</td><td>1000 tablets</td><td>05-2019</td></tr><tr><td>PLX-PB-013003</td><td>1000 tablets</td><td>05-2019</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following
<table><tr><th>Batch No.</th><th>Plexodol Tablets 75mg</th></tr><tr><td>PLX-PB-013001</td><td>26 packs left for RT stability</td></tr><tr><td>PLX-PB-013002</td><td>26 packs left for RT stability</td></tr><tr><td>PLX-PB-013003</td><td>26 packs left for RT stability</td></tr></table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-03-2018 to 30-09-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopies of following:
• Method for analysis of API (Supplier/Manufacturer of FPP) & COA for Tapentadol hydrochloride (Supplier).</td></tr>
</table>

14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopies of following: • FPP Test/Analysis Method & FPP Specifications (In-house) for Plexodol Tablets 75mg.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Tapentadol hydrochloride from M/s Precise Chemipharm at Zone II.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	Formulation of applied drug product is qualitatively similar to that of innovator Brand Palexia tablets 75mg.
18.	Record of comparative dissolution data.	The firm has submitted reports for comparative dissolution in three media including (0.1 N HCl) pH 1.2, Buffer pH 4.5 and Buffer pH 6.8.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes

Remarks of the Evaluator (VIII):

Sr. No.	Queries	Response
1.	Submit documents for the procurement of reference Standard.	Firm has stated that Tapentadol hydrochloride working standard was received alongwith shipment of API.
2.	Reference for selection of sampling time 60 minutes in dissolution testing.	Sampling time 60 minutes for dissolution testing is selected from USFDA dissolution database. However drug release results are above 90 minutes in 20 minutes at "2nd sampling time point" as shown in provided CDP data in Question 18 of dossier.
3.	Provide COA of API "Tapentadol hydrochloride" by FPP manufacturer.	Applicant has submitted COA of Tapentadol hydrochloride by Jenner Pharmaceuticals.
4.	Please provide procedure of CDP & reference for selection of time points for CDP & clarification for not performing CDP for applied drug product with innovator product. (Me too product).	Applicant has submitted that a Procedure & time point for CDP is same as USFDA dissolution database. Since innovator brand is not available in Pakistan so we used product from local manufacture " Tapento tablets by Sami Pharma, Registration No. 093064 for CDP analysis.

Decision: Registration Board decided as follows:

- **Accept the stability study data as the dissolution specifications falls within the definition of immediate release drug product and approved registration of Plexodol Tablets 75mg with Innovator's specifications by M/s Jenner Pharma, Lahore, wherein manufacturer will adopt the dissolution specifications i.e. NLT Q at 30 minutes in line with innovator product for commercial production batches.**
- **Furthermore, manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

1582.	Name and address of manufacturer / Applicant	M/s Jenner Pharma, Lahore
	Brand Name +Dosage Form + Strength	Plexodol Tablets 50mg
	Composition	Each film coated tablet contains: Tapentadol (as hydrochloride)……50mg
	Diary No. Date of R& I & fee	Dairy No. 910 dated 30.09.15 Rs:50,000 dated 29.09.2015
	Pharmacological Group	Analgesic, Opioids
	Type of Form	Form 5D
	Finished product Specifications	In house specifications/Manufacturer's specifications

	Pack size & Demanded Price	As per SRO Alu foil, PVC 10's
	Approval status of product in Reference Regulatory Authorities	Palexia Tablets by Grunenthal Ltd. UK Approved in USFDA
	Me-too status (with strength and dosage form)	N/A
	Previous Decision	Registration Board in its 254th meeting decided as follow: Deferred for Stability Data as per guidelines approved by the Board in 251st meeting.
	Evaluation by PEC	Now the firm has submitted stability studies data details of which are given below:

STABILITY STUDY DATA

Drug	Plexodol Tablets 50mg		
Name of Manufacturer	M/s Jenner Pharma, Lahore		
Manufacturer of API	M/s. Precise Chemipharm Pvt. Ltd.		
API Lot No.	Batch No. 6010032019		
Description of Pack (Container closure system)	alu/alu blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real Time: 12 Months Accelerated:06Months		
Frequency	Real Time: 0,3,6Months(on going) Accelerated: 0,1,2,3,4,6 Months		
Batch No.	PLX-PB-013001	PLX-PB-013002	PLX-PB-013003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation			
No. of Batches	03		
Date of Submission	Dy No.27741 , 20/12/2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted following COAs: **For API:** • Copy of COA for Tapentadol hydrochloride Batch No. 6010032019.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate declaring following information: **Certificate No**. 6090300 **Issued to**: M/s. Precise Chemipharm Pvt. Ltd. Address: C-384, T.T.C. Industrial Area M.I.D.C Village PAWNE, Navi Mumbai 400703, India. **Issued by**: Food & Drugs Administration, KonKan Division, Maharashtra State. **Validity**: Valid Till 21-09-2020.
3.	Protocols followed for conduction o stability study and details of tests.	Yes

4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of invoice dated 01-04-2019 attested by ADC, DRAP on 08-04-2019 declaring 0.6kg API Tapentadol hydrochloride (Batch No. 6010032019). Manufacturer of API as per submitted invoice: M/s. Precise Chemipharm Pvt. Ltd. Address: C-384, T.T.C. Industrial Area M.I.D.C Village PAWNE, Navi Mumbai 400703, India.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided following documents as per checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 20-12-2019 vide diary No.27740.

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Sofpas tablet 400mg/100mg (Sofosbuvir/Velpatasvir 400mg/100mg) Tablets", which was conducted on 10th of December, 2018 and was presented in 287th meeting of Registration board. Registration Board decided to approve registration of Sofpas tablet 400mg/100mg Tablets" by M/s. Wilshire Laboratories. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm demonstrated audit trail reports of data submitted for Sofpas testing. • The firm has two separate Memmert (Germany) stability chambers for Real Time and Accelerated stability studies which are equipped with data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice dated 01-04-2019 attested by ADC, DRAP on 08-04-2019 declaring 0.6kg API Tapentadol hydrochloride (Batch No. 6010032019). Manufacturer of API as per submitted invoice: M/s. Precise Chemipharm Pvt. Ltd. Address: C-384, T.T.C. Industrial Area M.I.D.C Village PAWNE, Navi Mumbai 400703, India.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted Following: **For Working Standard:** Firm has stated that Tapentadol hydrochloride working standard was received alongwith shipment of API. Copy of COA for Tapentadol hydrochloride Batch No. 6010032019. **For Impurity Standards:** Firm has stated that impurity standard is received through indenter M/s. Synapse Chemicals.
4.	Approval of API/ DML/GMP certificate of API manufacturer	The firm has submitted copy of GMP certificate declaring following information:

<table>
<tr><td></td><td>issued by regulatory authority of country of origin.</td><td>Certificate No. 6090300
Issued to: M/s. Precise Chemipharm Pvt. Ltd.
Address: C-384, T.T.C. Industrial Area M.I.D.C Village PAWNE, Navi Mumbai 400703, India.
Issued by: Food & Drugs Administration, KonKan Division, Maharashtra State.
Validity: Valid Till 21-09-2020.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted a document with the name rational for selection of manufacturer of API.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td>Applicant has submitted following COAs:
<u>For API:</u>
• Copy of COA for Tapentadol hydrochloride Batch No. 6010032019.
<u>For reference/working standard:</u>
Copy of COA for Tapentadol hydrochloride working standard Batch No. 6001012017.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices of the excipients used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff comprising of 03 members as per list involved in R&D</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>Yes</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Orders of following 03 Batches:
<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>PLX-PB-012001</td><td>1000 tablets</td><td>05-2019</td></tr><tr><td>PLX-PB-012002</td><td>1000 tablets</td><td>05-2019</td></tr><tr><td>PLX-PB-012003</td><td>1000 tablets</td><td>05-2019</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table><tr><th>Batch No.</th><th>Plexodol Tablets 75mg</th></tr><tr><td>PLX-PB-012001</td><td>26 packs left for RT stability</td></tr><tr><td>PLX-PB-012002</td><td>26 packs left for RT stability</td></tr><tr><td>PLX-PB-012003</td><td>26 packs left for RT stability</td></tr></table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-03-2018 to 30-09-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopies of following:
• Method for analysis of API (Supplier/Manufacturer of FPP) & COA for Tapentadol hydrochloride (Supplier).</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e.</td><td>The firm has submitted photocopies of following:
• FPP Test/Analysis Method & FPP Specifications (In-house) for Plexodol Tablets 75mg.</td></tr>
</table>

	chromatograms, lab reports, raw data sheets etc.)	
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Tapentadol hydrochloride from M/s Precise Chemipharm at Zone II.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	Formulation of applied drug product is qualitatively similar to that of innovator Brand Palexia tablets 75mg.
18.	Record of comparative dissolution data.	The firm has submitted reports for comparative dissolution in three media including (0.1 N HCl) pH 1.2, Buffer pH 4.5 and Buffer pH 6.8.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted declaration of software quality but not audit trail reports

Remarks of the Evaluator (VIII):

Sr. No.	Queries	Response
1.	Submit documents for the procurement of reference Standard.	Firm has stated that Tapentadol hydrochloride working standard was received alongwith shipment of API.
2.	Reference for selection of sampling time 60 minutes in dissolution testing.	Sampling time 60 minutes for dissolution testing is selected from USFDA dissolution database. However drug release results are above 90 minutes in 20 minutes at "2nd sampling time point" as shown in provided CDP data in Question 18 of dossier.
3.	Submit Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) as it is submitted in graphical form.	Applicant has submitted record of digital data logger for temperature & humidity for both accelerated & real time stability chambers.
4.	Provide COA of API "Tapentadol hydrochloride" by FPP manufacturer.	Applicant has submitted COA of Tapentadol hydrochloride by Jenner Pharmaceuticals.
5.	Pease provide procedure of CDP & reference for selection of time points for CDP & clarification for not performing CDP for applied drug product with innovator product.(me too product).	Applicant has submitted that a Procedure & time point for CDP is same as USFDA dissolution database. Since innovator brand is not available in Pakistan so we used product from local manufacture " Tapento tablets by Sami Pharma, Registration No. 093064 for CDP analysis.

Decision: Registration Board decided as follows:

- **Accept the stability study data as the dissolution specifications falls within the definition of immediate release drug product and approved registration of Plexodol Tablets 50mg with Innovator's specifications by M/s Jenner Pharma, Lahore, wherein manufacturer will adopt the dissolution specifications i.e. NLT Q at 30 minutes in line with innovator product for commercial production batches.**
- **Furthermore, manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

Case no. 08 Registration applications of Form 5F.

1583.	Name, address of Applicant / Marketing Authorization Holder	"M/s Bio Medics Medical System. F-597, F-Block, Satellite Town, Rawalpindi, Pakistan
	Name, address of Manufacturing site.	Grand Pharmaceutical (China) Co., Ltd. ADD.: No. 11, Lake Road, Jinyinhu Econogical Park, Dongxihu District, Wuhan, China
	Status of the applicant	□ Manufacturer □ **Importer** □Is involved in none of the above (contract giver) Firm has submitted agreement for contract manufacturing
	Intended use of pharmaceutical product	□ Domestic sale □ Export sale □ **Domestic sales**
	Dy. No. and date of submission	Dy. No. 6800 dated 15-02-2019,
	Details of fee submitted	PKR 50,000/-: 13-02-2019
	The proposed proprietary name / brand name	**Tirofiban Hydrochloride and Sodium Chloride Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100 ml solution contains: Tirofiban Hydrochloride…. 5 mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Antiplatelet drug
	Reference to Finished product specifications	In-House
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Wuhan Wuyao Pharmaceutical Co., Ltd. No.18, Wangfen Road, FuchiTown, Yangxin County, Hubei Province, China.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Not provided.
	Comparative Dissolution Profile Data (Details of reference product & study)	Not Applicable
	Process validation data of product	Submitted
	Analytical method validation/verification of product	It is stated in 3.P.5.3 that All analytical procedures for Tirofiban Hydrochloride and Sodium Chloride Injection 100 ml: 5 mg used in the routine test are according to National state drug standards YBH12132004 Monograph with no adjustment. Therefore, there is no need to do the validation of the method. If there is any adjustment or change about the analytical method, we will do the validation for the method and documentation will be submitted or informed to the authorities. The suitability of analytical method has to be done before testing the product.
	Stability studies of product	Submitted at zone IV b conditions

Summary of Evaluation: **-------**
Decision: Deferred for submission of stability study data of drug substance both accelerated & real time conducted in accordance with zone IV A conditions and complete presentation of Form5F data in agenda.

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No. 6800 dated 15-02-2019, PKR: 50,000/- dated 13-02-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		**Applicant Information** Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: **"M/s Bio Medics Medical System.** **F-597, F-Block, Satellite Town, Rawalpindi, Pakistan**
	1.3.2	Name, address and contact details of Manufacturing site. Grand Pharmaceutical (China) Co., Ltd. ADD.: No. 11, Lake Road, Jinyinhu Econogical Park, Dongxihu District, Wuhan, China
	1.3.3	Specify whether the Applicant is: a. □ Manufacturer b. □ **Importer** c. □ Is involved in none of the above (contract giver)
	1.3.4	Valid Drug Manufacturing License (DML) of manufacturer / Applicant or Drug Sale License, whichever is applicable. **Status: License to sell drug as Distributor** **Address: M/s Bio Medics Medical System F-597 F Block Sattellite Town, District Rawalpindi.** **Validity: 15-02-2020**
	1.3.5	Evidence of approval of manufacturing facility / Approved Section from Licensing Authority
	1.3.6	List of already approved registered drugs in this section
	1.3.7	Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance
	1.3.8	Manufacturer's Site Master File and Credential (for importer)
1.4		**Type of Application** Submitted
	1.4.1	Application is for the registration of: □ New Drug Product (NDP) □**Generic Drug Product (GDP)**
	1.4.1	Pharmaceutical product is intended for: □**Domestic sale** □ Export sale □ Domestic and Export sales
	1.4.2	For imported products, please specify one of following: □**Finished Pharmaceutical Product Import** □ Bulk Import and local repacking (specify status of bulk) □ Bulk Import Local Repacking for Export purpose only
	1.4.3	Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976. □ Domestic Manufacturing □ Export Purpose Only

		N/A
1.5		**Detailed Information of Drug, Dosage From & Labelling Claims** Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. **Tirofiban Hydrochloride and Sodium Chloride Injection**
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit 5mg /100ml
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trade mark certification / clearance. **Tirofiban Hydrochloride and Sodium Chloride Injection**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. As per SRO
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) **B01AC: Platelet aggregation inhibitors excl. heparin**
	1.5.6	Pharmacopoeial reference / Status of applied formulation Chinese Pharmacopoeia
	1.5.7	Route of administration Intravenous route of administration
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. N/A
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Approved in USFDA.
	1.5.10	Dosage form of applied drug **Solution for Injection**
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens **Submitted**
	1.5.12	Description of Batch numbering system
	1.5.13	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined.
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the

		specifications. In both cases, the validation of specifications shall be done by the applicant.
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals.
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		**Miscellaneous Information** Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix -
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: a. Name and address of API manufacturer. b. Approval of manufacturing facility of API by regulatory body of country and validity. c. Vendor qualification / audit is □ Document based □ Site inspection based d. Reason for point c.
	COPP **Original, legalized CoPP** **Issued by:** Hubei Food & Drug Administration **Certificate No:**20180064 GMP status: it confirms the GMP of manufacturer and free sale status of product in country of origin. Validity: The certificate is valid till November 2020.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content *Submitted*

2.2 CTD Introduction *Submitted*

2.3 Quality Overall Summary (QOS)* *Submitted*

(Detailed information regarding QOS may be found at the following link)
https://extranet.who.int/prequal/sites/default/files/documents/82%20Module%202.3%20QOS_March2017.docx

1.3 QUALITY OVERALL SUMMARY (QOS)

2.3	**Drug substance(API)** Generalinformation *Submitted* Manufacture *Submitted* Characterization *Submitted* Control of drugsubstance *Submitted* Referencestandards *Submitted* Container closuresystem *Submitted* Stability *Not Submitted*
	Comments

	Drugproduct Descriptionandcompositionofthedrugproduct Submitted Pharmaceuticaldevelopment Submitted Componentsofthedrugproduct 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing processdevelopment Submitted Container closuresystem Submitted Manufacture Submitted Control ofexcipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closuresystem Submitted Stability Submittted
	Comments
2.4	Non-Clinical Overview Not applicable
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Not applicable
2.7	**Clinical summary** Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	**GENERAL INFORMATION** (May not refer to DMF)	
	3.2.S.1.1	**Nomenclature *Submitted***
	3.2.S.1.2	**Structure *Submitted***
	3.2.S.1.3	**Generalproperties *Submitted***
	Comments	
3.2.S.2	**MANUFACTURER**	
	3.2.S.2.1	**Manufacturer(s) *Submitted***
	3.2.S.2.2	**Description of Manufacturing Process and Process Controls *Not submitted***
	3.2.S.2.3	**Control of Materials *Not submitted***
	3.2.S.2.5	**Process Validation and/or Evaluation *Submitted***
	.	
3.2.S.3	**CHARACTERIZATION**	
	3.2.S.3.1	**Elucidation of Structure and other Characteristics *Submitted***
	3.2.S.3.2	**Impurities *Submitted***
	Comments	

3.2.S.4	**CONTROL OF DRUG SUBSTANCE (API)**	
	3.2.S.4.1	**Specification** ***Submitted***
		Chinese pharmacopoeial Specifications
	3.2.S.4.2	**Analytical procedures** ***Submitted***
	3.2.S.4.3	**Validation of analytical procedures** ***Submitted***
		It is stated in 3.P.5.3 that All analytical procedures for Tirofiban Hydrochloride and Sodium Chloride Injection 100 ml: 5 mg used in the routine test are according to National state drug standards YBH12132004 Monograph with no adjustment. Therefore, there is no need to do the validation of the method. If there is any adjustment or change about the analytical method, we will do the validation for the method and documentation will be submitted or informed to the authorities. The suitability of analytical method has to be done before testing the product.
	3.2.S.4.4	**Batch analysis** ***Submitted***
		Comments
	3.2.S.4.5	**Justification of specifications** ***Submitted***
		Comments
3.2.S.5		**REFERENCE STANDARDS OR MATERIALS** (Do NOT refer to DMF) ***Submitted***
		Comments
3.2.S.6		**CONTAINER CLOSURE SYSTEMS** ***Submitted***
		Preserve in tightly close containers, protected from light, store in room, dry place.
3.2.S.7	**STABILITY**	
	3.2.S.7.1	**Stability Summary and Conclusions** ***Not Submitted***
	3.2.S.7.2	**Post-approval Stability Protocol and Stability Commitment** ***Not Submitted***
	3.2.S.7.3	**Stability Data** ***Submitted***

3.2.P DRUG PRODUCT

3.2.P.1	**DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT** ***Submitted***	
	Comments	
3.2.P.2	**PHARMACEUTICAL DEVELOPMENT**	
	3.2.P.2.1	**Components of the Drug Product**
		3.2.P.2.1.1 Drug Substance ***Submitted***
		3.2.P.2.1.2 Excipients ***Submitted***
	3.2.P.2.2	**Drug Product**
		3.2.P.2.2.1 Formulation Development ***Submitted***

		Pharmaceutical Equivalence through Comparative Dissolution Profile ***Not Applicable***
		3.2.P.2.2.2 Overages ***Not Applicable***
		3.2.P.2.2.3 Physicochemical and Biological Properties ***Submitted***
	3.2.P.2.3	**Manufacturing Process Development** ***Submitted***
	3.2.P.2.4	**Container Closure System** ***Submitted***
	3.2.P.2.5	**Microbiological Attributes** ***Submitted***
	3.2.P.2.6	**Compatibility** ***Not Submitted*** The Applicant has stated that Tirofiban Hydrochloride and Sodium Chloride Injection 100 ml: 5 mg is administered by the injection route. No compatibility data provided.
3.2.P.3	**MANUFACTURE**	
	3.2.P.3.1	**Manufacturer(s)** ***Submitted***
		Comments
	3.2.P.3.2	**Batch formula** ***Submitted***
		Comments
	3.2.P.3.3	**Description of manufacturing process and process controls** ***Submitted***
		Comments
	3.2.P.3.4	**Controls of critical steps and intermediates** ***Submitted***
		Comments
	3.2.P.3.5	**Process validation and/or evaluation** ***Submitted***
3.2.P.4	**CONTROL OF EXCIPIENTS**	
	3.2.P.4.1	**Specifications** ***Submitted*** Chinese Pharmacopoeial Specifications
		Comments
	3.2.P.4.2	**Analytical procedures** ***Submitted***
		Comments
	3.2.P.4.3	**Validation of analytical procedures** ***Submitted***
		All analytical procedures for Tirofiban Hydrochloride and Sodium Chloride Injection 100 ml: 5 mg used in the routine test are according to National state drug standards YBH12132004 Monograph with no adjustment. Therefore, there is no need to do the validation of the method. If there is any adjustment or change about the analytical method, we will do the validation for the method and documentation will be submitted or informed to the authorities. The suitability of analytical method has to be done before testing the product.
	3.2.P.4.4	**Justification of specifications** (as applicable) ***Submitted***
	3.2.P.4.5	**Excipients of Human or Animal Origin** ***Not applicable*** All excipients used are all synthetic origin. These excipients are definitely

		without risk of TSE contamination as per applicant's statement.
	3.2.P.4.6	**Novel Excipients** ***Not applicable***
	Comments	
3.2.P.5	**CONTROLS OF DRUG PRODUCT**	
	3.2.P.5.1	**Specification(s)** ***Submitted***
		Comments
	3.2.P.5.2	**Analytical procedures** ***Submitted***
		Comments
	3.2.P.5.3	**Validation of analytical procedures** ***Submitted***
		All analytical procedures for Tirofiban Hydrochloride and Sodium Chloride Injection 100 ml: 5 mg used in the routine test are according to National state drug standards YBH12132004 Monograph with no adjustment. Therefore, there is no need to do the validation of the method. If there is any adjustment or change about the analytical method, we will do the validation for the method and documentation will be submitted or informed to the authorities. The suitability of analytical method has to be done before testing the product.
	3.2.P.5.4	**Batch analysis** ***Submitted***
		CertificatesofAnalysisforfinisheddosageform
		Comments
	3.2.P.5.5	**Characterization of impurities** ***Submitted***
		Comments
	3.2.P.5.6	**Justification of specifications** ***Submitted***
		Comments
3.2.P.6		**Reference Standards or Materials** ***Submitted***
		Comments
.7		**CONTAINER CLOSURE SYSTEM** ***Submitted***
		Primary packaging: Type-A infusion bottle made of soda lime glass, halogenated butyl rubber stopper for injection, aluminum and plastics combined caps for infusion bottle.
3.2.P.8	**STABILITY**	
	3.2.P.8.1	**Stability summary and conclusion (Finished Dosage Form)** ***Submitted***
		Comments
	3.2.P.8.2	**Post-approval Stability Protocol and Stability Commitment** ***Not applicable***
		The applicant has stated that since complete stability studies of 36 months are submitted, post-approval stability commitment is not required.
	3.2.P.8.3	**Stability** ***Submitted***
		The firm has submitted 6 month accelerated stability study data and 36 months long term stability study data for three batches at zone IV b conditions.
Decision: Deferred for submission of stability study data of drug substance both accelerated & real time conducted in accordance with Zone IV A conditions.		

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

a. New cases

1584.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pciposevt. Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore,
	Brand Name + Dosage Form and Strength	Arglipmet-D 50/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…..50mg Metformin HCl……1000mg
	Dairy No. date of R &I fee	Dy.No 42388 dated 11-12-2018 Rs. 20,000/- Dated 11-12-2018
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50 mg vildagliptin and 1,000 mg metformin hydrochloride) of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/1000mg Tablets by Novartis Pharma (Reg. No. 66107)
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the directorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm submitted undertaking signed by qualified persons along with list of equipment's used for the quality control of raw material and finished products.
	Decision: Approved as per innovator's specifications	
1585.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Arglipmet 50/850 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……50mg Metformin HCl……850mg
	Dairy No. date of R &I fee	Dy.No 42389 dated 11-12-2018 Rs.20,000/- Dated 11-12-2018
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50 mg vildagliptin and 850 mg metformin hydrochloride) of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/850mg TABLETS by Novartis Pharma (Reg. No. 66106)

	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the directorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm submitted undertaking signed by qualified persons along with list of equipment's used for the quality control of raw material and finished products.
	Decision: Approved as per innovator's specifications	
1586.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt Ltd. Plot 2.5km Defence Road,Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Armethrin 30gm Cream
	Composition	Each gram Contains: Permethrin…..5% w/w
	Dairy No. date of R &I fee	Dy.No 42398 dated 11-12-2018 Rs.20,000/- Dated 11-12-2018
	Pharmacological Group	Ectoparasiticides, Incl. Scabicides, Insecticides And Repellents
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Permethrin cream 5% w/w of USFDA approved
	Me-too-status	LOTRIX CRM by M/s WELLCOME Pharma (Reg. No. 10516)
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the directorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm submitted complete form 5 mentioning the composition duly signed by the qualified persons. • Firm submitted master formulation, manufacturing outline, list of equipment's used in production and quality control and commitments as per decision of 251st meeting of Registration Board.
	Decision: Approved as per innovator's specifications	

1587.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Clobisol Cream 15gm
	Composition	Each gram contains: Clobetasol Propionate…… 0.5mg (0.05% w/w)
	Dairy No. date of R &I fee	Dy.No 42396 dated 11-12-2018 Rs.20,000/- Dated 11-12-2018
	Pharmacological Group	Corticosteroids, Dermatological Preparations
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved (Aluminium tube)
	Me-too-status	Clobeta Cream by M/s Saffron Pharmaceuticals (Reg. No. 46429)
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the directorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm submitted complete form 5 mentioning the composition duly signed by the qualified persons. • Firm submitted master formulation, manufacturing outline, list of equipment's used in production and quality control and commitments as per decision of 251st meeting of Registration Board.
	Decision: Approved.	
1588.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Cosmid 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide……..100mg
	Dairy No. date of R &I fee	Dy.No 42393 dated 11-12-2018 Rs.20,000/- Dated 11-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Lacosamide STADA 100mg film-coated tablet (MHRA Approved)
	Me-too-status	Lacolit 100mg Tablet by The Searle Company Limited, (Reg. No.77127)
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the

		firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the directorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm submitted undertaking signed by qualified persons along with list of equipment's used for the quality control of raw material and finished products.
	Decision: Approved as per innovator's specifications	
1589.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Cosmid 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide……..50mg
	Dairy No. date of R &I fee	Dy.No 42392 dated 11-12-2018 Rs.20,000/- Dated 11-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Lacosamide Aspire 50 mg film-coated tablets (MHRA Approved)
	Me-too-status	Lacolit 50 mg Tablet by The Searle Company Limited, (Reg. No.77126)
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the directorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm submitted undertaking signed by qualified persons along with list of equipment's used for the quality control of raw material and finished products.
	Decision: Approved as per innovator's specifications	
1590.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Dexason-N 15gm Cream
	Composition	Each gram contains: Neomycin sulfate…….5mg (0.5%) Dexamethasone sodium phosphate…….1mg (0.1%)
	Dairy No. date of R &I fee	Dy.No 42395 dated 11-12-2018 Rs.20,000/- Dated 11-12-2018

	Pharmacological Group	Corticosteroids, combinations with Antibiotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified
	Me-too-status	Could not be verified
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the directorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm submitted revised form 5 mentioning the composition but not considering the salt factor in case of dexamethasone and without submission of fee. • Firm submitted undertaking signed by the qualified persons. • Firm submitted master formulation but weight of API was not adjusted considering the salt factor • Firm submitted manufacturing outline • Approval status of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and me-too status could not be verified. • Firm submitted list of equipment's used in production and quality control and commitments as per decision of 251st meeting of Registration Board.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of formulation considering the salt factor in case of dexamethasone and submission of fee along with adjustment of API weight in master formulation considering the salt factor**	
1591.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt. Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Rezolid 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…….400mg
	Dairy No. date of R &I fee	Dy.No 42390 dated 11-12-2018 Rs.20,000/- Dated 11-12-2018
	Pharmacological Group	Oxazolidinone Antibiotic
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	12's, As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYVOX 400mg film-coated tablets Tablet USFDA Approved. Discontinued **Federal Register determination that product

		was not discontinued or withdrawn for safety or efficacy reasons* (as per USFDA website)
	Me-too-status	Nezocin Tablets 400mg by M/s Brookes Pharmaceuticals (Reg. No.55004)
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the irectorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm replied that they will use polymorphic form S (Form III). • Firm submitted undertaking signed by qualified persons along with list of equipment's used for the quality control of raw material and finished products. • LINEZOLID SANDOZ 600mg Pharmaceutical development The substance exhibits at least three polymorphic forms, and one chiral centre. Linezolid has the S-configuration. The polymorph manufactured is Form-III. Linezolid can exist in different polymorphic forms. While in the innovator product polymorphic form II is present, the applied product uses drug substance with polymorphic form III. Since the bioequivalence of the applied product Linezolid 600 mg film-coated tablets (polymorphic form III) versus the reference product (polymorphic form II) has been demonstrated, it can be assumed that polymorphic forms does not affect in-vivo performance. Reference: Linezolid Sandoz 600 mg, film-coated tablets (linezolid) NL/H/2965/001/DC (Date: 8 January 2015) • https://mri.cts-mrp.eu/Human/Downloads/NL_H_2965_001_PAR.pdf
	Decision: Approved as per innovator's specifications	
1592.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt. Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Rezolid 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…..…600mg
	Dairy No. date of R &I fee	Dy.No 42391 dated 11-12-2018 Rs.20,000/- Dated 11-12-2018
	Pharmacological Group	Oxazolidinone Antibiotic
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	12's, As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYVOX 600mg film coated Tablets USFDA Approved.

	Me-too-status	Nezocin Tablets 600mg by M/s Brookes Pharmaceuticals (Reg. No.55005)
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the irectorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm replied that they will use polymorphic form S (Form III). • Firm submitted undertaking signed by qualified persons along with list of equipment's used for the quality control of raw material and finished products. • LINEZOLID SANDOZ 600mg Pharmaceutical development The substance exhibits at least three polymorphic forms, and one chiral centre. Linezolid has the S-configuration. the polymorph manufactured is Form-III. Linezolid can exist in different polymorphic forms. While in the innovator product polymorphic form II is present, the applied product uses drug substance with polymorphic form III. Since the bioequivalence of the applied product Linezolid 600 mg film-coated tablets (polymorphic form III) versus the reference product (polymorphic form II) has been demonstrated, it can be assumed that polymorphic forms does not affect in-vivo performance. Reference: Linezolid Sandoz 600 mg, film-coated tablets (linezolid) NL/H/2965/001/DC (Date: 8 January 2015) https://mri.cts-mrp.eu/Human/Downloads/NL_H_2965_001_PAR.pdf
	Decision: Approved as per innovator's specifications	
1593.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt. Ltd. Plot 2.5km Defence Road, Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Roxi 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…….8mg
	Dairy No. date of R &I fee	Dy.No 42394 dated 11-12-2018 Rs.20,000/- 11-12-2018
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too-status	Zafon 8mg Tablet by M/s Getz Pharma (Reg. No.58589)
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was:

		Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the irectorate of Medical Devices.
	Remark of the Evaluator [XI]	• Firm submitted undertaking signed by qualified persons along with list of equipment's used for the quality control of raw material and finished products.
	Decision: Approved as per innovator's specifications	
1594.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical Industries Pvt Ltd. Plot 2.5km Defence Road,Off Multan Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Wintomint 50gm Ointment
	Composition	Each gram Contains: Methyl Salicylate…121.7mg
	Dairy No. date of R &I fee	Dy.No 42397 dated 11-12-2018 Rs.20,000/- 11-12-2018
	Pharmacological Group	Salicylic acid preparations
	Type of form	Form 5
	Finished product specifications	In house
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too-status	Could not be confirmed
	GMP Status	The firm was inspected on 18-09-2019 and conclusion of inspection was: Based on the inspection of the manufacturing facility and evaluation of documents, the panel is of the opinion that the firm M/s Arsons Pharmaceuticals Lahore as operating at satisfactory level of GMP compliance of following sections on the day of inspection: 1- Tablet (General, Psychotropic) 2- Capsule (General) 3- Cream/Ointment/Gel (General) Firm was given several advises for improvements which are given in detail in the report. Detailed report of other sections which come under Medical Devices is forwarded to the directorate of Medical Devices.
	Remark of the Evaluator [XI]	• Approval status of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting and me-too status could not be verified. • Firm submitted revised form 5 mentioning the composition and undertaking signed by the qualified persons. • Firm submitted master formulation, manufacturing outline, list of equipment's used in production and quality control and commitments as per decision of 251st meeting of Registration Board.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**	

	• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1595.	Name and address of manufacture / Applicant	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name + Dosage Form and Strength	Amlop 8mg/5mg Tablet
	Composition	Each Tablet Contains: Perindopril tert-butylamine…..8mg Amlodipine (as besylate)…..5mg
	Dairy No. date of R &I fee	Dy.No 44469 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	ACE inhibitors and calcium channel blockers
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	Ferrogold 8/5mg Tablets by Next Pharmaceutical Products (Pvt) Ltd, (Reg. No.84928)
	GMP Status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1596.	Name and address of manufacture / Applicant	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name + Dosage Form and Strength	Amlop 4mg/10mg Tablet
	Composition	Each Tablet Contains: Perindopril tert-butylamine…..4mg Amlodipine (as besylate)..…10mg
	Dairy No. date of R &I fee	Dy.No 44467 dated 31-12-2018 Rs.20,000/- 31-12-2018
	Pharmacological Group	ACE inhibitors and calcium channel blockers
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	Ferrogold 4/10mg Tablets by Next Pharmaceutical Products (Pvt) Ltd, (Reg. No.84929)
	GMP Status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1597.	Name and address of manufacture / Applicant	M/s Scilife Pharma Pvt Ltd.Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name + Dosage Form+ Strength	Amlop 8/10mg Tablet
	Composition	Each Tablet Contains: Perindopril tert-butylamine..…8mg Amlodipine (as besylate)..…10mg
	Dairy No. date of R &I fee	Dy.No 44468 dated 31-12-2018 Rs.20,000/- 31-12-2018
	Pharmacological Group	ACE inhibitors and calcium channel blockers
	Type of form	Form-5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	Ferrogold 8/10mg Tablets by Next Pharmaceutical Products (Pvt) Ltd, (Reg. No.84927)
	GMP Status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1598.	Name and address of manufacture / Applicant	M/s Scilife Pharma Pvt Ltd.Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name + Dosage Form and Strength	Amlop 4/5mg Tablet
	Composition	Each Tablet Contains: Perindopril tert-butylamine..…4mg Amlodipine (as besylate)..…5mg
	Dairy No. date of R &I fee	Dy.No 44466 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	ACE inhibitors and calcium channel blockers
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	Ferrogold 4/5mg Tablets by M/s Next Pharmaceutical (Reg. No.84926)
	GMP Status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1599.	Name and address of manufacture / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form and Strength	Clari 250mg Tablet
	Composition	Each film coated tablet contains: Clarithromycin……..250mg
	Dairy No. date of R &I fee	Dy.No 39613 dated 03-12-2018 Rs.20,000/- Dated 30-11-2018
	Pharmacological Group	Macrolides
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 250 mg Film-coated Tablets. MHRA approved
	Me-too-status	Clarital 250mg Tablet. By Arsons Pharmaceuticals Industries (Pvt) Ltd., (Reg. No. 85501)
	GMP Status	Last GMP inspection conducted on 04-07-2018 and report concludes that their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1600.	Name and address of manufacture / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form and Strength	Clari 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin..…….500mg
	Dairy No. date of R &I fee	Dy.No 39614 dated 03-12-2018 Rs.20,000/- Dated 30-11-2018
	Pharmacological Group	Macrolides
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 500 mg Film-coated Tablets. MHRA approved
	Me-too-status	Clarital 500mg Tablet. By M/s Arsons Pharmaceuticals (Reg. No. 85500)
	GMP Status	Last GMP inspection conducted on 04-07-2018 and report concludes that their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1601.	Name and address of manufacture / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form and Strength	Clari Dry Suspension 125mg/5ml
	Composition	Each 5ml reconstituted suspension contains: Clarithromycin (27.5% taste mask granules)....……..125mg Source of granules: Surge laboratories
	Dairy No. date of R &I fee	Dy.No 39611 dated 03-12-2018 Rs.20,000/- Dated 30-11-2018
	Pharmacological Group	Macrolides
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved As granules for oral suspension
	Me-too-status	Clarabac Dry Suspension 125mg/5ml by M/s Global Pharmaceuticals. (Reg#73136)
	GMP Status	Last GMP inspection conducted on 04-07-2018 and report concludes that their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have submitted source of granules "Surge laboratories" along with stability studies data of three batches, GMP certificate of surge laboratories and COA of granules • The firm submitted revised manufacturing outline mentioning filling and packing processes • The firm have submitted revised master formulation adjusting the weight of API and excipients as per their batch size. • The firm have revised their master formulation and removed sodium cyclamate from their formulation
	Decision: Approved	

1602.	Name and address of manufacture / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form and Strength	Clari Dry Suspension 250mg/5ml
	Composition	Each 5ml reconstituted suspension contains: Clarithromycin (27.5% taste mask granules)…..250mg Source of granules: Surge laboratories
	Dairy No. date of R &I fee	Dy.No 39612 dated 03-12-2018 Rs.20,000/- Dated 30-11-2018
	Pharmacological Group	Macrolides
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved As granules for oral suspension
	Me-too-status	Clarithro DS Dry Suspension by M/s Nabiqasim Industries, (Reg#73693)
	GMP Status	Last GMP inspection conducted on 04-07-2018 and report concludes that their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm have submitted source of granules "Surge laboratories" along with stability studies data of three batches, GMP certificate of surge laboratories and COA of granules • The firm submitted revised manufacturing outline mentioning filling and packing processes • The firm have revised their master formulation and removed sodium cyclamate from their formulation
	Decision: Approved	
1603.	Name and address of manufacture / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name + Dosage Form and Strength	Pyrol -T Plus 37.5/325mg Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol…...…37.5mg Paracetamol…..325mg
	Dairy No. date of R &I fee	Dy.No 39610 dated 03-12-2018 Rs.20,000/- Dated 30-11-2018
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	Distalgesic Tablets by M/s Atco Lab., (Reg#73865)
	GMP Status	Last GMP inspection conducted on 04-07-2018 and report concludes that their current GMP compliance level is rated as GOOD.
	Remark of the Evaluator [XI]	• The firm has submitted correct label claim as per reference formulation without submission of applicable fee. The correct label claim is; Each Film Coated Tablet Contains: Tramadol HCl ...…37.5mg Paracetamol…..325mg Moreover the firm adjusted the weight of API in

		master formulation considering the salt factor. • The firm submitted revised form 5 duly signed by the qualified persons on the undertaking
	Decision: Deferred for submission of applicable fee for correction of label claim	
1604.	Name and address of manufacture / Applicant	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Sodium Bicarbonate 5% w/v Injection IV/IM
	Composition	Each 1ml Ampoule Contains: Sodium Bicarbonate ……50mg (5% w/v)
	Dairy No. date of R &I fee	Dy.No 40277 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Diluent
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	2ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended diluent for Artesunate injection
	Me-too-status	Sodium Bicarbonate 50mg/ml Injection of M/s Tabros Pharma (Reg#57721)
	GMP Status	The firm was inspected on 25.10.2018 wherein the firm was considered to be operating at satisfactory level of cGMP compliance.
	Remark of the Evaluator [XI]	• The product is present in 1ml pack size (50mg/ml) in combo pack of Artesunate injection. W.H.O. prequalified. • Firm have specified 2ml volume for registration. • Firm have revised the master formulation. • Firm submitted complete manufacturing outline and type of primary packaging material of applied formulation
	Decision: Approved	
1605.	Name and address of manufacture / Applicant	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Sodium Chloride 0.9% w/v Injection IM/IV
	Composition	Each 5ml Ampoule contains: Sodium Chloride……..45mg (0.9% w/v)
	Dairy No. date of R &I fee	Dy.No 40279 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Diluent
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended diluent for Artesunate injection
	Me-too-status	Sacro Injection of Macter Intr. Karachi. (Reg.#079756)
	GMP Status	The firm was inspected on 25.10.2018 wherein the firm was considered to be operating at satisfactory level of cGMP compliance.
	Remark of the Evaluator [XI]	• The product is present in 5ml pack size (9mg/ml) in combo pack of Artesunate injection. W.H.O. prequalified. • Firm have specified 10ml volume for registration. • Firm submitted complete manufacturing outline and type of primary packaging material of applied

		formulation
	Decision: Approved	
1606.	Name and address of manufacture / Applicant	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Brand Name + Dosage Form+ Strength	Falcon 120mg powder for Injection
	Composition	Each Vial Contains: Artesunate ..……120mg
	Dairy No. date of R &I fee	Dy.No 40278 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antimalarial
	Type of form	Form-5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO approved injectable artesunate 120mg (WHO Approved formulation)
	Me-too-status	Gen-M 120mg Injection of M/s Genix Pharma (Pvt) Ltd. (Reg.#76073)
	GMP Status	The firm was inspected on 25.10.2018 wherein the firm was considered to be operating at satisfactory level of cGMP compliance.
	Remark of the Evaluator [XI]	• Firm submitted complete manufacturing outline along with use of type I glass container as primary packaging container
	Decision: Deferred for confirmation of manufacturing facility	
1607.	Name and address of manufacture / Applicant	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Falcon 60mg powder for Injection
	Composition	Each Vial Contains: Artesunate …….60mg
	Dairy No. date of R &I fee	Dy.No 40276 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antimalarial
	Type of form	Form-5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO approved injectable artesunate 60mg (WHO Approved formulation)
	Me-too-status	Misonate 60mg Injection of M/s Tabros Pharma (Pvt.) Ltd. (Reg.# 57719)
	GMP Status	The firm was inspected on 25.10.2018 wherein the firm was considered to be operating at satisfactory level of cGMP compliance.
	Remark of the Evaluator [XI]	• Firm submitted complete manufacturing outline along with use of type I glass container as primary packaging container
	Decision: Deferred for confirmation of manufacturing facility	
1608.	Name and address of manufacture / Applicant	M/s Friends Pharma Pvt. Ltd. 31-km, Ferozepur Road, Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Water for Injection 10ml
	Composition	Each ampoule contains: Sterile water for Injection…10ml
	Dairy No. date of R &I fee	Dy.No 43170 dated 18-12-2018 Rs.20,000/- Dated 18-12-2018
	Pharmacological Group	Diluent

	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too-status	076482; Water for Injection 10ml By Healthtek Kar.
	GMP Status	The firm was inspected on 08-03-2019 and conclusion of report is: Overall the Evaluation of Inspection report is Good.
	Remark of the Evaluator [XI]	• Firm have revise the label claim to sterile water for injection and mentioned use of type I glass container
	Decision: Approved	
1609.	Name and address of manufacture / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore
	Brand Name + Dosage Form and Strength	Bevate-G Cream
	Composition	Each gram contains: Betamethasone (as Dipropionate)…0.05% w/w Gentamycin (as Sulphate)…0.1% w/w
	Dairy No. date of R &I fee	Dy.No 42017 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Corticosteroids, Combinations With Antibiotics
	Type of form	Form-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Diprogenta cream by MSD (Germany Approved)
	Me-too-status	Effigenta Cream by Mass Pharma (Reg. No. 024375)
	GMP Status	Inspection for grant of GMP certificate dated 12-02-2018 concluded that the firm has maintained a fair level of GMP compliance as per Schedule B-II of the Drugs (Licensing, Registration & Advertising) Rules 1976. However, the firm was advised to procure more reference standards, conduct mock recall of finished products and to install data loggers with alarm system in the refrigerator and stability chambers.
	Remark of the Evaluator [XI]	• Firm has provided evidence of manufacturing facility/section approval as well as revised the quantity of API in master formulation considering the salt factor accordingly.
	Decision: Approved as per innovator's specifications	
1610.	Name and address of manufacture / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd.Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore
	Brand Name + Dosage Form + Strength	Bevate Lotion 0.1% w/w
	Composition	Each gm contains: Betamethasone as valerate…0.1% w/w
	Dairy No. date of R &I fee	Dy.No 42016 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Corticosteroids
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Betnovate Lotion 0.1% w/w by M/s Glaxo Wellcome UK Limited (MHRA Approved)
	Me-too-status	Betamethasone Lotion 0.1% by M/s Werrick

		Pharmaceuticals (Reg#051176)
	GMP Status	Inspection for grant of GMP certificate dated 12-02-2018 concluded that the firm has maintained a fair level of GMP compliance as per Schedule B-II of the Drugs (Licensing, Registration & Advertising) Rules 1976. However, the firm was advised to procure more reference standards, conduct mock recall of finished products and to install data loggers with alarm system in the refrigerator and stability chambers.
	Remark of the Evaluator [XI]	• Firm submitted complete form 5. • Firm submitted the revised label claim as w/w instead of w/v. • Firm submitted evidence of manufacturing facility/section approval
	Decision: Deferred for submission of applicable fee for correction of label claim from w/v to w/w.	
1611.	Name and address of manufacture / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd.85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan
	Brand Name + Dosage Form + Strength	Q-Cip 250mg/5ml Granules for Dry Suspension
	Composition	Each 5ml suspension contains: Ciprofloxacin (Taste mask granules 22.2%) ……...250mg Source of Ciprofloxacin taste masked granules: M/s Surge laboratories (Pvt.) Ltd Pakistan
	Dairy No. date of R &I fee	Dy.No 39869 dated 04-12-2018 Rs.20,000/- 04-12-2018
	Pharmacological Group	Fluoroquinolones
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ciproxin 250mg/5ml granules and solvent for oral suspension by Bayer (MHRA Approved)
	Me-too-status	Ciprosons Dry Susp. of M/s Nawabsons Laboratories, (Reg.# 48098)
	GMP Status	The firm was inspected on 19-09-2018 and 03-10-2018 for Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections (cream and ointment (general) and cGMP
	Remark of the Evaluator [XI]	• Firm have revised form 5 and master formulation along with submission of Rs. 5000/- fee vide slip No. 00815800 date 30.01.2020 for revision of formulation. However the COA of granules indicates that granules contains ciprofloxacin hydrochloride while the reference formulation contains ciprofloxacin base. • Firm have provided the certificate of analysis of taste make granules, GMP certificate and stability studies of three batches from M/s Surge laboratories (Pvt) Ltd
	Decision: Deferred for clarification as the taste maske granules contain ciprofloxacin HCl while the reference formulation contain ciprofloxacin base.	
1612.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, *Contract Manufactured by:* M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Seafix 200mg Capsules
	Composition	Each Capsule Contains: Cefixime as trihydrate …200mg
	Dairy No. date of R &I fee	Dy.No 43185 dated 18-12-2018 Rs.50,000/- 18-12-2018

	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	JP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AEMPS of Spain
	Me-too-status	Cefim 200mg Capsule by M/s Hilton Pharma (Pvt) Ltd, (Reg#34664)
	GMP Status	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with applicant signatures and revised the label claim as "Each Capsule Contains Cefixime as trihydrate 200mg" instead of Each Capsule Contains Cefixime 200mg only" • The firm submitted revised master formulation of manufacturer signed by technical staff of manufacturer. • Firm has submitted revised manufacturing outline mentioning all the steps. • The firm submitted contract manufacturing agreement between Sigma Pharma and Medisure Laboratories. • The firm submitted list of 05 approved sections of applicant (Sigma Pharma) • The firm submitted list of 09 approved products for contract manufacturing approved in 291st DRB meeting. • The firm submitted list of 12 applied products for contract manufacturing
	Decision: Approved	
1613.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan *Contract Manufactured by:* M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Seafix 200mg/5ml Suspension
	Composition	Each 5ml contains: Cefixime as trihydrate…200mg
	Dairy No. date of R &I fee	Dy.No 43180 dated 18-12-2018 Rs.50,000/- Dated 18-12-2018
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX 200mg/5ml Dry Powder Suspension Lupin Ltd. USFDA Approved.
	Me-too-status	Rofixime DS Suspension by SPL Pharmaceuticals (Pvt) Ltd, (Reg#45506)
	GMP Status	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with applicant signatures and revised the label claim as "Each 5ml Contains Cefixime as trihydrate 200mg" instead of Each 5ml Contains Cefixime 200mg only"

		• The firm submitted revised master formulation of manufacturer signed by technical staff of manufacturer. • The firm submitted copy of contract manufacturing agreement between Sigma Pharma and Medisure Laboratories • The firm submitted list of 05 approved sections of applicant (Sigma Pharma) • The firm submitted list of 09 approved products for contract manufacturing approved in 291st DRB meeting. • The firm submitted list of 12 applied products for contract manufacturing
	• **Decision: Approved**	
1614.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan *Contract Manufactured by:* M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Fotay 1gm Injection
	Composition	Each Vial Contains: Cefotaxime (as sodium)..…1gm
	Dairy No. date of R &I fee	Dy.No 43178 dated 18-12-2018 Rs.50,000/- Dated 18-12-2018
	Pharmacological Group	Cephalosporine
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefotaxime 1g powder for solution for injection. MHRA approved
	Me-too-status	Setrofin Injection 1gm by SPL Pharmaceuticals (Pvt) Ltd, (Reg#45513)
	GMP Status	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with applicant signatures and revised the label claim as “Each Vial Contains Cefotaxime (as sodium) 1g” instead of Each Vial Contains Cefotaxime 1g only” along with submission of Rs. 5000/- on slip No. 1915912 dated 12.02.2020 • The firm submitted the use of type II glass container while the reference formulation is packed in vials of clear glass hydr. class III with halogenated butyl rubber stopper • The firm submitted revised master formulation of manufacturer signed by technical staff of manufacturer and revised the weight of API considering the salt factor. • The firm submitted copy of contract manufacturing agreement between Sigma Pharma and Medisure Laboratories • The firm submitted list of 05 approved sections of applicant (Sigma Pharma) • The firm submitted list of 09 approved products for

		contract manufacturing approved in 291st DRB meeting. • The firm submitted list of 12 products applied for contract manufacturing
	Decision: Deferred for use of type of primary packaging material (use of type II glass container)	
1615.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, *Contract Manufactured by:* M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi
	Brand Name + Dosage Form+ Strength	Fotay 500mg Injection
	Composition	Each Vial Contains: Cefotaxime (as sodium) ……500mg
	Dairy No. date of R &I fee	Dy.No 43177 dated 18-12-2018 Rs.50,000/- 18-12-2018
	Pharmacological Group	Cephalosporine
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefotaxime 500 mg powder for solution for injection. MHRA approved
	Me-too-status	Trigoren Injection 500mg by Trigon Pharmaceutical (Pvt) Ltd, (Reg#45827)
	GMP Status	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with applicant signatures and revised the label claim as "Each Vial Contains Cefotaxime (as sodium) 500mg" instead of Each Vial Contains Cefotaxime 500mg only" along with submission of Rs. 5000/- on slip No. 1915910 dated 12.02.2020 • The firm submitted revised master formulation of manufacturer signed by technical staff of manufacturer and revised the weight of API considering the salt factor. • The firm submitted the use of type II glass container while the reference formulation is packed in vials of clear glass hydr. class III with halogenated butyl rubber stopper • The firm submitted copy of contract manufacturing agreement between Sigma Pharma and Medisure Laboratories • The firm submitted list of 05 approved sections of applicant (Sigma Pharma) • The firm submitted list of 09 approved products for contract manufacturing approved in 291st DRB meeting. • The firm submitted list of 12 products applied for contract manufacturing
	Decision: Deferred for use of type of primary packaging material (use of type II glass container)	
1616.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, *Contract Manufactured by:* M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Fotay 2gm Injection
	Composition	Each Vial Contains:

		Cefotaxime (as sodium) ..…2gm
	Dairy No. date of R &I fee	Dy.No 43179 dated 18-12-2018 Rs.50,000/- Dated 18-12-2018
	Pharmacological Group	Cephalosporine
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefotaxime 2g powder for solution for injection. MHRA approved
	Me-too-status	Claforan 2g Injection Sanofi Aventis (Reg# 076156)
	GMP Status	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with applicant signatures and revised the label claim as "Each Vial Contains Cefotaxime (as sodium) 2g" instead of Each Vial Contains Cefotaxime 2g only" along with submission of Rs. 5000/- on slip No. 1915911 dated 12.02.2020 • The firm submitted revised master formulation of manufacturer signed by technical staff of manufacturer and revised the weight of API considering the salt factor. • The firm submitted the use of type II glass container while the reference formulation is packed in vials of clear glass hydr. class III with halogenated butyl rubber stopper • The firm submitted copy of contract manufacturing agreement between Sigma Pharma and Medisure Laboratories • The firm submitted list of 05 approved sections of applicant (Sigma Pharma) • The firm submitted list of 09 approved products for contract manufacturing approved in 291st DRB meeting. • The firm submitted list of 12 products applied for contract manufacturing
	Decision: Deferred for use of type of primary packaging material (use of type II glass container)	
1617.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan *Contract Manufactured by:* M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Fotay 250mg Injection
	Composition	Each Vial Contains: Cefotaxime (as sodium) ..…250mg
	Dairy No. date of R &I fee	Dy.No 43181 dated 18-12-2018 Rs.50,000/- 18-12-2018
	Pharmacological Group	Cephalosporine
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CEFOTAXIMA NORMON 250 Mg POWDER AND SOLVENT FOR SOLUTION INJECTABLE IV EFG. CIMA approved
	Me-too-status	Ceftop 250Mg Injection by Saydon Pharmaceutical (Reg#36930)

	GMP Status	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with applicant signatures and revised the label claim as "Each Vial Contains Cefotaxime (as sodium) 250mg" instead of Each Vial Contains Cefotaxime 250mg only" along with submission of Rs. 5000/- on slip No. 1915909 dated 12.02.2020 • The firm submitted revised master formulation of manufacturer signed by technical staff of manufacturer and revised the weight of API considering the salt factor. • The firm submitted copy of contract manufacturing agreement between Sigma Pharma and Medisure Laboratories • The firm submitted list of 05 approved sections of applicant (Sigma Pharma) • The firm submitted list of 09 approved products for contract manufacturing approved in 291st DRB meeting. • The firm submitted list of 12 products applied for contract manufacturing
	Decision: Approved	
1618.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan *Contract Manufactured by:* M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Vift 200mg/100ml Infusion
	Composition	Each 100ml Vial Contains: Ciprofloxacin as lactate…200mg
	Dairy No. date of R &I fee	Dy.No 43173 dated 18-12-2018 Rs.50,000/- Dated 18-12-2018
	Pharmacological Group	Fluoroquinolones
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin 2mg/ml solution for infusion (MHRA approved)
	Me-too-status	Riget 200Mg/100ml Infusion by Saydon Pharmaceutical Industries (Pvt) Ltd (Reg#36936)
	GMP Status	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with applicant signatures • Firm has submitted revised manufacturing outline mentioning all the steps. • The firm submitted revised master formulation of manufacturer signed by technical staff of manufacturer. Moreover revised the weight of API considering the salt factor • The firm submitted the use type II glass container and the reference formulation is also packed in Type II clear glass, internally siliconised, colourless bottles

		• The firm submitted copy of contract manufacturing agreement between Sigma Pharma and Medisure Laboratories. • The firm submitted list of 05 approved sections of applicant (Sigma Pharma) • The firm submitted list of 09 approved products for contract manufacturing approved in 291st DRB meeting. • The firm submitted list of 12 applied products for contract manufacturing
	Decision: Approved	
1619.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan *Contract Manufactured by:* M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Veloft 500mg/100ml Infusion
	Composition	Each 100ml vial contains: Levofloxacin (as Hemihydrate)…500mg
	Dairy No. date of R &I fee	Dy.No 43175 dated 18-12-2018 Rs.50,000/- Dated 18-12-2018
	Pharmacological Group	Fluoroquinolone
	Type of form	Form-5
	Finished product specifications	JP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levofloxacin 500mg/100ml solution for infusion (MHRA Approved)
	Me-too-status	Livogale 500mg/100ml Injection by Uni-Tiech Pharmaceutials, (Reg#47046)
	GMP Status	GMP Certificate Issued to Medisure Labortaries Pakistan Pvt Ltd Karachi on 02-10-2019
	Remark of the Evaluator XI	• Firm has submitted revised form 5 with applicant signatures • Firm has submitted revised manufacturing outline mentioning all the steps. • The firm has revised the weight of API in master formulation considering the hemihydrate form • The firm submitted copy of contract manufacturing agreement between Sigma Pharma and Medisure Laboratories. • The firm submitted list of 05 approved sections of applicant (Sigma Pharma) • The firm submitted list of 09 approved products for contract manufacturing approved in 291st DRB meeting. • The firm submitted list of 12 applied products for contract manufacturing
	Decision: Approved	
1620.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi,
	Brand Name + Dosage Form + Strength	Amadon Tablet 2.5mg
	Composition	Each Tablet Contains: Amlodipine (as beylate)…2.5mg
	Dairy No. date of R &I fee	Dy.No 43174 dated 18-12-2018 Rs.20,000/- 18-12-2018

	Pharmacological Group	Calcium Channel Blockers
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NORVASC 2.5mg Tablets USFDA approved
	Me-too-status	Amdipine Tablets 2.5mg by Nabiqasim Industries (Pvt) Ltd, (Reg#29754)
	GMP Status	GMP Certificate Issued on 19-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted the revised form 5 mentioning the label claim along with commitments as per decision of 251st meeting of Registration Board.
	Decision: Approved	
1621.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Amadon Tablet 5mg
	Composition	Each Tablet Contains: Amlodipine (as beylate)…..5mg
	Dairy No. date of R &I fee	Dy.No 43183 dated 18-12-2018 Rs.20,000/- Dated 18-12-2018
	Pharmacological Group	Calcium Channel Blockers
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NORVASC 5mg Tablets USFDA approved
	Me-too-status	Amlocard 5mg Tablets by Pharmatec Pakistan (Reg#20555)
	GMP Status	GMP Certificate Issued on 19-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted the revised form 5 mentioning the label claim along with commitments as per decision of 251st meeting of Registration Board
	Decision: Approved	
1622.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Amadon Tablet 10mg
	Composition	Each Tablet Contains: Amlodipine (as beylate)..…10mg
	Dairy No. date of R &I fee	Dy.No 43182 dated 18-12-2018 Rs.20,000/- Dated 18-12-2018
	Pharmacological Group	Calcium Channel Blockers
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NORVASC 10mg Tablets USFDA approved
	Me-too-status	Amlocard 10mg Tablets by Pharmatec Pakistan (Reg#20556)
	GMP Status	GMP Certificate Issued on 19-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted the revised form 5 mentioning the label claim along with commitments as per decision of 251st meeting of Registration Board.

	Decision: Approved	
1623.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Mesop 200mcg Tablet
	Composition	Each Tablet Contains: Misoprostol (as 1% dispersion)…200mcg
	Dairy No. date of R &I fee	Dy.No 43176 dated 18-12-2018 Rs.20,000/- Dated 18-12-2018
	Pharmacological Group	Prostaglandin
	Type of form	Form-5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec tablets (USFDA Approved)
	Me-too-status	Prosotec 200mcg Tablet by Atco Laboratories (Reg#58356)
	GMP Status	GMP Certificate Issued on 19-10-2019
	Remark of the Evaluator [XI]	• Firm has submitted the revised form 5 mentioning the label claim along with commitments as per decision of 251st meeting of Registration Board. • Misoprostol is used as 1% dispersion which is an intermediate and not the active substance. Do we need additional documents, source fixation and fee? • Approved with boxed warning of ―misoprostol administration to women who are pregnant can cause birth defects, abortion, premature birth or uterine rupture.
	Decision: Approved with IP specifications and boxed warning of ―misoprostol administration to women who are pregnant can cause birth defects, abortion, premature birth or uterine rupture.	
1624.	Name and address of manufacture / Applicant	M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Venof XR 75mg Capsule
	Composition	Each Extended release capsule contains: Venlafaxine HCl sustained release pellets (33%) equivalent to Venlafaxine……75mg" Source of pellets: Vision Pharma
	Dairy No. date of R &I fee	Dy.No 43184 dated 18-12-2018 Rs.20,000/- Dated 18-12-2018
	Pharmacological Group	Other antidepressants
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	EFFEXOR XR (venlafaxine Extended-Release) Capsules USFDA approved
	Me-too-status	Vfx Capsule 75mg of M/s Bio-Mark Pharmaceuticals (Reg.#82659)
	GMP Status	GMP Certificate Issued on 19-10-2019
	Remark of the Evaluator [XI]	• Firm submitted the documents confirming source of pellets, stability studies data, GMP certificate of supplier (Vision Pharma). • Firm submitted revised master formulation adjusting

		the weight of API considering the salt factor
	Decision: Approved	
1625.	Name and address of manufacture / Applicant	M/s The Searle Company Limited., F-319, S.I.T.E, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Femesis 10/10 mg Tablet
	Composition	Each film coated delayed Release Tablet Contains: Doxylamine Succinate…10mg Pyridoxine Hydrochloride…10mg
	Dairy No. date of R &I fee	Dy.No 43099 dated 18-12-2018 Rs.20,000/- Dated 10-12-2018
	Pharmacological Group	Antihistamines
	Type of form	Form-5
	Finished product specifications	Manufacturer‘s specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too-status	Vomipreg Tablet by Nexus Pharma (Reg.#75838)
	GMP Status	GMP Certificate Issued on 18-05-2018
	Remark of the Evaluator [XI]	• Firm have submitted revised manufacturing outlines mentioning the blistering and packaging process.
	Decision: Approved as per innovator’s specifications	
1626.	Name and address of manufacture / Applicant	M/s Vega Pharmaceuticals Pvt Ltd. Plot No. 4, 30-Km Pharma City, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Vepril 10mg Tablet
	Composition	Each Tablet Contains: Lisinopril dihydrate eq to Lisinopril…10mg
	Dairy No. date of R &I fee	Dy.No 43221 dated 19-12-2018 Rs.20,000/- Dated 19-12-2018
	Pharmacological Group	ACE Inhibitor
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	14’s; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lisinopril 10mg Tablets (MHRA Approved)
	Me-too-status	Lace 10 Tablets by Brookes Pharmaceutical Labs, Reg.#23813)
	GMP Status	The firm was inspected on 17-07-2017 by a panel of experts wherein it was observed that the firm has maintained a good level of GMP compliance as per Schedule B-II of Drugs (Licensing, Registration & Advertising) Rules 1976.
	Remark of the Evaluator [XI]	• Firm have submitted revised master formulation considering the hydrated form and adjusting the weight of API.
	Decision: Approved	
1627.	Name and address of manufacture / Applicant	M/s Vega Pharmaceuticals Pvt Ltd. Plot No. 4, 30-Km Pharma City, Multan Road, Lahore
	Brand Name + Dosage Form + Strength	Vepril 20mg Tablet
	Composition	Each Tablet Contains: Lisinopril dihydrate eq to Lisinopril…20mg
	Dairy No. date of R &I fee	Dy.No 43222 dated 19-12-2018 Rs.20,000/- Dated 19-12-2018
	Pharmacological Group	ACE Inhibitor
	Type of form	Form-5

	Finished product specifications	USP
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lisinopril 20mg Tablets (MHRA Approved)
	Me-too-status	Lace 20 Tablets by Brookes Pharmaceutical (Reg.#23814)
	GMP Status	The firm was inspected on 17-07-2017 by a panel of experts wherein it was observed that the firm has maintained a good level of GMP compliance as per Schedule B-II of Drugs (Licensing, Registration & Advertising) Rules 1976.
	Remark of the Evaluator [XI]	• Firm have submitted revised master formulation considering the hydrated form and adjusting the weight of API.
	Decision: Approved	
1628.	Name and address of manufacture / Applicant	M/s Vega Pharmaceuticals Pvt Ltd. Plot No. 4, 30-Km Pharma City, Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Vepril 5mg Tablet
	Composition	Each Tablet Contains: Lisinopril dihydrate eq to Lisinopril…5mg
	Dairy No. date of R &I fee	Dy.No 43220 dated 19-12-2018 Rs.20,000/- Dated 19-12-2018
	Pharmacological Group	ACE Inhibitor
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lisinopril 5mg Tablets (MHRA Approved)
	Me-too-status	Lace 5 Tablets by Brookes Pharmaceutical (Reg.#23812)
	GMP Status	The firm was inspected on 17-07-2017 by a panel of experts wherein it was observed that the firm has maintained a good level of GMP compliance as per Schedule B-II of Drugs (Licensing, Registration & Advertising) Rules 1976.
	Remark of the Evaluator [XI]	• Firm have submitted revised master formulation considering the hydrated form and adjusting the weight of API.
	Decision: Approved	
1629.	Name and address of manufacture / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name + Dosage Form+ Strength	Montaza Sachet 4mg
	Composition	Each sachet contains: Montelukast as Sodium …4mg
	Dairy No. date of R &I fee	Dy.No 40271 dated 05-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Leukotriene receptor antagonists
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Montelukast 4 mg granules (MHRA Approved)
	Me-too-status	Lukomon 4mg Sachet by Platinum pharmaceuticals (Reg.#70839)
	GMP Status	"GMP certificate Issued on 23-05-2018."
	Remark of the Evaluator [XI]	• The firm has submitted complete manufacturing

		outline mentioning the sealing and packing process. • The firm has submitted revised master formulation adjusting the weight of API considering the salt factor. • The firm have submitted list of equipments used in sachet production section and commitments as per decision of 251st meeting of Registration Board.
	Decision: Approved	
1630.	Name and address of manufacture / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Zafonate Injection 60mg/ml
	Composition	Each Vial Contains: Artesunate powder for injection…60mg
	Dairy No. date of R &I fee	Dy.No 42317 dated 11-12-2018 Rs.20,000/- Dated 10-12-2018
	Pharmacological Group	Antimalarial
	Type of form	Form-5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO approved injectable artesunate 60mg (WHO Approved formulation)
	Me-too-status	Misonate 60mg Injection of M/s Tabros Pharma (Pvt.) Ltd. (Reg.# 57719)
	GMP Status	"GMP certificate Issued on 23-05-2018."
	Remark of the Evaluator [XI]	• The firm has also applied for 1ml ampoule of 5% sodium bicarbonate solution and 5ml ampoule of 0.9% sodium chloride solution in a box in same application. • The firm submitted that they will use type I glass container (vial) of 5ml. • Evidence of section approval was not submitted • The firm submitted commitments as per decision of 251st meeting of Registration Board.
	Decision: Deferred for following: • **Confirmation of manufacturing facility.** • **Clarification as firm has also applied for 1ml ampoule of 5% sodium bicarbonate solution and 5ml ampoule of 0.9% sodium chloride solution in a box in same application**	
1631.	Name and address of manufacture / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Binan Z Injection
	Composition	Each 1ml ampoule contains: Hydroxyprogesterone caproate..…250mg Estradiol valerate..…5mg
	Dairy No. date of R &I fee	Dy.No 42668 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Progestogens and Estrogens Combination
	Type of form	Form-5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Gravibinian by Bayer schering Pharma AG Germany (Could not be confirmed)
	Me-too-status	Z-Bron Injection by Pharma Health Pakistan (Pvt) Ltd, (Reg.# 77108)
	GMP Status	"GMP certificate Issued on 23-05-2018."
	Remark of the Evaluator [XI]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board could not be

		confirmed. • The firm submitted that they will use type I glass container and submitted commitments as per decision of 251st meeting of Registration Board.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of manufacturing facility (steroidal hormone ampoule section)**	
1632.	Name and address of manufacture / Applicant	M/s Venus Pharma. 23 km, Multan Road, Lahore *Contract Manufactured by:* M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Mexime 100mg/5ml Suspension
	Composition	Each 5ml Suspension Contains: Cefixime trihydrate Eq. to Cefixime …100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40300 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	30ml; 60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX® 100mg/5ml powder for oral suspension (US FDA) Approved.
	Me-too-status	Cexime Suspension 100mg/5ml Akson Pharmaceutical (Pvt) Ltd, (Reg. 29937)
	GMP Status	GMP Certificate issued on 12-03-2018
	Remark of the Evaluator XI	• The firm submitted list of 04 approved sections of applicant (Venus Pharma) • The firm submitted list of 07 applied products for contract manufacturing • The firm did not have any product on contract manufacturing (confirmed from section)
	Decision: Deferred for following: • **confirmation whether M/s Venus has registration of same molecule or otherwise** • **capcacity assessment of M/s Cunningham Pharmaceuticals**	
1633.	Name and address of manufacture / Applicant	M/s Venus Pharma. 23 km, Multan Road, Lahore *Contract Manufactured by:* M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Vesofin 500mg IM Dry powder Injection
	Composition	Each Vial Contains: Sterile Ceftriaxone (as Sodium)…….500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40305 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 500mg powder for solution for injection MHRA Approved
	Me-too-status	Agrocef 500mg Inj IM by Agror Pharma (Reg. 077919)
	GMP Status	GMP Certificate issued on 12-03-2018

	Remark of the Evaluator [XI]	• The firm submitted the use of type III glass vial for the applied product while the container for reference formulation is type III glass vial. • The firm submitted list of 04 approved sections of applicant (Venus Pharma) • The firm submitted list of 07 applied products for contract manufacturing • The firm did not have any product on contract manufacturing (confirmed from section)
	Decision: Deferred for following: • **confirmation whether M/s Venus has registration of same molecule or otherwise** • **capcacity assessment of M/s Cunningham Pharmaceuticals**	
1634.	Name and address of manufacture / Applicant	M/s Venus Pharma. 23 km, Multan Road, Lahore *Contract Manufactured by:* M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form+ Strength	Vesofin 250mg IV Dry powder Injection
	Composition	Each Vial Contains: Sterile Ceftriaxone (as Sodium)……250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40303 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin 250mg IV Inj MHRA Approved
	Me-too-status	Efxone 250mg Inj IV by Candid Pharmaceuticals (Reg. 087354)
	GMP Status	GMP Certificate issued on 12-03-2018
	Remark of the Evaluator [XI]	• The firm submitted the use of type III glass vial for the applied product and the container for reference formulation is also type I glass vial. • The firm submitted list of 04 approved sections of applicant (Venus Pharma) • The firm submitted list of 07 applied products for contract manufacturing • The firm did not have any product on contract manufacturing (confirmed from section)
	Decision: Deferred for following: • **Use of type of primary packaging material (use of type III glass vial).** • **confirmation whether M/s Venus has registration of same molecule or otherwise** • **capcacity assessment of M/s Cunningham Pharmaceuticals**	
1635.	Name and address of manufacture / Applicant	M/s Venus Pharma. 23 km, Multan Road, Lahore *Contract Manufactured by:* M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Vesofin 500mg IV Dry powder Injection
	Composition	Each Vial Contains: Sterile Ceftriaxone (as Sodium)……500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40304 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 500mg powder for solution for injection MHRA Approved
	Me-too-status	Agrocef 500mg Inj IV by Agror Pharma (Reg. 077917)
	GMP Status	GMP Certificate issued on 12-03-2018
	Remark of the Evaluator [XI]	• The firm submitted the use of type III glass vial for the applied product while the container for reference formulation is type III glass vial. • The firm submitted list of 04 approved sections of applicant (Venus Pharma) • The firm submitted list of 07 applied products for contract manufacturing • The firm did not have any product on contract manufacturing (confirmed from section)
	Decision: Deferred for following: • **confirmation whether M/s Venus has registration of same molecule or otherwise** • **capcacity assessment of M/s Cunningham Pharmaceuticals**	
1636.	Name and address of manufacture / Applicant	M/s Venus Pharma. 23 km, Multan Road, Lahore *Contract Manufactured by:* M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mexime-DS 200mg/5ml Suspension
	Composition	Each 5ml Suspension Contains: Cefixime trihydrate Eq. to Cefixime …200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40301 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	30ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX® 200mg/5ml powder for oral suspension (US FDA) Approved.
	Me-too-status	Regcef 200mg/5ml DS Regal Pharmaceutical (Pvt) Ltd, (Reg. 098276)
	GMP Status	GMP Certificate issued on 12-03-2018
	Remark of the Evaluator [XI]	• The firm submitted list of 04 approved sections of applicant (Venus Pharma) • The firm submitted list of 07 applied products for contract manufacturing • The firm did not have any product on contract manufacturing (confirmed from section)
	Decision: Deferred for following: • **confirmation whether M/s Venus has registration of same molecule or otherwise** • **capcacity assessment of M/s Cunningham Pharmaceuticals**	
1637.	Name and address of manufacture / Applicant	M/s Venus Pharma. 23 km, Multan Road, Lahore *Contract Manufactured by:* M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Mexime 400mg Capsule
	Composition	Each Capsule Contains: Cefixime (as Trihydrate)…….400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40302 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	JP

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX® capsules 400mg, (USFDA approved)
	Me-too-status	Xalfocin 400mg Capsule by Martin Dow Karachi (Reg. 80646)
	GMP Status	GMP Certificate issued on 12-03-2018
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation adjusting the weight of API considering the hydrated form. • The firm submitted list of 04 approved sections of applicant (Venus Pharma) • The firm submitted list of 07 applied products for contract manufacturing • The firm did not have any product on contract manufacturing (confirmed from section)
	Decision: Deferred for following: • **confirmation whether M/s Venus has registration of same molecule or otherwise** • **capcacity assessment of M/s Cunningham Pharmaceuticals**	
1638.	Name and address of manufacture / Applicant	M/s Venus Pharma. 23 km, Multan Road, Lahore *Contract Manufactured by:* M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Vesofin 1gm IV Dry powder Injection
	Composition	Each Vial Contains: Sterile Ceftriaxone (as Sodium)……1gm
	Dairy No. date of R &I fee	Form-5 Dy.No 40306 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Cephalosporin
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin IV 1g Inj MHRA Approved
	Me-too-status	Agrocef 1g Inj IV by Agror Pharma (Reg. 077918)
	GMP Status	GMP Certificate issued on 12-03-2018
	Remark of the Evaluator [XI]	• The firm submitted the use of type III glass vial for the applied product while the container for reference formulation is type I glass vial. • The firm submitted list of 04 approved sections of applicant (Venus Pharma) • The firm submitted list of 07 applied products for contract manufacturing • The firm did not have any product on contract manufacturing (confirmed from section)
	Decision: Deferred for following: • **Use of type of primary packaging material (use of type III glass vial).** • **confirmation whether M/s Venus has registration of same molecule or otherwise** • **capcacity assessment of M/s Cunningham Pharmaceuticals**	
1639.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form Strength	Aprex Capsule 125mg
	Composition	Each Capsule Contains: Aprepitant…….125mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40725 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antiemetics and antinauseants

		ATC code: A04AD12
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	2's; 3's; 10's; 20's; 30's; 40's; 50's; 60's; 70's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	EMEND 125mg capsules USFDA Approved
	Me-too-status	Emvoid 125mg capsule by Global Pharmaceuticals (Reg#098150)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1640.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Aprex Capsule 80mg
	Composition	Each Capsule Contains: Aprepitant…..…80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40749 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antiemetics and antinauseants ATC code: A04AD12
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	2's; 3's; 10's; 20's; 30's; 40's; 50's; 60's; 70's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	EMEND 80mg capsules USFDA Approved
	Me-too-status	Emvoid 80mg capsule by Global Pharmaceuticals (Reg#098149)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1641.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd.L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form+ Strength	Aprex Capsule 40mg
	Composition	Each Capsule Contains: Aprepitant……40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40748 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antiemetics and antinauseants ATC code: A04AD12
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	2's; 3's; 10's; 20's; 30's; 40's; 50's; 60's; 70's; 80's;

		90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	APREPITANT RMB (aprepitant) 40mg capsule TGA Approved
	Me-too-status	Emvoid 40mg capsule by Global Pharmaceuticals (Reg#098148)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1642.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Liskoxime Tablet 400mg
	Composition	Each Film Coated Tablet Contains: Cefixime Trihydrate eq to Cefixime…..400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40731 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Cephalosporine
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 20's; 30's; 40's; 50's; 60's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX 400mg tablets USFDA Approved Discontinued "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons"
	Me-too-status	Fixitil-T DS 400mg tablets by Tabros Pharma (Reg. 083787)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Deferred for confirmation of manufacturing facility	
1643.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Losart Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Losartan Potassium……25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41195 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 20's; 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Losartan Potsasium 25mg tablets MHRA Approved
	Me-too-status	Vezaar 25mg tablets by Vega Pharmaceuticals (Reg.

		085886)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1644.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Olmax 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil.…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41211 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BENICAR tablets USFDA Approved
	Me-too-status	Olmisan 5mg tablets by Highnoon Laboratories (Reg. 092271)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1645.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Albezole Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Albendazole …….200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39982 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anthelmintic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ALBENZA tablets USFDA Approved
	Me-too-status	Zentmaf 200mg tablets by Mafins Pharma (Reg. 088979)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"

	Remark of the Evaluator [XI]	•
	Decision: Approved	
1646.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Domlis Tablet 400mg
	Composition	Each Tablet Contains: Doxofylline…..400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39984 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Xanthines
	Type of form	Form 5
	Finished product specifications	Manufacturers' specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Doxofillina ABC 400 mg tablet by M/s ABC Farmaceutici SpA (Italian Medicine Agency Approved)
	Me-too-status	Phylox 400mg tablet by M/s Bio-Mark Pharmaceuticals (Reg. # 094661)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• No deposite slip is attached with the dossier. However the dossier is endorsed for submission of Rs 20,000/- and challan No. 0723717 dated 01-12-2018
	Decision: Approved subject to verification of fee challan as per decision of 285th meeting of Registration Board	
1647.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Fabulis 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat……80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39992 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antigout preparation
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	20's; 30's; 40's; 50's; 60's; 70's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ULORIC 80mg tablets USFDA Approved
	Me-too-status	Febuxin 80mg tablet by AGP Ltd (Reg. 081105)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	

1648.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Fabulis 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat……40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39991 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antigout preparation
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	20's; 30's; 40's; 50's; 60's; 70's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ULORIC 40mg tablets USFDA Approved
	Me-too-status	Febuxin 40mg tablet by AGP Ltd (Reg. 081104)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1649.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	E-Best Syrup 5mg/5ml
	Composition	Each 5ml contains: Ebastine……5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39986 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anti-histamine
	Type of form	Form 5
	Finished product specifications	Manufacturer specification
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ebastel 1mg/ml oral solution of Almirall, Spanish medicine agency Approved
	Me-too-status	Olivestin syrup by Hiranis Pharmaceutical (Reg#076519)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1650.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form+ Strength	Monti Tablet 4mg
	Composition	Each chewable tablet contains: Montelukast as Sodium …..4mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39987 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018

	Pharmacological Group	Leukotriene receptor antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair Chewable Tablet USFDA Approved
	Me-too-status	Asthiven 4mg Chewable Tablets of M/s Scilife Pharma (Reg.# 092754)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1651.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Citap Oral Solution 1mg/5ml
	Composition	Each 5ml Contains: Cinitapride (as Acid Tartrate).....1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39990 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Pro-kinetic agent
	Type of form	Form 5
	Finished product specifications	Manufacturers specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cidine 1mg/5ml Oral solution by ALMIRALL, SA (Spain Approved)
	Me-too-status	Cidine of M/s Highnoon Laboratories (Reg. No. 069457)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1652.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Citap Tablet 1mg
	Composition	Each Tablet Contains: Cinitapride (as acid tartrate).....1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39989 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Pro-kinetic agent
	Type of form	Form 5
	Finished product specifications	Manufacturers specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cidine 1mg tablets (Spain Approved)
	Me-too-status	Cinlite 1mg tablet by M/s PharmEvo (Reg#090995)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of

		inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1653.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Mate Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Topiramate……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39995 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Aristo 100mg tablets MHRA Approved
	Me-too-status	Neutop 100mg tablets by M/s Nabiqasim Industries (Reg#089056)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1654.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form+ Strength	Mate Tablet 25mg
	Composition	Each Film Coated Tablet Contains: Topiramate…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39993 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Cadila 25mg tablets MHRA Approved
	Me-too-status	Neutop 25mg tablets by M/s Nabiqasim Industries (Reg#076387)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1655.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Mate Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Topiramate…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39994 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Teva 50mg tablets MHRA Approved
	Me-too-status	Neutop 50mg tablets by M/s Nabiqasim Industries (Reg#076388)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1656.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd.L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Zinkrol 20mg dispersible Tablet
	Composition	Each dispersible tablet contans: Zinc sulphate Monohydrate eq to zinc.…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39981 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Other Mineral Supplements ATC Code; A12C
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified Zincfant Tablet 20 mg manufactured by Laboratories Pharmaceutique s Rodael –France
	Me-too-status	Tablet Zink 20 mg by M/s Well & Well (Pvt.) Ltd (Reg. No. 80390)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The manufacturer have claimed USP specifications while monograph for dispersible tablets are not available in any pharmacopeia (USP, BP, IP, JP).
	Decision: Approved as per innovator's specifications	
1657.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Kufend Syrup 0.3mg/ml
	Composition	Each ml contains: Terbutaline Sulfate…0.3mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39985 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018

	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bricanyl 0.3 mg/ml Syrup. MHRA approved
	Me-too-status	Butali Liquid Syrup. BY M/s Fynk Pharmaceuticals (Reg No. 79712)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm has claimed USP monograph while the official monograph is not available in any pharmacopeias (USP, BP, JP,IP)
	Decision: Approved as per innovator's specifications	
1658.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Liskoxime Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Cefixime Trihydrate eq to Cefixime…..200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40730 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Cephalosporine
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 20's; 30's; 40's; 50's; 60's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX 200mg tablets USFDA Approved Discontinued "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons"
	Me-too-status	Wizy 200mg tablets by Zephyr Pharmatec (Reg. 088322)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Deferred for confirmation of manufacturing facility	
1659.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Arile 10mg Tablet
	Composition	Each tablet contains: Aripiprazole……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40746 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antipsychotics
	Type of form	Form 5
	Finished product specifications	USP

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Abilify Tablets USFDA Approved
	Me-too-status	Pipzol 10mg Tablet by M/s High Q Pharmaceuticals (Reg#073613)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1660.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Perfect Capsule 20mg
	Composition	Each Capsule Contains: Fluxetine as HCl.…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40744 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fluoxetine 20mg Capsules MHRA Approved
	Me-too-status	Dyflex 20mg capsule by M/s Dynatis Pakistan (Reg#095449)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1661.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Olix Plus 6mg/25mg Capsule
	Composition	Each Capsule Contains: Olanzapine.…6mg Fluoxetine as HCl…..25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40747 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antipsychotic/ antidepressant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SYMBYAX (USFDA Approved)
	Me-too-status	Co-Depricap 6/25mg Capsule of M/s Nabiqasim Industries (Reg. 076135)

	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1662.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Olix Plus 12mg/25mg Capsule
	Composition	Each Capsule Contains: Olanzapine……12mg Fluoxetine as HCl……25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40747 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antipsychotic/ antidepressant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SYMBYAX (USFDA Approved)
	Me-too-status	Co-Depricap 12/25mg Capsule of M/s Nabiqasim Industries (Reg. 097334)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1663.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Naplis Plus Tablet 500mg/85mg
	Composition	Each Film Coated Tablet Contains: Naproxen Sodium…500mg Sumatriptan as Succinate…85mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40739 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Propionic acid derivatives and Selective serotonin (5HT1) agonists
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TREXIMET 500mg/85mg tablets USFDA Approved
	Me-too-status	Imtaxen 500/85mg Tablet by M/s Shaigan Pharmaceuticals (Reg#081678)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory

		level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1664.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Candy Tablet 16mg
	Composition	Each Tablet Contains: Candesartan Cilexetil ……16mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41197 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND 16mg tablets US-FDA approved
	Me-too-status	Trutan 16mg tablets by M/s Rotex Pharma (Reg#085395)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1665.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Olmax 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil.…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41210 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BENICAR tablets USFDA Approved
	Me-too-status	Olmisan 20mg tablets by Highnoon Laboratories (Reg. 092273)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1666.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Olmax 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…….40mg

	Dairy No. date of R &I fee	Form-5 Dy.No 41208 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BENICAR tablets USFDA Approved
	Me-too-status	Olmisan 40mg tablets by Highnoon Laboratories (Reg. 092274)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1667.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Zolmax Tablet 5mg
	Composition	Each film coated Tablet Contains: Zolmitriptan……5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41183 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Selective serotonin (5HT1) agonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zolmitriptan 5 mg tablets MHRA Approved
	Me-too-status	Zolmiton 5mg tablets of M/s CKD Pharmaceuticals (Reg#081786)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1668.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Lamotrin 25mg Tablet
	Composition	Each Tablet Contains: Lamotrigine ……25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41209 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	LAMICTAL 25mg Tablets (USFDA approved)
	Me-too-status	Epictal 25mg Tablet of M/s Pakistan Pharmaceuticals (Reg#089241)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1669.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Lamotrin 100mg Tablet
	Composition	Each Tablet Contains: Lamotrigine …..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41203 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LAMICTAL 100mg Tablets (USFDA approved)
	Me-too-status	Epictal 100mg Tablet of M/s Pakistan Pharmaceuticals (Reg#089243)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1670.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Glucoset 50mg Tablet
	Composition	Each film coated tablet contains: Sitagliptin as phosphate monohydrate ..…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41190 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Blood Glucose Lowering Drugs, Excl. Insulins
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	JANUVIA 50mg tablets USFDA Approved
	Me-too-status	Sigten 50mg tablets by M/s Innvotek Pharmaceuticals (Reg#099256)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was

		noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1671.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Glucoset 100mg Tablet
	Composition	Each film coated tablet contains: Sitagliptin as phosphate monohydrate ….100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41189 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Blood Glucose Lowering Drugs, Excl. Insulins
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	JANUVIA 100mg tablets USFDA Approved
	Me-too-status	Sigten 100mg tablets by M/s Innvotek Pharmaceuticals (Reg#099257)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1672.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Fatilor AM 5/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate.….5mg Artorvastatin (as calcium trihydrate)..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40738 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	10's; 20's; 30's; 40's; 50's; 60's; 70's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET tablets USFDA Approved
	Me-too-status	Zodip Plus 10 tablet by M/s Zafa Pharmceuticals (Reg#083293)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Firm has mentioned the type of hydrated form of

		atorvastatin calcium in label claim alongwith adjustment of weight of API in master formulation considering the salt factor.
	Decision: Approved as per innovator's specifications	
1673.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Fatilor AM 10/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…….10mg Artorvastatin (as calcium trihydrate)……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40737 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer specifications
	Pack size and Demand Price	10's; 20's; 30's; 40's; 50's; 60's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET tablets USFDA Approved
	Me-too-status	Letor 10/10 tablet by M/s CKD Pharmceuticals (Reg#086717)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Firm has mentioned the type of hydrated form of atorvastatin calcium in label claim alongwith adjustment of weight of API in master formulation considering the salt factor.
	Decision: Approved as per innovator's specifications	
1674.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Klomifen Tablet 50mg
	Composition	Each Tablet Contains: Clomiphene Citrate…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40745 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Ovulation stimulants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 20's; 30's; 40's; 50's; 60's; 70's; 80's; 90's; 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clomid 50mg Tablets MHRA Approved
	Me-too-status	Closet 50mg tablet by Medpharm Research Lab (Reg. 100558)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance.

		(Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Firm have submitted revised master formulation adjusting the weight of API without considering the salt factor.
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs (277th DRB meeting).	
1675.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Ease SR 15mg Capsule
	Composition	Each Extended Release Capsule Contains: Cyclobenzaprine HCl (sustained release pellets 22%)……15mg Source of Pellets: Vision Pharma
	Dairy No. date of R &I fee	Form-5 Dy.No 41207 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Skeletal Muscle relaxant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AMRIX 15mg extended release capsule of USFDA approved
	Me-too-status	Ezibenz SR 15mg capsules of M/s Global Pharma (Reg. 079433)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Firm have submitted GMP certificate of Vision Pharma, Certificate of Analysis and stability study data of 3 batches of pellets • Firm have submitted master formulation and complete manufacturing outline mentioning all the steps.
	Decision: Approved	
1676.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Sorelax Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…..10mg (corresponding to 7.5mg Solifenacin)
	Dairy No. date of R &I fee	Form-5 Dy.No 40728 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Urinary antispasmodics
	Type of form	Form 5
	Finished product specifications	Manugacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Solifenacin succinate 10mg Film-coated Tablets MHRA Approved
	Me-too-status	Uricontrol 10mg tablets by M/s OBS Pakistan (Reg. 081071)

	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1677.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Levit XR 500mg Tablet
	Composition	Each film coated extended release tablet contains: Levetiracetam.…500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41212 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA XR extended-release tablets USFDA Approved
	Me-too-status	Lepsira XR 500mg tablets by Scilife Pharma (Reg. 100440)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Firm have revised the formulation from uncoated to film coated tablets with submission of Rs. 5000/- on slip No. 1977702 dated 02.03.2020. Moreover firm revise the label claim as well as master formulation.
	Decision: Approved	
1678.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Ziprox Capsule 20mg
	Composition	Each Capsule Contains: Ziprasidone HCl eq to Ziprasidone…..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39996 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	ANTIPSYCHOTICS, Indole derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZIPROX ziprasidone (as hydrochloride) 20mg capsule TGA Approved
	Me-too-status	Zipronia 20mg capsule by M/s Ipram International (Reg. 082362)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory

		level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm was asked to revise the label claim as each capsule contain Ziprasidone HCl monohydrate eq to Ziprasidone……20mg (as available in USFDA) instead of Ziprasidone HCl eq to Ziprasidone……20mg alongwith revision of master formulation considering the hydrated form of API. The firm submitted that their product is available in TGA as Ziprasidone HCl eq to Ziprasidone……20mg and did not revise the label claim and master formulation considering the hydrated form.
	Decision: Approved	
1679.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Ziprox Capsule 40mg
	Composition	Each capsule contains: Ziprasidone HCl eq to Ziprasidone…….40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39997 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	ANTIPSYCHOTICS, Indole derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZIPROX ziprasidone (as hydrochloride) 40mg capsule TGA Approved
	Me-too-status	Zipronia 40mg capsule by M/s Ipram International (Reg. 082363)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm was asked to revise the label claim as each capsule contain Ziprasidone HCl monohydrate eq to Ziprasidone……40mg (as available in USFDA) instead of Ziprasidone HCl eq to Ziprasidone……40mg alongwith revision of master formulation considering the hydrated form of API. The firm submitted that their product is available in TGA as Ziprasidone HCl eq to Ziprasidone……40mg and did not revise the label claim and master formulation considering the hydrated form. • The firm submitted revised master formulation and manufacturing outline duly signed by the technical persons.
	Decision: Approved	
1680.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Ziprox Capsule 60mg
	Composition	Each capsule contains: Ziprasidone HCl eq to Ziprasidone……60mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39998 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018

	Pharmacological Group	ANTIPSYCHOTICS, Indole derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZIPROX ziprasidone (as hydrochloride) 60mg capsule TGA Approved
	Me-too-status	Zipronia 60mg capsule by M/s Ipram International (Reg. 082360)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm was asked to revise the label claim as each capsule contain Ziprasidone HCl monohydrate eq to Ziprasidone……60mg (as available in USFDA) instead of Ziprasidone HCl eq to Ziprasidone……60mg alongwith revision of master formulation considering the hydrated form of API. The firm submitted that their product is available in TGA as Ziprasidone HCl eq to Ziprasidone……60mg and did not revise the label claim and master formulation considering the hydrated form.
	Decision: Approved	
1681.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Ziprox Capsule 80mg
	Composition	Each Capsule Contains: Ziprasidone HCl monohydrate eq to Ziprasidone……80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39999 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	ANTIPSYCHOTICS, Indole derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZIPROX ziprasidone (as hydrochloride) 80 mg capsule (TGA Approved)
	Me-too-status	Zipronia 80mg capsule by M/s Ipram International (Reg. 082361)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Firm submitted revised form 5, undertaking, commitments, master formulation and manufacturing outline duly signed by the technical persons.
	Decision: Approved	
1682.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Ferolis Plus Drops
	Composition	Each ml contains: Iron (III) hydroxide polymaltose complex eq to elemental iron…50mg

	Dairy No. date of R &I fee	Form-5 Dy.No 39988 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Haemitinic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Maltofer Drops TGA Australia Approved
	Me-too-status	Maltofer Drops by M/s Getz Pharma (Reg#28927)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation as per label claim
	Decision: Approved	
1683.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form+ Strength	Iromax Capsule 150mg
	Composition	Each Capsule Contains: Iron polysaccharide complex eq. to elemental iron.....150mg
	Dairy No. date of R &I fee	Form-5 Dy.No 39983 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Hematinic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Ferricure 150mg Capsule by M/s S.J & G Fazul Ellahie (Reg#050637)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm was asked about the provision of evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, in response the firm submitted that iron preparations are not considered as drug by various reference regulatory authorities and provide evidence from 276th DRB meeting minutes.
	Decision: Approved as per innovator's specifications	
1684.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd.L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Full Iron Plus Tablet 100mg/0.35mg
	Composition	Each chewable Tablet Contains: Iron as iron (III)-hydroxide polymaltose complex eq to elemental Iron.....100mg Folic Acid.....0.35mg

	Dairy No. date of R &I fee	Form-5 Dy.No 40729 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Iron in combination with folic acid
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Inofer-F Chewable Tablet by Kaizen Pharmaceuticals (Reg#81171)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm was asked about the provision of evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, in response the firm submitted that iron preparations are not considered as drug by various reference regulatory authorities and provide evidence from 293rd DRB meeting minutes.
	Decision: Approved as per innovator's specifications	
1685.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Comfort Tablet 250mg/250mg/25mg
	Composition	Each Tablet Contains: Acetaminophen.…250mg Magnesium salicylate.…250mg Pamabrom…..25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40742 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Analgesics & Diuretic combination
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pamprin tablets USFDA (Could not be verified)
	Me-too-status	Dolmi Extra Tablet by Genix Pharma (Reg#73561)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting could not be verified • The firm submitted revised form 5 duly signed by technical person. • The firm have claimed USP monograph, however the monograph is not available in any pharmacopeia.

<table>
<tr><td></td><td colspan="2">Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting</td></tr>
<tr><td rowspan="11">1686.</td><td>Name and address of manufacture / Applicant</td><td>M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi</td></tr>
<tr><td>Brand Name + Dosage Form and Strength</td><td>Tramofix SR 100mg tablet</td></tr>
<tr><td>Composition</td><td>Each sustained release tablet contains: Tramadol Hydrochloride…..100mg</td></tr>
<tr><td>Dairy No. date of R &I fee</td><td>Form-5 Dy.No 40736 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018</td></tr>
<tr><td>Pharmacological Group</td><td>Opioid Analgesic</td></tr>
<tr><td>Type of form</td><td>Form 5</td></tr>
<tr><td>Finished product specifications</td><td>USP</td></tr>
<tr><td>Pack size and Demand Price</td><td>As per SRO</td></tr>
<tr><td>Approval status of product in Reference Regulatory Authorities</td><td>Tramulief SR 100mg prolonged-release tablets MHRA Approved</td></tr>
<tr><td>Me-too-status</td><td>Zultra SR 100mg M/s Wilshire Laboratories (Reg#80713)</td></tr>
<tr><td>GMP Status</td><td>The firm was inspected on 24.04.2018, conclusion of inspection was:
“Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)”</td></tr>
<tr><td>Remark of the Evaluator [XI]</td><td>• The firm have applied for capsule dosage form and following deficiencies were communicated to the firm:
• The applied formulation is not as per reference formulation. The reference formulation consists of extended release film coated white beads and an immediate release tablet encapsulated in white opaque, size 1, 0 and 00, hard gelatin capsules in following combination.
Tramadol ER Capsule Configuration
<table>
<tr><td>Capsule Strength</td><td>IR-Tablet Strength</td><td>ER-Beads Strength</td></tr>
<tr><td>100 mg</td><td>25 mg</td><td>75 mg</td></tr>
</table>
Revise the formulation as per reference formulation.
• Revise the weight of API in master formulation without considering the salt factor
• Provide evidence of equipments used in manufacturing of applied formulation

Later on the firm replied the change of dosage form Tramofix SR 100mg capsule to Tramofix SR 100mg tabelts along with submission of Rs. 20000/- on deposite slip#1977704 dated 10.03.2020</td></tr>
<tr><td colspan="2">Decision: Deferred for rectification of short comings</td></tr>
<tr><td rowspan="4">1687.</td><td>Name and address of manufacture / Applicant</td><td>M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi</td></tr>
<tr><td>Brand Name + Dosage Form + Strength</td><td>De-Stress Capsule 20mg</td></tr>
<tr><td>Composition</td><td>Each Delayed Release Capsule Contains: Duloxetine HCl (as enteric coated pellets 17.0%) eq to Duloxetine.…20mg
Source: Vision Pharmaceuticals</td></tr>
</table>

	Dairy No. date of R &I fee	Form-5 Dy.No 40733 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CYMBALTA capsules USFDA Approved
	Me-too-status	Dulife 20mg capsules of M/s Evolution Pharmaceuticals (Reg. 091960)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation adjusting the weight of API considering the salt factor. • The firm submitted valid GMP certificate of manufacturer of pellets
	Decision: Approved	
1688.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	De-Stress Capsule 30mg
	Composition	Each Delayed Release Capsule Contains: Duloxetine HCl (as enteric coated pellets 17.0%) eq to Duloxetine…….30mg Source: Vision Pharmaceuticals
	Dairy No. date of R &I fee	Form-5 Dy.No 40732 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CYMBALTA capsules USFDA Approved
	Me-too-status	Dulife 30mg capsules of M/s Evolution Pharmaceuticals (Reg. 091961)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation adjusting the weight of API considering the salt factor. • The firm submitted valid GMP certificate of manufacturer of pellets
	Decision: Approved	
1689.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	De-Stress Capsule 40mg
	Composition	Each Delayed Release Capsule Contains: Duloxetine HCl (as enteric coated pellets 17.0%) eq to Duloxetine.…40mg Source: Vision Pharmaceuticals

	Dairy No. date of R &I fee	Form-5 Dy.No 40734 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Duloxetine 40mg gastro-resistant capsules, MHRA Approved
	Me-too-status	Dulife 40mg capsules of M/s Evolution Pharmaceuticals (Reg. 091962)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation adjusting the weight of API considering the salt factor. • The firm submitted valid GMP certificate of manufacturer of pellets
	Decision: Approved	
1690.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	De-Stress Capsule 60mg
	Composition	Each Delayed Release Capsule Contains: Duloxetine HCl (as enteric coated pellets 17.0%) eq to Duloxetine…..60mg Source: Vision Pharmaceuticals
	Dairy No. date of R &I fee	Form-5 Dy.No 40735 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CYMBALTA capsules USFDA Approved
	Me-too-status	Dulife capsules 60mg capsules of M/s Evolution Pharmaceuticals (Reg. 091963)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation adjusting the weight of API considering the salt factor. • The firm submitted valid GMP certificate of manufacturer of pellets
	Decision: Approved	
1691.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Dirin Capsule 50mg
	Composition	Each Capsule Contains: Diacerein……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40727 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018

	Pharmacological Group	Anti-arthritis, ATC code: M01AX21.
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diacerein Biogaran 50mg Capsule (ANSM, France approved).
	Me-too-status	Sylij 50mg Capsule by Martin Dow Ltd (Reg#82268)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm has claimed USP specifications while the product is not present in available pharmacopoeia (USP, BP, IP, JP). • The firm submitted commitments as per decision of 251st meeting of Registration Board.
	Decision: Approved as per innovator's specifications	
1692.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Telsart Tablet 80mg
	Composition	Each Tablet Contains: Telmisartan……80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41194 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MICARDIS tablets USFDA Approved
	Me-too-status	Telmi 80mg tablets by M/s Crystolite Pharmaceuticals (Reg#082444)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm did not submit undertaking in form 5.
	Decision: Deferred for submission of undertaking at the end of Form 5.	
1693.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Ezomax Tablet 2mg
	Composition	Each film coated Tablet Contains: Eszopiclone……2mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41214 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Benzodiazepine related drugs
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	LUNESTA tablets USFDA approved
	Me-too-status	Suzocil 2mg tablet by M/s Martin Dow Ltd (Reg. 081142)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised form5 correcting the name of molecule in label claim as eszopiclone instead of eszolpiclone
	Decision: Approved	
1694.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Ezomax Tablet 3mg
	Composition	Each film coated Tablet Contains: Eszopiclone…..3mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41213 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Benzodiazepine related drugs
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LUNESTA tablets USFDA approved
	Me-too-status	Suzocil 3mg tablet by M/s Martin Dow Ltd (Reg. 082986)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised form5 correcting the name of molecule in label claim as eszopiclone instead of eszolpiclone
	Decision: Approved	
1695.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Ezomax Tablet 1mg
	Composition	Each film coated Tablet Contains: Eszopiclone……1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41191 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Benzodiazepine related drugs
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LUNESTA tablets USFDA approved
	Me-too-status	Suzocil 1mg tablet by M/s Martin Dow Ltd

		(Reg. 081121)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised form5 correcting the name of molecule in label claim as eszopiclone instead of eszolpiclone
	Decision: Approved	
1696.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Bezo 10mg Tablet
	Composition	Each film coated Tablet Contains: Bisoprolol fumarate…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41198 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Beta-blocking agents, selective
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bisoprolol Fumarate 10mg Film-coated Tablets MHRA approved.
	Me-too-status	Bisolol 10mg tablet By M/s Paramount Pharmaceuticals (Reg. # 079559)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Firm have submitted revised form 5 correcting the label claim as per reference formulation along with submission of Rs. 5000/- on deposit slip # 1977501 date 10.03.2020, duly signed by technical staff
	Decision: Approved	
1697.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Olmax AM 20mg/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…20mg Amlodipine Besylate…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41206 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of form	Form 5
	Finished product specifications	Manufacturer's specification
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 20mg/5mg tablets of (USFDA Approved)
	Me-too-status	Olesta AM 20/5mg of M/s Searle Pakistan (Reg#076187)

	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm didn't revise the label claim considering the salt factor (in case of Amlodipine as Besylate) as per reference formulation along with submission of applicable fee and state that their product claim is as per FDA claim and didn't revise the weight of API in master formulation considering the salt factor. • The firm submitted revised form 5 duly signed by technical staff.
	Decision: Deferred for revision of formulation/correction of label claim considering the salt factor (in case of Amlodipine as Besylate) as per reference formulation along with submission of applicable fee	
1698.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Olmax AM 40mg/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…..40mg Amlodipine besylate……5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41205 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of form	Form 5
	Finished product specifications	Manufacturer's specification
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 40mg/5mg tablets of (USFDA Approved)
	Me-too-status	Olesta AM 40/5mg of M/s Searle Pakistan (Reg#076188)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm didn't revise the label claim considering the salt factor (in case of Amlodipine as Besylate) as per reference formulation along with submission of applicable fee and state that their product claim is as per FDA claim and didn't revise the weight of API in master formulation considering the salt factor.
	Decision: Deferred for revision of formulation/correction of label claim considering the salt factor (in case of Amlodipine as Besylate) as per reference formulation along with submission of applicable fee	
1699.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Olmax AM 20mg/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan medoxomil…..20mg Amlodipine Besylate…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41210 dated 07-12-2018 Rs.20,000/-

		Dated 07-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of form	Form 5
	Finished product specifications	Manufacturer's specification
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 20mg/10mg tablets of (USFDA Approved)
	Me-too-status	Olesta AM 20/10mg by M/s Searle Pakistan (Reg#076189)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm didn't revise the label claim considering the salt factor (in case of Amlodipine as Besylate) as per reference formulation along with submission of applicable fee and state that their product claim is as per FDA claim and didn't revise the weight of API in master formulation considering the salt factor.
	Decision: Deferred for revision of formulation/correction of label claim considering the salt factor (in case of Amlodipine as Besylate) as per reference formulation along with submission of applicable fee	
1700.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Zolmax Tablet 2.5mg
	Composition	Each film coated Tablet Contains: Zolmitriptan……2.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41184 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Selective serotonin (5HT1) agonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zolmitriptan 2.5 mg tablets MHRA Approved
	Me-too-status	Zolmiton 2.5mg tablets of M/s CKD Pharmaceuticals (Reg#081785)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 duly signed by technical staff.
	Decision: Approved	
1701.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Levit 1gm Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam.…1000mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40743 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018

	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA tablets USFDA Approved
	Me-too-status	Speppra 1000mg tablets by Spencer & Company (Reg. 092780)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted commitments as per decision of 251st meeting of Registration Board.
	Decision: Approved	
1702.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Lamotrin 50mg Tablet
	Composition	Each Tablet Contains: Lamotrigine .…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41204 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LAMICTAL 50mg Tablets (USFDA approved) Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Epictal 50mg Tablet of M/s Pakistan Pharmaceuticals (Reg#089242)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 duly signed by technical persons.
	Decision: Approved	
1703.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Metlis oral solution 5mg/5ml
	Composition	Each ml contains: Metoclopramide HCl……1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41186 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Propulsives
	Type of form	Form 5
	Finished product specifications	USP (oral solution)

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metoclopramide hydrochloride 5mg/5ml oral solution MHRA Approved
	Me-too-status	Briclop syrup 5mg/5ml by M/s British Pharmaceuticals (Reg#094669)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised complete form 5 (1st page was missing).
	Decision: Approved	
1704.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Loxen 60mg Tablet
	Composition	Each Tablet Contains: Loxoprofen Sodium as hydrate.....60mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41188 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti-inflammatory
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA (uncoated)
	Me-too-status	Loxofen 60mg tablets by M/s Hicon Pharmaceuticals (Reg#092502)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised master formulation adjusting the weight of API considering the hydrated form. Moreover revised form 5 duly signed by technical persons was also submitted.
	Decision: Approved with JP specifications	
1705.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Ease SR 30mg Capsule
	Composition	Each Capsule contains: Cyclobenzaprine HCl (extended release pellets 22%)……30mg Source of Pellets: Vision Pharma
	Dairy No. date of R &I fee	Form-5 Dy.No 41185 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Skeletal Muscle relaxant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	AMRIX 30mg extended release capsule of USFDA approved
	Me-too-status	Cyclorest ER 30mg capsules of M/s Martin Dow (Reg. 080638)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted valid GMP certificate of manufacturer of pellets, Certificate of Analysis and stability study data of 3 batches of pellets. Moreover the firm also submitted master formulation
	Decision: Approved	
1706.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Ease 10mg Tablet
	Composition	Each film coated tablet contains: Cyclobenzaprine HCl.…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41187 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Skeletal Muscle relaxant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FLEXERIL 10mg tablets USFDA Approved Discontinued "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons"
	Me-too-status	Cybem 10mg tablets by M/s Sami Pharmaceuticals (Reg#085595)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 duly signed by technical persons.
	Decision: Approved	
1707.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	K-Plus 10mEq Tablet
	Composition	Each extended release tablet contains: Potassium citrate ……10mEq (1080mg)
	Dairy No. date of R &I fee	Form-5 Dy.No 41182 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Urinary Alkalinizing agent
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference	Urocit-K Extended-release tablets USFDA Approved

	Regulatory Authorities	
	Me-too-status	Exocite XR 10mEq tablets by M/s Vision Pharmaceuticals (Reg#080827)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm have submitted revised master formulation adjusting the weight of API considering the salt factor.
	Decision: Approved	
1708.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Admire 250mg/5ml Oral Solution
	Composition	Each 5ml contains: Sodium valproate eq to valproic acid …250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41193 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti-convulsant.
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	APO-VALPROIC (valproic acid) oral solution (250mg/5mL) Health Canada Approved
	Me-too-status	Valpromed 250mg/5ml syrup Medicraft Pharmaceuticals (Reg. 095166)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1709.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	IBU-Profen 800mg SR Tablet
	Composition	Each film coated sustained release tablet contains: Ibuprofen……800mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41196 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Analgesic & Antipyretic
	Type of form	Form 5
	Finished product specifications	BP (Prolonged release tablets)
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Brufen Retard 800mg tablet (Approved in MHRA as sustained-release tablet)
	Me-too-status	Brufen Retard 800mg tablet by M/s Abbott (Reg#018388) as provided by the firm could not be confirmed in the applied strength
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory

		level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm could not be verified
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
1710.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form and Strength	Pediamax Liquid oral solution
	Composition	Each 500ml contains: Sodium Chloride.....1.75mg Trisodium Citrate Dihydrate.....1.45gm Potassium Chloride.....0.75mg Glucose Anhydrous.....10.0gm
	Dairy No. date of R &I fee	Form-5 Dy.No 41215 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Oral Rehydration salt
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO standard ORS formulation could not be verified
	Me-too-status	Pedialife of M/s. Scotmann Pharmaceuticals (Reg#43740)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting could not be verified • Firm submitted list of QC equipments indicating autoclave and inform that they will perform terminal sterilization. • Firm has claimed USP specifications while the official monograph is not available in any pharmacopeias (USP, BP, JP, IP).
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting	
1711.	Name and address of manufacture / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Ketofen 100mg Tablet
	Composition	Each enteric coated Tablet Contains: Ketoprofen……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40741 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Propionic acid derivatives ATC Code; M01AE
	Type of form	Form 5
	Finished product specifications	Manufacturer's Specification

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KETOPROFEN-E enteric-coated tablets (50mg, 100mg) Health Canada Approved
	Me-too-status	Protifen 100mg EC Tablets by M/s Gray's Pharmaceutical (Reg#34486)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remark of the Evaluator [XI]	• The firm has provided evidence for the applied product in health Canada.
	Decision: Approved as per innovator's specifications	
1712.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Mczip 30mg Tablets
	Composition	Each Film Coated Tablet Contains: Mirtazapine…..30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41493 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Remeron film-coated 30mg tablet. USFDA approved
	Me-too-status	Remirta 30mg Tablet by M/s Aries Pharmaceuticals (Reg# 82606)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1713.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form+ Strength	Mczip 15mg Tablets
	Composition	Each Film Coated Tablet Contains: Mirtazapine.…15mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41694 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Other antidepressants
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Remeron film-coated 15mg tablet. USFDA approved
	Me-too-status	Remirta 15mg Tablet by M/s Aries Pharmaceuticals (Reg# 82605)

	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1714.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Quepson 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine (as Fumarate)..…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41669 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antipsychotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 200mg) MHRA Approved.
	Me-too-status	Qusel Tablet 25mg by M/s Hilton pharma, (Reg No. 37684)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1715.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Quepson 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine (as Fumarate)..…200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41671 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antipsychotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 200mg) MHRA Approved.
	Me-too-status	Qusel Tablet 200mg by M/s Hilton pharma, (Reg No. 37690)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring

		following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1716.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Quepson 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine (as Fumarate)..…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41670 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antipsychotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 200mg) MHRA Approved.
	Me-too-status	Qusel Tablet 100mg by M/s Hilton pharma, (Reg No. 37685)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1717.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Racitam 750mg Tablet
	Composition	Each film coated tablet contains: Levetiracetam…..750mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41657 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA tablets USFDA Approved
	Me-too-status	Lepsira 750mg tablets by Scilife Pharma (Reg. 100439)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas.

		Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1718.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Mcept 10m Tablets
	Composition	Each Film Coated Tablet Contains: Rivaroxaban.....10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41696 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antithrombotic Agents
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto film-coated tablets (2.5mg, 10mg, 15mg, 20mg) by USFDA Approved.
	Me-too-status	Roxaban 10mg Tablet by M/s Genetics Pharmaceuticals (Reg# 85163)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1719.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form + Strength	Mcept 20m Tablets
	Composition	Each Film Coated Tablet Contains: Rivaroxaban.....20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41695 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antithrombotic Agents
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto film-coated tablets (2.5mg, 10mg, 15mg, 20mg) by USFDA Approved.
	Me-too-status	Roxaban 20mg Tablet by M/s Genetics Pharmaceuticals (Reg# 85164)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per

		cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1720.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Mcept 15mg Tablets
	Composition	Each Film Coated Tablet Contains: Rivaroxaban.....15mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41697 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antithrombotic Agents
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto film-coated tablets (2.5mg, 10mg, 15mg, 20mg) by USFDA Approved.
	Me-too-status	Roxaban 15mg Tablet by M/s Genetics Pharmaceuticals (Reg# 85165)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1721.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form + Strength	Isperison 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone…..1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41662 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antipsychotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperidone 1mg Film-Coated Tablets MHRA approved
	Me-too-status	Neo-Risp Tablet 1mg by Wilshire laboratories, (Reg#85184)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections.

		However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1722.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Isperison 2mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone…..2mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41650 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antipsychotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperidone 2mg film coated tablets MHRA Approved
	Me-too-status	Neo-Risp Tablet 2mg by Wilshire laboratories, (Reg#85185)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1723.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Tercofine 250mg Tablets
	Composition	Each Tablet Contains: Terbinafine (as HCl)..…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41673 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antifungals for systemic use
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 250mg tablets MHRA Approved
	Me-too-status	Fibet Tablet 250mg by M/s Bio-Mark Pharmaceuticals (Reg#85717)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation

		system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1724.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Famoson 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Famotidine…..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41690 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	H2-receptor antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Famotidine 40mg Film Coated Tablets MHRA Approved
	Me-too-status	Famitol 40mg film-coated Tablet by Wimits Pharmaceuticals, (Reg#85770)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1725.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Famoson 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Famotidine…..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41689 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	H2-receptor antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Famotidine 20mg Film Coated Tablets MHRA Approved
	Me-too-status	Welcid-20mg film-coated Tablet by M/s Well & Well Pharma (Reg# 81681)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and

		manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1726.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Klarimac 250mg Tablets
	Composition	Each Film Coated Tablet Contains: Clarithromycin.…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41647 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Macrolides
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 250mg film-coated tablets MHRA Approved
	Me-too-status	Clarital 250mg Tablet by M/s Arsons Pharmaceuticals (Reg#85501)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1727.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Klarimac 500mg Tablets
	Composition	Each Film Coated Tablet Contains: Clarithromycin…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41648 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Macrolides
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 500mg film-coated tablets MHRA Approved
	Me-too-status	Clarital 500mg Tablet by M/s Arsons Pharmaceuticals (Reg#85500)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."

	Remark of the Evaluator [XI]	•
	Decision: Approved	
1728.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form+ Strength	Ranomac 500mg XR Tablets
	Composition	Each film coated extended release tablet contains: Ranolazine.…500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41649 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti-ischemic and anti-anginal
	Type of form	Form 5
	Finished product specifications	Innovator Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	RANEXA extended-release tablets USFDA Approved
	Me-too-status	Angiwell-XR 500mg Tablet by OBS Pharma (Reg#83190)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1729.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form+ Strength	Levocet 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Levocetirizine dihydrochloride…..5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41688 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Piperazine derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	XYZAL 5mg film coated tablet USFDA Approved
	Me-too-status	Norzin 5mg film coated tablets by M/s Nortech Pharmaceuticals (Reg# 77965)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1730.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Tramcol Tablets 37.5/325mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl..…37.5mg Paracetamol…..325mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41675 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol hydrochloride/Paracetamol 37.5mg/325mg Film-coated Tablets MHRA Approved
	Me-too-status	Distalgesic Tablets by M/s Atco Lab., (Reg#73865)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1731.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Desloson 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Desloratadine…..5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41680 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antihistamine
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarinex 5mg film coated tablet USFDA Approved.
	Me-too-status	Desatil Tablets 5mg by Aries Pharma (Reg#84270)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1732.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Amval 5/160 mg Tablets
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)..…5mg Valsartan…..160mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41665 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/160mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/160 of M/s Jupiter Pharma (Reg.#081932)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1733.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Amval 10/160 mg Tablets
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)..…10mg Valsartan…..160mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41664 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 10mg/160mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 10/160 of M/s Jupiter Pharma (Reg.#081933)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and

		manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1734.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Amval 5/80 mg Tablets
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)..…5mg Valsartan…..80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41663 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/80mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/80 of M/s Jupiter Pharma (Reg.#081931)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1735.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Mecet 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Cetirizine hydrochloride…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41687 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Piperazine derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cetirizine Hydrochloride 10mg film coated tablet (MHRA approved)
	Me-too-status	Cetrovil 10mg Tablets by M/s Drugpharm (Reg# 36250)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and

		manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 with signatures of technical staff on undertaking.
	Decision: Approved	
1736.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Opimate 100mg Tablets
	Composition	Each Film Coated Tablet Contains: Topiramate.…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41686 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Aristo 100mg tablets MHRA Approved
	Me-too-status	Neutop 100mg tablets by M/s Nabiqasim Industries (Reg#089056)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 with signatures of technical staff on undertaking.
	Decision: Approved	
1737.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Opimate 50mg Tablets
	Composition	Each Film Coated Tablet Contains: Topiramate…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41685 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Teva 50mg film-coated tablets MHRA Approved
	Me-too-status	Neutop 50mg tablets by M/s Nabiqasim Industries (Reg#076388)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation

		system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm submitted correct master formulation of the applied product. Previously master formulation of some other product was submitted. • The firm submitted revised form 5 with signatures of technical staff on undertaking.
	Decision: Approved	
1738.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Opimate 25mg Tablets
	Composition	Each Film Coated Tablet Contains: Topiramate.…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41668 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Aristo 25mg film-coated tablets MHRA Approved
	Me-too-status	Neutop 25mg tablets by M/s Nabiqasim Industries (Reg#076387)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 with signatures of technical staff on undertaking.
	Decision: Approved	
1739.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form + Strength	Tercofine 125mg Tablets
	Composition	Each Tablet Contains: Terbinafine (as HCl).…125mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41672 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antifungals for systemic use
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 125mg tablets MHRA Approved
	Me-too-status	Fibet Tablet 125mg by M/s Bio-Mark Pharmaceuticals (Reg#85716)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per

		cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 with signatures of technical staff on undertaking.
	Decision: Approved	
1740.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Misoson 200mcg Tablets
	Composition	Each Tablet Contains: Misoprostol (as 1% dispersion with HPMC)…..200mcg
	Dairy No. date of R &I fee	Form-5 Dy.No 41682 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Prostaglandin
	Type of form	Form 5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec tablets (USFDA Approved)
	Me-too-status	Prosotec 200mcg Tablet by Atco Laboratories Limited (Reg#58356)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 with signatures of technical staff on undertaking. • The firm has claimed manufacturer's specifications and the product is present in International pharmacopoeia • Misoprostol is used as 1% dispersion which is an intermediate and not the active substance. Do we need additional documents, source fixation and fee? • Approved with boxed warning of ―misoprostol administration to women who are pregnant can cause birth defects, abortion, premature birth or uterine rupture.
	Decision: Approved as per International Pharmacopeia specifications.	
1741.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form+ Strength	Vastacol 20mg Tablets
	Composition	Each Film Coated Tablet Contains: Atorvastatin (as calcium trihydrate) ……20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41679 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of form	Form 5
	Finished product specifications	USP

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LIPITOR tablets USFDA Approved
	Me-too-status	Atorviz 20mg tablets by Tabros Pharma (Reg#098541)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm has submitted revised form 5, revised the label claim mentioning the hydrated form of API. Moreover the firm has submitted revised master formulation adjusting the weight of API considering the hydrated form. • The firm submitted revised form 5 with signatures of technical staff on undertaking.
	Decision: Approved	
1742.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form+ Strength	Vastacol 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Atorvastatin (as calcium trihydrate).….10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41678 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LIPITOR tablets USFDA Approved
	Me-too-status	Atorviz 10mg tablets by Tabros Pharma (Reg#098542)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm has submitted revised form 5, revised the label claim mentioning the hydrated form of API. Moreover the firm has submitted revised master formulation adjusting the weight of API considering the hydrated form.
	Decision: Approved	
1743.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Mcolnate 70mg Tablets
	Composition	Each Tablet Contains:

		Alendronate (as Sodium Trihydrate)…..70mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41677 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Bisphosphonate, for the treatment of bone diseases
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FOSAMAX tablets USFDA Approved
	Me-too-status	Alidium 70mg Tablets by M/s Panacea Pharmaceuticals (Reg. # 81428)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with revise label claim from film coated tablets to uncoated tablets along with submission of Rs. 5000/- on deposite slip #1941458 dated 19.03.2020
	Decision: Approved	
1744.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Roxison 125mg Dry Powder Suspension
	Composition	Each 5mL after reconstitution contains: Cefuroxime (as axetil)…… 125mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41681 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Cephalosporin Antibiotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zinnat 125mg/5mL granules for oral Suspension (MHRA approved)
	Me-too-status	Vegarox 125mg Dry Powder Suspension By M/S Vega Pharmaceuticals (Reg#78767)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 revising the label claim as "Each 5mL after reconstitution contains cefuroxime as axetil equal to 125mg along with submission of Rs. 5000/- on deposit slip#1941459 dated 19.03.2020

		• The firm has applied for powder for suspension while the reference formulation contains granules for oral suspension. Upon clarification the firm replied that will use granular sugar instead of powder sugar.
	Decision: Approved	
1745.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	M-Tarel 20mg Tablets
	Composition	Each Film Coated Tablet Contains: Trimetazidine dihydrochloride.…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41667 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- angina
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	RIMETAZE 20mg film-coated tablet (ANSM approved)
	Me-too-status	Metab 20mg Tablet By Nabi-Qasim (Reg. # 081039)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with revised label claim as "Each film Coated Tablet Contains: Trimetazidine dihydrochloride…..20mg" considering the salt factor along with submission of Rs. 5000/- on deposit slip#1941456 dated 19.03.2020. Moreover the firm also submitted revised master formulation adjusting the weight of API considering the salt factor. • Firm submitted revised form 5 along with undertaking duly signed by the technical staff.
	Decision: Approved with JP specifications	
1746.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	M-Tarel 35mg XR Tablets
	Composition	Each modified release film Coated Tablet Contains: Trimetazidine dihydrochloride…..35mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41666 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- angina
	Type of form	Form 5
	Finished product specifications	Innovators specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRANETIZ 35mg, modified release film-coated tablet (ANSM approved)
	Me-too-status	Trikat MR 35mg tablet of Next Pharma (Reg.# 084467)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is

		properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• Firm has submitted revised form 5 with revised label claim as "Each modified release film Coated Tablet Contains: Trimetazidine dihydrochloride…..35mg" considering the salt factor along with submission of Rs. 5000/- on deposit slip#1941457 dated 19.03.2020. Moreover the firm also submitted revised master formulation adjusting the weight of API considering the salt factor. • Firm submitted revised form 5 along with undertaking duly signed by the technical staff.
	Decision: Approved as per innovator's specifications	
1747.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Dicloson SR 100mg Tablets
	Composition	Each film coated sustained release tablet contains: Diclofenac sodium.…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 41674 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VOLTAREN-XR 100mg tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Sintral SR Tablets 100mg by M/s Neomedix Pharmaceuticals (Reg# 81413)
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1748.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form + Strength	Mctans 12.5/50/200mg Tablets
	Composition	Each Film Coated Tablet Contains: Carbidopa (as Monohydrate).…12.5mg Levodopa.…50mg Entacapone…..200mg
	Dairy No. date of R &I fee	Dy.No 41660 dated 07-12-2018 Rs.50,000/- Dated 07-

		12-2018
	Pharmacological Group	Anti-parkinson's, Dopa and dopa derivatives
	Type of form	Form-5D
	Finished product specifications	Innovator specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	STALEVO 50 tablets USFDA Approved
	Me-too-status	
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm has applied on Form 5-D. Stability study data was asked and the firm informed that stability study is under process and data will be submitted after completion of study.
	Decision: Deferred for confirmation of generic status of the product	
1749.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Mctans 25/100/200mg Tablets
	Composition	Each Film Coated Tablet Contains: Carbidopa (as Monohydrate)..…25mg Levodopa…..100mg Entacapone…..200mg
	Dairy No. date of R &I fee	Dy.No 41661 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Anti-parkinson's, Dopa and dopa derivatives
	Type of form	Form-5D
	Finished product specifications	Innovator specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	STALEVO 100 tablets USFDA Approved
	Me-too-status	
	GMP Status	"Last GMP inspection report dated 15-02-2018 declaring following "General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remark of the Evaluator [XI]	• The firm has applied on Form 5-D. Stability study data was asked and the firm informed that stability study is under process and data will be submitted after completion of study.
	Decision: Deferred for confirmation of generic status of the product	

1750.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura *Contract Manufactured by:* M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan
	Brand Name + Dosage Form and Strength	Katoromac 30mg Injection IV/IM
	Composition	Each ml contains: Ketorolac Trometamol……30mg
	Dairy No. date of R &I fee	Dy.No 41770 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketorolac Trometamol 30mg/ml solution for injection MHRA Approved
	Me-too-status	Syntor 30 mg Injection IV/IM by Synchro Pharma (Reg#83365)
	GMP Status	GMP certificate issued on 14.09.2018
	Remark of the Evaluator [XI]	• Firm has submitted SOP for performing terminal sterilization of Katoromac 30mg Injection • The firm submitted list of 05 approved sections of applicant (Mcolson Research Laboratories) • The firm submitted list of 08 approved products for contract manufacturing • The firm submitted list of 19 applied products for contract manufacturing • General Liquid Ampoule injection section is available in the firm as mentioned in the letter No. F. 1-35/2007-Lic (Vol-I) dated 14th June, 2017.
	Decision: Approved	
1751.	Name and address of manufacture / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura *Contract Manufactured by:* M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan
	Brand Name + Dosage Form and Strength	Mac- D 5mg Injection Oral/IM
	Composition	Each ml contains: Cholecalciferol…..5mg (200,000IU)
	Dairy No. date of R &I fee	Dy.No 41769 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Vitamin D3 analogue
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU/1ml oral solution in ampoule (ANSM France approved) Vitamin D3 Good 200,000 IU/1ml IM solution for injection (ANSM France approved)
	Me-too-status	D-Rick Injection by Caliph Pharmaceuticals (Pvt.) Ltd, (Reg#82563)
	GMP Status	GMP certificate issued on 14.09.2018
	Remark of the Evaluator [XI]	• General Liquid Ampoule injection section is available in the firm as mentioned in the letter No. F. 1-35/2007-

		Lic (Vol-I) dated 14th June, 2017. • The manufacturer has claimed BP specifications while monograph for applied product is not available in any pharmacopeia (USP, BP, IP, JP). • The firm submitted list of 05 approved sections of applicant (Mcolson Research Laboratories) • The firm submitted list of 08 approved products for contract manufacturing • The firm submitted list of 19 applied products for contract manufacturing • Firm has submitted SOP for performing sterilization of Mac-D Injection and informed that; • The filling of Mac-D injection is carried out in aseptic area • The sterilization of Mac-D injection is carried out through filtration by using (0.22 Micron) filters • The terminal sterilization of Mac-D injection is not carried out due to following reason; • It is oil base injection therefore terminal sterilization is not carried out. • Vitamin D3 is heat sensitive material therefore is not terminally sterilized by autoclave
	Decision: Approved as per innovator's specifications	
1752.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Side 200mg Tablet
	Composition	Each Tablet Contains: Amisulpride…..200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4111 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amisulpride 200mg Tablets (MHRA Approved)
	Me-too-status	Amiride Tablet 200mg by M/s Shrooq Pharmaceuticals (Pvt) Ltd (Reg#063102)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted the 1st page of form 5 duly signed by the signatory.
	Decision: Deferred for signatures as per requirement.	
1753.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Atrachol 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin (as calcium trihydrate)..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4142 dated 30-01-2019 Rs.20,000/-

		Dated 29-01-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LIPITOR 10mg tablets USFDA Approved
	Me-too-status	Atorviz 10mg tablets by Tabros Pharma (Reg#098542)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• Firm has applied with manufacturer specifications but official monograph is available in USP.
	Decision: Approved with USP specifications	
1754.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Atrachol 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin (as calcium trihydrate)…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4143 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LIPITOR 20mg tablets USFDA Approved
	Me-too-status	Atorviz 20mg tablets by Tabros Pharma (Reg#098541)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• Firm has applied with manufacturer specifications but official monograph is available in USP.
	Decision: Approved with USP specifications	
1755.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Bisprol 2.5mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…..2.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4136 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bisoprolol Fumarate 2.5mg Tablets MHRA Approved
	Me-too-status	Abcor 2.5mg Tablet BY M/s Asian Continental (Reg#83924)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1756.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Bisprol 10mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4138 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bisoprolol Fumarate 10mg Tablets MHRA Approved
	Me-too-status	Abcor 10mg Tablet by M/s Asian Continental (Reg#83926)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1757.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Bisprol 5mg Tablet
	Composition	Each Tablet Contains: Bisoprolol Fumarate…..5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4137 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bisoprolol Fumarate 5mg Tablets MHRA Approved
	Me-too-status	Abcor 5mg Tablet by M/s Asian Continental (Reg#83925)

	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm provided the evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Approved	
1758.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Cavid 6.25mg Tablets
	Composition	Each Film Coated Tablet Contains: Carvedilol……6.25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4104 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COREG 6.25 mg film-coated tablet USFDA Approved
	Me-too-status	Hidilol 6.25mg Tablets by M/s Helix Pharma (Reg#53014)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.
	Decision: Deferred for signatures as per requirement.	
1759.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Cavid 3.125mg Tablets
	Composition	Each Film Coated Tablet Contains: Carvedilol……3.125mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4103 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COREG 3.125mg film-coated tablet USFDA Approved
	Me-too-status	Carlov 3.125mg Tablet by M/s Hilton Pharma (Reg#36423)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of

		DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.
	Decision: Deferred for signatures as per requirement.	
1760.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Cavid 12.5mg Tablets
	Composition	Each Film Coated Tablet Contains: Carvedilol…..12.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4105 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COREG 12.5mg film-coated tablet USFDA Approved
	Me-too-status	Hidilol 12.5mg Tablets by M/s Helix Pharma (Reg#50365)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.
	Decision: Deferred for signatures as per requirement.	
1761.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Thymin 20mg Tablets
	Composition	Each Film Coated Tablet Contains: Escitalopram (as Oxalate)…..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4133 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lexapro 20mg film-coated tablets USFDA Approved
	Me-too-status	Belexa 20mg Tablet by M/s Lisko Pakistan (Reg#82144)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way

		of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1762.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Laget 200mg Capsule
	Composition	Each Capsule Contains: Fenofibrate…..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4134 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Lipid Modifying Agents (Fibrates)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fenofibrate 200 mg Capsules MHRA Approved
	Me-too-status	Lipogin Capsule 200mg by M/s Himont Pharmaceuticals (Reg# 80904)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1763.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Laget 67mg Capsule
	Composition	Each Capsule Contains: Fenofibrate…..67mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4135 (30-1-2019) Rs.20,000/- 29-1-2019
	Pharmacological Group	Lipid Modifying Agents (Fibrates)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fenofibrate 67 mg Capsules MHRA Approved
	Me-too-status	Corfibrate 67mg Capsule by M/s OBS (Reg#73645)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1764.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Diryl M 1/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Glimepiride…..1mg Metformin HCl…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4121 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drug
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amaryl M as provided by the firm but could not be confirmed
	Me-too-status	Diabold Plus tablet of M/s Barrett Hodgson (Reg. # 076011)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm provided evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting which could not be verified. • The firm submitted 1st page of Form 5 duly signed by the signatory. • Firm have applied for innovator's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1765.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Diryl M 2/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Glimepiride…..2mg Metformin HCl…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4122 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drug
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amaryl M as provided by the firm but could not be confirmed
	Me-too-status	Diabold Plus tablet of M/s Barrett Hodgson (Reg. # 076012)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends

		grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm provided evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting which could not be verified. • The firm submitted 1st page of Form 5 duly signed by the signatory. • Firm have applied for innovator's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting	
1766.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Aptisant 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride HCl…150mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4102 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Propulsives
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton 150mg tablet as provided by the firm but could not be confirmed
	Me-too-status	ITP 150mg Tablet by M/s Sami Pharmaceuticals (Reg#75852)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • The firm provided evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting which could not be verified. • Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting	
1767.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Metfin 500mg Tablets
	Composition	Each Film Coated Tablet Contains:

		Metformin HCl…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4120 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Biguanide (Antidiabetic)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metformin 500mg film coatedTablets MHRA Approved
	Me-too-status	Glucomin 500mg Tablet by M/s Lisko Pakistan (Reg#82146)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.
	Decision: Deferred for signatures as per requirement.	
1768.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Miragon 50mg ER Tablets
	Composition	Each film coated extended release tablet contains: Mirabegron…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4119 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Urinary Anti- spasmodics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ extended-release tablets USFDA Approved
	Me-too-status	Mirabet 50mg tablets of CCL Pharma (Reg#090503)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • The applied formulation needs submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version. • Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Deferred for submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting	

1769.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Miragon 25mg ER Tablets
	Composition	Each film coated extended release tablet contains: Mirabegron…..25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4118 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Urinary Anti- spasmodics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MYRBETRIQ extended-release tablets USFDA Approved
	Me-too-status	Mirabet 25mg tablets of CCL Pharma (Reg#090378)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • The applied formulation needs submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version. • Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Deferred for submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting	
1770.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Nandil 10mg Tablet
	Composition	Each Tablet Contains: Nicorandil…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4123 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	IKOREL Nicorandil 10mg tablet un-coated. TGA approved
	Me-too-status	Nicogina 10mg Tablet by M/s Macter International (Reg. No. 67049)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section

		b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1771.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Nandil 20mg Tablet
	Composition	Each Tablet Contains: Nicorandil.…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4124 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	IKOREL Nicorandil 20mg un-coated tablet. TGA approved
	Me-too-status	Nicogina 20mg Tablet by M/s Macter International (Reg. No. 67050)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1772.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Odine 35/450mg Tablets
	Composition	Each tablet contains Orphenadrine Citrate…..35mg Paracetamol……450mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4106 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Muscle relaxant / Antipyretic& Analgesic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Norgesic tablet (uncoated) 35mg/450mg TGA Approved
	Me-too-status	Nuberol 35/450mg Tablet by M/s Searle Pakistan (Reg. # 020373)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory.

		• Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Deferred for signatures as per requirement.	
1773.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Lagab Capsules 50mg
	Composition	Each Capsule Contains: Pregabalin…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4107 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica 50mg capsules USFDA approved
	Me-too-status	Gabica 50mg Capsule by M/s Getz Pharma (Reg#48725)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Deferred for signatures as per requirement.	
1774.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Lagab Capsules 100mg
	Composition	Each Capsule Contains: Pregabalin…..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4109 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA 100mg Capsules USFDA Approved
	Me-too-status	Gabica 100mg Capsule by M/s Getz Pharma (Reg#47366)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section

	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Deferred for signatures as per requirement.	
1775.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Lagab Capsules 75mg
	Composition	Each Capsule Contains: Pregabalin…..75mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4108 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other antiepileptics
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LYRICA 75mg Capsules USFDA Approved
	Me-too-status	Gabica 75mg Capsule by M/s Getz Pharma (Reg#47365)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • Firm have applied for manufacturer's specifications and and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Deferred for signatures as per requirement.	
1776.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Risperin 1mg Tablets
	Composition	Each Film Coated Tablet Contains: Risperidone…..1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4139 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other antipsychotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperidone 1mg Film-Coated Tablets MHRA approved
	Me-too-status	Neo-Risp Tablet 1mg by Wilshire laboratories, (Reg#85184)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan

		Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1777.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Risperin 2mg Tablets
	Composition	Each Film Coated Tablet Contains: Risperidone.….2mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4140 (30-1-2019) Rs.20,000/- 29-1-2019
	Pharmacological Group	Other antipsychotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 2mg film coated tablet MHRA approved
	Me-too-status	Neo-Risp Tablet 2mg by M/s Wilshire laboratories, (Reg#85185)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1778.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Risperin 3mg Tablets
	Composition	Each Film Coated Tablet Contains: Risperidone.….3mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4141 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other antipsychotics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 3mg film coated tablet MHRA approved
	Me-too-status	Neo-Risp Tablet 3mg by M/s Wilshire laboratories, (Reg#85186)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1779.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Tamsin 0.4mg Capsule
	Composition	Each modified release Capsule Contains: Tamsulosin HCl (as SR pellets 0.2%)……0.4mg (Source of Pellets: Vision Pharma)
	Dairy No. date of R &I fee	Form-5 Dy.No 4115 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tamurex 400 micrograms prolonged-release capsules (MHRA approved)
	Me-too-status	Timsol 0.4 mg Capsule by M/s Scilife Pharma (Reg#82094)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • The firm submitted GMP Certificate of supplier of pellets (Vision Pharma) which expired on 25.01.2019
	Decision: Deferred for signatures as per requirement and GMP Certificate of supplier of pellets (Vision Pharma).	
1780.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Toprex 25mg Tablets
	Composition	Each Film Coated Tablet Contains: Topiramate…..25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4418 dated 31-01-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Cadila 25mg Film-coated tablets MHRA Approved
	Me-too-status	Neutop 25mg tablets by M/s Nabiqasim Industries (Reg#076387)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1781.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Toprex 50mg Tablets
	Composition	Each Film Coated Tablet Contains: Topiramate…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4419 dated 31-01-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Teva 50mg film coated tablets MHRA Approved
	Me-too-status	Neutop 50mg tablets by M/s Nabiqasim Industries (Reg#076388)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1782.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Valtan 160mg Tablets
	Composition	Each Film Coated Tablet Contains: Valsartan…..160mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4126 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Valsartan 160mg Film-coated Tablets (MHRA Approved)
	Me-too-status	Valseta 160mg Tablet by Maple Pharma (Reg#83348)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved.	
1783.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Valtan 80mg Tablets
	Composition	Each Film Coated Tablet Contains: Valsartan…..80mg

	Dairy No. date of R &I fee	Form-5 Dy.No 4125 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Valsartan 80mg Film-coated Tablets (MHRA Approved)
	Me-too-status	Valseta 80mg Tablet by Maple Pharma (Reg#83347)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1784.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Valtan-M165 Tablet 160/5mg
	Composition	Each Film Coated Tablet Contains: Valsartan…..160mg Amlodipine (as besylate)…..5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4128 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/160mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/160 of M/s Jupiter Pharma (Reg.#081932)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1785.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Valtan-M 170 Tablet 160/10mg
	Composition	Each Film Coated Tablet Contains: Valsartan..…160mg Amlodipine (as besylate)..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4129 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and Calcium

		channel blockers
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 10mg/160mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 10/160 of M/s Jupiter Pharma (Reg.#081933)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommend grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section a) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1786.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Valtan-M 85 Tablet 80/5mg
	Composition	Each Film Coated Tablet Contains: Valsartan.…80mg Amlodipine (as besylate).…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4127 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and Calcium channel blockers
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/80mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/80 of M/s Jupiter Pharma (Reg.#081931)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommend grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. b) Tablet (General) Section a) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1787.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Valtan plus Tablet 160/25mg
	Composition	Each Film Coated Tablet Contains: Valsartan…..160mg Hydrochlorothiazide.…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4132 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of form	Form 5

	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Valsartan and Hydrochlorothiazide 160 mg/25 mg film-coated tablets MHRA Approved.
	Me-too-status	Cova-H 160mg/25mg Tablet by M/s Getz Pharma (Reg# 83312)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1788.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Valtan-M 170 plus Tablet 160/10/12.5mg
	Composition	Each Film Coated Tablet Contains: Valsartan…..160mg Amlodipine (as besylate) …..10mg Hydrochlorothiazide …..12.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4129 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	EXFORGE HCT 10/160/12.5mg Tablets US-FDA approved
	Me-too-status	Exforge HCT 10/160/12.5mg film coated tablets by Novartis Pharma (Reg#69550)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1789.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Valtan-M165 plus Tablet 160/5/12.5mg
	Composition	Each Film Coated Tablet Contains: Valsartan…..160mg Amlodipine (as besylate) ..…5mg Hydrochlorothiazide …..12.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4128 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations

	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	EXFORGE HCT 5/160/12.5mg Tablets US-FDA approved
	Me-too-status	Exforge HCT film- coated tablets 5/160/12.5mg by M/s Novartis Pharma (Reg#069548)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1790.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Lazinc 20mg Dispersible Tablet
	Composition	Each Dispersible Tablet contains: Zinc sulphate Monohydrate eq to elemental zinc…..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4112 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Other Mineral Supplements ATC Code; A12C
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified Zincfant Tablet 20 mg manufactured by Laboratories Pharmaceutique s Rodael –France
	Me-too-status	Tablet Zink 20 mg by M/s Well & Well (Pvt.) Ltd (Reg. No. 80390)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • The manufacturer have claimed USP specifications while monograph for dispersible tablets are not available in any pharmacopeia (USP, BP, IP, JP).
	Decision: Approved as per innovator's specifications	
1791.	Name and address of manufacture / Applicant	M/s Aptcure Pvt Ltd; 8- Pharma City, 30 km Multan Road, Lahore
	Brand Name + Dosage Form and Strength	Zip 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Zolmitriptan.…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4101 dated 30-01-2019 Rs.20,000/- Dated 29-01-2019
	Pharmacological Group	Selective serotonin (5HT1) agonists

	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zolmitriptan 5mg film coated tablets MHRA Approved
	Me-too-status	Zolmiton 5mg tablets of M/s CKD Pharmaceuticals (Reg#081786)
	GMP Status	The firm was inspected on 24-11-2017 for renewal of DML and conclusion of inspection was: In the light of inspection conducted by panel and based on the findings, the panel of inspectors recommends grant of renewal of drug manufacturing license by way of formulation of M/s Aptcure (Pvt) Ltd., 30km Multan Road Lahore for the following sections. a) Tablet (General) Section b) Capsule (General) Section
	Remark of the Evaluator [XI]	• The firm submitted 1st page of Form 5 duly signed by the signatory. • The manufacturer have claimed manufacturer's specifications while the official monograph is present in USP.
	Decision: Deferred for signatures as per requirement	
1792.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Clearin 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin…...500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 79 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Macrolides
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarithromycin 500mg film-coated tablets MHRA Approved
	Me-too-status	Clarital 500mg Tablet by M/s Arsons Pharmaceuticals (Reg#85500)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1793.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Clearin 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin.…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 80 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Macrolides
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference	Clarithromycin 250mg Film-coated Tablets. MHRA

	Regulatory Authorities	approved
	Me-too-status	Clarital 250mg Tablet. By Arsons Pharmaceuticals (Reg. No. 85501)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1794.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Mebevetor 135mg Tablet
	Composition	Each Film Coated Tablet Contains: Mebeverine Hydrochloride…135mg
	Dairy No. date of R &I fee	Form-5 Dy.No 73 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anticholinergic
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mebeverine Hydrochloride 135mg film-coated tablets (MHRA Approved)
	Me-too-status	IBSA 135mg Tablet by M/s Ray Pharma (Reg.#66708)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator [XI]	• The manufacturer have claimed innovator's specifications while official monograph available in BP.
	Decision: Approved with BP specifications	
1795.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Naproin 275mg Tablet
	Composition	Each Film Coated Tablet Contains: Naproxen Sodium…275mg
	Dairy No. date of R &I fee	Form-5 Dy.No 67 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	APRANAX 275mg film-coated tablets. ANSM approved
	Me-too-status	Xaprox 275mg Tablet by M/s Park Davis (Reg#67373)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1796.	Name and address of manufacture / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name + Dosage Form and Strength	Naproin 550mg Tablet
	Composition	Each Film Coated Tablet Contains: Naproxen Sodium.…550mg
	Dairy No. date of R &I fee	Form-5 Dy.No 68 dated 01-01-2019 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAIDS
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	APRANAX 550mg film-coated tablets. ANSM approved
	Me-too-status	Xaprox tablets 550mg of M/s Park Davis (Reg.# 067374)
	GMP Status	The firm was inspected on 05-07-2018 and conclusion of inspection was: Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1797.	Name and address of manufacture / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Celcib 200mg Capsules
	Composition	Each hard gelatin capsule contains: Celecoxib…..200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 3359 dated 24-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Non-steroidal anti-inflammatory and antirheumatic drugs, NSAIDs, Coxibs, ATC code: M01AH01.
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Celebrex 200mg capsule (MHRA Approved)
	Me-too-status	Celexx 200mg Capsule of M/s Getz Pharma (Reg. # 028693)
	GMP Status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remark of the Evaluator [XI]	• No official monograph is available for the applied formulation.
	Decision: Approved as per innovator's specifications	
1798.	Name and address of manufacture / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Celcib 100mg Capsules
	Composition	Each hard gelatin capsule contains: Celecoxib…..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 3360 dated 24-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Non-steroidal anti-inflammatory and antirheumatic drugs, NSAIDs, Coxibs, ATC code: M01AH01.
	Type of form	Form 5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Celebrex 100mg capsule (MHRA Approved)
	Me-too-status	Celexx 100mg Capsule of M/s Getz Pharma (Reg. # 028694)
	GMP Status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remark of the Evaluator [XI]	• No official monograph is available for the applied formulation.
	Decision: Approved as per innovator's specifications	
1799.	Name and address of manufacture / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Lesu 50mg Tablets
	Composition	Each Tablet Contains: Levosulpiride…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 3358 dated 24-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 50mg tablets AIFA Italy Approved.
	Me-too-status	Sulvoric 50mg Tablet by M/s High-Q (Reg#070485)
	GMP Status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remark of the Evaluator [XI]	• The firm has claimed In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Approved as per innovator's specifications	
1800.	Name and address of manufacture / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Lesu 25mg Tablets
	Composition	Each Tablet Contains: Levosulpiride…..25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 3357 dated 24-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25 mg tablets, AIFA AItaly approved.
	Me-too-status	Sulvoric 25mg Tablet by M/s High-Q (Reg#070484)
	GMP Status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.

	Remark of the Evaluator [XI]	• The firm has claimed In-House specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Approved as per innovator's specifications	
1801.	Name and address of manufacture / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Olinex-F 6mg/25mg Capsule
	Composition	Each hard gelatin capsule contains: Olanzapine.…6mg Flouxetine as HCl.…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 3362 dated 24-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Antipsychotic/ antidepressant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SYMBYAX 6/25mg capsule (USFDA Approved)
	Me-too-status	Co-Depricap 6/25mg Capsule of M/s Nabiqasim Industries (Reg. 076135)
	GMP Status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1802.	Name and address of manufacture / Applicant	M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name + Dosage Form and Strength	Olinex-F 3mg/25mg Capsule
	Composition	Each hard gelatin capsule contains: Olanzapine…..3mg Flouxetine as HCl…..25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 3361 dated 24-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Antipsychotic/ antidepressant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SYMBYAX 3/25 mg capsule USFDA Approved
	Me-too-status	Co-Depricap 3/25mg Capsule of M/s Nabiqasim Industries (Reg. 076136)
	GMP Status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1803.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Fenamed 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Aceclofenac…..100mg

	Dairy No. date of R &I fee	Form-5 Dy.No 4190 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aceclofenac 100mg Film-coated Tablets MHRA Approved
	Me-too-status	Ace-100 Tablets by M/s Aries Pharmaceutical (Reg#84268)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	• The firm has claimed innovator's specifications and the product is not present in available Pharmacopoeia (USP, BP, IP, JP)
	Decision: Approved as per innovator's specifications	
1804.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Medvasc 10mg Tablet
	Composition	Each Tablet Contains: Amlodipine (as besylate).....10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4185 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Calcium Channel Blockers
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NORVASC (2.5mg, 5mg, 10mg) Tablets USFDA approved
	Me-too-status	Sofvasc 10mg Tablets by M/s Wilson's Pharmaceuticals (Reg#20183)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1805.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Medvastatin 20mg Tablet

	Composition	Each Film Coated Tablet Contains: Atorvastatin (as calcium trihydrate)..…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4191 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LIPITOR (10, 20, 40, 80mg) tablets USFDA Approved
	Me-too-status	Atorviz 20mg tablets by Tabros Pharma (Reg#098541)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	• The firm has claimed JP specifications and the product is present in USP.
	Decision: Approved with USP specifications	
1806.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Meduloric 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat..…80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4183 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antigout preparation
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ULORIC (40, 80mg) tablets USFDA Approved
	Me-too-status	Febuxin 80mg tablet by AGP Ltd (Reg. 081105)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	• The firm has claimed innovator's specifications and the product is not present in available Pharmacopoeia (USP, BP, IP, JP)
	Decision: Approved as per innovator's specifications	
1807.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Meduloric 40mg Tablet

	Composition	Each Film Coated Tablet Contains: Febuxostat…..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4189 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antigout preparation
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ULORIC (40mg,80mg) tablets USFDA Approved
	Me-too-status	Febuxin 40mg tablet by AGP Ltd (Reg. 081104)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	• The firm has claimed innovator's specifications and the product is not present in available Pharmacopoeia (USP, BP, IP, JP)
	Decision: Approved as per innovator's specifications	
1808.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Levisomed 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4192 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 50mg tablets AIFA Italy Approved.
	Me-too-status	Sulvoric 50mg Tablet by M/s High-Q (Reg#070485)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	• The firm has claimed innovator's specifications and the product is not present in available Pharmacopoeia (USP, BP, IP, JP)
	Decision: Approved as per innovator's specifications	

1809.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Levisomed 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…..25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4197 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25mg tablets, AIFA AItaly approved.
	Me-too-status	Sulvoric 25mg Tablet by M/s High-Q (Reg#070484)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	• The firm has claimed innovator's specifications and the product is not present in available Pharmacopoeia (USP, BP, IP, JP)
	Decision: Approved as per innovator's specifications	
1810.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Levisomed 100mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4186 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 100mg tablets, AIFA AItaly approved.
	Me-too-status	Sulvoric 100mg Tablet by M/s High-Q (Reg#070486)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	• The firm has claimed innovator's specifications and the product is not present in available Pharmacopoeia (USP, BP, IP, JP)

	Decision: Approved as per innovator's specifications	
1811.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Mebevomed 135mg Tablet
	Composition	Each Film Coated Tablet Contains: Mebeverine HCl..…135mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4188 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Anticholinergic
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mebeverine Hydrochloride 135mg film-coated tablets (MHRA Approved)
	Me-too-status	IBSA 135mg Tablet by M/s Ray Pharma (Reg.#66708)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1812.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Medlukast 5mg chewable tablet
	Composition	Each chewable tablet Contains: Montelukast (as Sodium)..…5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4182 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair (4mg, 5 mg) Chewable Tablet USFDA Approved
	Me-too-status	Nohist Chewable Tablet 5mg by M/s Bio-Mark Pharmaceuticals (Reg.# 85712)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1813.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Medlukast 10mg tablet
	Composition	Each Film Coated Tablet Contains: Montelukast (as Sodium)……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4184 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair 10mg film coated Tablet USFDA Approved
	Me-too-status	Nohist fim coated Tablet 10mg by M/s Bio-Mark Pharmaceuticals (Reg.# 85713)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1814.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Paroximed 25mg CR Tablet
	Composition	Each enteric, film coated controlled release tablet contains: Paroxetine (as HCl)…..25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4193 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Paxil CR extended-releasTablet (12.5mg, 25mg, 37.5mg) (USFDA Approved) Approved with boxwarning. Warning: Suicidal Thoughts And Behaviors
	Me-too-status	Panox CR Tablet 25mg by M/s Regal Pharmaceuticals (Reg#081954)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.

	Remark of the Evaluator [XI]	•
	Decision: Approved with boxwarning Warning: Suicidal Thoughts And Behaviors	
1815.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Paroximed 12.5mg CR Tablet
	Composition	Each enteric, film coated controlled release tablet contains: Paroxetine (as HCl)..…12.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4194 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Paxil CR extended-releasTablet (12.5mg, 25mg, 37.5mg) (USFDA Approved) Approved with boxwarning. Warning: Suicidal Thoughts And Behaviors
	Me-too-status	Panox CR Tablet 12.5mg by M/s Regal Pharmaceuticals (Reg#081953)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	•
	Decision: Approved with boxwarning Warning: Suicidal Thoughts And Behaviors	
1816.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Paroximed 37.5mg CR Tablet
	Composition	Each enteric, film coated controlled release tablet contains: Paroxetine (as HCl)..…37.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4195 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Paxil CR extended-releas Tablet (12.5mg, 25mg, 37.5mg) (USFDA Approved) Approved with boxwarning. Warning: Suicidal Thoughts And Behaviors
	Me-too-status	Peroxa CR 37.5 mg Tablet by M/s Lisko Pakistan (Reg#82148)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of

		manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	•
	Decision: Approved with boxwarning Warning: Suicidal Thoughts And Behaviors	
1817.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Medoxicam 20mg Dispersible Tablet
	Composition	Each dispersible tablet contains: Piroxicam…..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4181 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Genrx dispersible tablets 20mg TGA, Australia Approved
	Me-too-status	Dirocam 20mg Dispersible Tablets by M/s Dyson Research Laboratories (Reg#62812)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1818.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Topiramed 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate..…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4187 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Teva 50mg film coated tablets MHRA Approved
	Me-too-status	Neutop 50mg tablets by M/s Nabiqasim Industries (Reg#076388)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of

		manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1819.	Name and address of manufacture / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name + Dosage Form and Strength	Zafimed 10mg tablet
	Composition	Each Film Coated Tablet Contains: Zafirlukast…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 4196 dated 30-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of form	Form 5
	Finished product specifications	Innovator's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Accolate (10mg, 20mg) Film Coated Tablets USFDA Approved.
	Me-too-status	Upkast Tablets 10mg by M/s SJ & G Fazul Ellahie (Reg#47419)
	GMP Status	The firm was inspected on 12-04-2019 and recommendations of inspection was; Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remark of the Evaluator [XI]	• The firm has claimed innovator's specifications and the product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Approved as per innovator's specifications	

1820.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Celecap 100mg Capsule
	Composition	Each Capsule Contains: Celecoxib…..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8900 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Non-steroidal anti-inflammatory and antirheumatic drugs, NSAIDs, Coxibs, ATC code: M01AH01.
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Celebrex 100mg capsule (MHRA Approved)
	Me-too-status	Celexx 100mg Capsule of M/s Getz Pharma (Reg. # 028694)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018

	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1821.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Celecap 200mg Capsule
	Composition	Each Capsule Contains: Celecoxib…..200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8894 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Non-steroidal anti-inflammatory and antirheumatic drugs, NSAIDs, Coxibs, ATC code: M01AH01.
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Celebrex 200mg capsule (MHRA Approved)
	Me-too-status	Celexx 200mg Capsule of M/s Getz Pharma (Reg. # 028693)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1822.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Co Irbethiazide 300mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…..300mg Hydrochlorothiazide…..12.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8898 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)/ diuretics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AVALIDE (12.5mg:300mg) film coated tablets USFDA Approved
	Me-too-status	Co- Irbisaff 300mg/12.5mg Tablet by M/s Saffron Pharmaceuticals (Reg#77190)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1823.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Co Irbethiazide 300mg/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan……300mg Hydrochlorothiazide.…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8896 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)/diuretics
	Type of form	Form 5
	Finished product specifications	USP

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AVALIDE (25mg:300mg) film coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Irbest Plus Tablets 300mg/25mg by M/s Highnoon Laboratories, (Reg#79680)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1824.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	CO-Irbethiazide 150mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…..150mg Hyrdochlorothiazide…..12.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8889 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)/diuretics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AVALIDE (12.5mg:150mg) film coated tablets USFDA Approved
	Me-too-status	Co- Irbisaff 150mg/12.5mg Tablet by M/s Saffron Pharmaceuticals (Reg#77191)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1825.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Levipil Tablet 1gm
	Composition	Each Film Coated Tablet Contains: Levetiracetam…..1gm
	Dairy No. date of R &I fee	Form-5 Dy.No 6542 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA (250mg, 500mg, 750mg, 1000mg) film coated tablets USFDA Approved
	Me-too-status	Elicia 1000mg Tablet of Martin Dow (Reg.#081157)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1826.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Levipil Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Levetiracetam…..500mg

	Dairy No. date of R &I fee	Form-5 Dy.No 6537 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA (250mg, 500mg, 750mg, 1000mg) film coated tablets USFDA Approved
	Me-too-status	Episaf Tablet 500mg by Saffron Pharmaceuticals (Reg#81384)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1827.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Levipil Tablet 250mg
	Composition	Each Film Coated Tablet Contains: Levetiracetam…..250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6538 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA (250mg, 500mg, 750mg, 1000mg) film coated tablets USFDA Approved
	Me-too-status	Episaf Tablet 250mg by Saffron Pharmaceuticals (Reg#81383)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1828.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Levipil Tablet 750mg
	Composition	Each Film Coated Tablet Contains: Levetiracetam…..750mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6540 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KEPPRA (250mg, 500mg, 750mg, 1000mg) film coated tablets USFDA Approved
	Me-too-status	Episaf Tablet 750mg by Saffron Pharmaceuticals (Reg#81385)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1829.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	C-Praz 20mg/1680mg Sachet
	Composition	Each sachet contains: Omeprazole…..20mg Sodium Bicarbonate…..1680mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8899 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Proton pump inhibitor/ Antacid
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zegerid Sachet 20mg/1680mg powders USFDA approved
	Me-too-status	RULING+ sachet 20mg/1680mg M/s High-Q. (Reg#070634)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm has caimed USP specifications while the official monograph is not present in any available pharmacoepias.
	Decision: Approved as per innovator's specifications	
1830.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	C-Praz 40mg/1680mg Sachet
	Composition	Each sachet contains: Omeprazole..…40mg Sodium Bicarbonate…..1680mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8901 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Proton pump inhibitor/ Antacid
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zegerid Sachet 40mg/1680mg powders USFDA approved
	Me-too-status	RULING+ sachet 40mg/1680mg by M/s High-Q. (Reg#070633)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	• The firm has caimed USP specifications while the official monograph is not present in any available pharmacoepias.
	Decision: Approved as per innovator's specifications	
1831.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Epimate 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6536 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5

	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Teva 50mg film-coated tablets MHRA Approved
	Me-too-status	Neutop 50mg tablets by M/s Nabiqasim Industries (Reg#076388)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1832.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Epimate 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate.…200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6546 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Teva 200mg film-coated tablets MHRA Approved
	Me-too-status	Epik 200mg Tablets by M/s PharmEvo (Reg#48560)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1833.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Epimate 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate.…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6541 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate teva 25mg film coated tablets MHRA Approved
	Me-too-status	Neutop 25mg tablets by M/s Nabiqasim Industries (Reg#076387)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1834.	Name and address of manufacture / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name + Dosage Form and Strength	Epimate 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate…..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6545 dated 14-02-2019 Rs.20,000/-

		Dated 14-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Teva 100mg film-coated tablets MHRA Approved
	Me-too-status	Neutop 100mg tablets by M/s Nabiqasim Industries (Reg#089056)
	GMP Status	GMP Certificate issued on 12-03-2018 based upon inspection conducted on 31.01.2018
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1835.	Name and address of manufacture / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name + Dosage Form and Strength	Dipsar Tablet 10mg/20mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate.…10mg Olmesartan Medoxomil.…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6709 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 10mg/20mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 10/20mg by M/s Searle Pakistan (Reg#076189)
	GMP Status	The firm was inspected on 18-08-2017 and Conclusion of inspection was: Keeping in view the above facts, overall GMP compliance found GOOD as of today the management has been advised to continue the process of up gradation and submit the compliance report on the observations made within two weeks positively especially sterile area.
	Remark of the Evaluator [XI]	• The firm submitted duly signed 1st page of Form 5
	Decision: Deferred for signatures as per requirement	
1836.	Name and address of manufacture / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name + Dosage Form and Strength	Dipsar Tablet 10mg/40mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate.…10mg Olmesartan Medoxomil…..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6710 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 10mg/40mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 10/40mg by M/s Searle Pakistan (Reg#076190)

	GMP Status	The firm was inspected on 18-08-2017 and Conclusion of inspection was: Keeping in view the above facts, overall GMP compliance found GOOD as of today the management has been advised to continue the process of up gradation and submit the compliance report on the observations made within two weeks positively especially sterile area.
	Remark of the Evaluator [XI]	• The firm submitted duly signed 1st page of Form 5
	Decision: Deferred for signatures as per requirement	
1837.	Name and address of manufacture / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name + Dosage Form and Strength	Dipsar Tablet 5/20mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Olmesartan Medoxomil…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6712 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 5mg/20mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 5/20mg of M/s Searle Pakistan (Reg#076187)
	GMP Status	The firm was inspected on 18-08-2017 and Conclusion of inspection was: Keeping in view the above facts, overall GMP compliance found GOOD as of today the management has been advised to continue the process of up gradation and submit the compliance report on the observations made within two weeks positively especially sterile area.
	Remark of the Evaluator [XI]	• The firm submitted duly signed 1st page of Form 5
	Decision: Deferred for signatures as per requirement	
1838.	Name and address of manufacture / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name + Dosage Form and Strength	Dipsar Tablet 5/40mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Olmesartan Medoxomil…40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6711 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 5mg/40mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 5/40mg of M/s Searle Pakistan (Reg#076188)
	GMP Status	The firm was inspected on 18-08-2017 and Conclusion of inspection was: Keeping in view the above facts, overall GMP compliance found GOOD as of today the management has been advised to continue the process of up gradation

		and submit the compliance report on the observations made within two weeks positively especially sterile area.
	Remark of the Evaluator [XI]	• The firm submitted duly signed 1st page of Form 5
	Decision: Deferred for signatures as per requirement	
1839.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Astecoline 250mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Citicoline as Sodium…250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6219 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Psycho- stimulant and Nootropic
	Type of form	Form 5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	2ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Citicoline Panpharma 250 mg/ 2 ml, solution for injection (IM, IV) ampoule. ANSM approved
	Me-too-status	Neurains 250mg Injection of M/s Searle IV Solution (Reg. #079675)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate • The firm have submitted revised manufacturing outline showing terminal setrilzation of the product. • The firm submitted the use of type I glass ampoule as primary packaging material.
	Decision: Approved as per innovator's specifications	
1840.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Astecoline 500mg/4ml Injection
	Composition	Each 4ml Ampoule Contains: Citicoline as Sodium…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6220 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Psycho- stimulant and Nootropic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	4ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Citicoline Panpharma 500 mg/ 4 ml, solution for injection (IM, IV) ampoule. ANSM approved
	Me-too-status	Citicoline Injection 500mg (Ampule) By M/S Asia Pharm Ind (Reg#21958) (Does Not Depict Filled Volume)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate • The firm have submitted revised manufacturing outline showing terminal setrilzation of the product. • The firm submitted the use of type I glass ampoule as primary packaging material.
	Decision: Approved as per innovator's specifications	

1841.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Astemine 30mg/ml Injection
	Composition	Each ml contains: Ketorolac Tromethamine…..30mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6218 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketorolac Tromethamine Injection (15mg/ml, 30mg/ml, IV/IM) USFDA approved.
	Me-too-status	Toralac Injection 30mg/ml by M/s Vision Pharmaceuticals (Reg#50290)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate • The firm have submitted revised manufacturing outline showing terminal setrilzation of the product. • The firm submitted the use of type I glass ampoule as primary packaging material.
	Decision: Approved	
1842.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Ecalas 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid..…600mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6214 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Oxazolidinone Antibiotic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYVOX 600mg film coated Tablets USFDA Approved.
	Me-too-status	Nezocin Tablets 600mg by Brookes Pharmaceuticals (Reg. No.55005)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate • The firm submitted master formulation and manufacturing outline of the applied product • The firm submitted the use of polymorphic form III of linezolid in the applied formulation
	Decision: Approved as per innovator's specifications	
1843.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Ecalas 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…..400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6213 dated 13-02-2019 Rs.20,000/-

		Dated 11-02-2019
	Pharmacological Group	Oxazolidinone Antibiotic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYVOX 400mg film-coated tablets Tablet USFDA Approved Discontinued**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons* (as per USFDA website)
	Me-too-status	Nezocin Tablets 400mg by Brookes Pharmaceuticals (Reg. No.55004)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate • The firm submitted master formulation and manufacturing outline of the applied product • The firm submitted the use of polymorphic form III of linezolid in the applied formulation
	Decision: Approved as per innovator's specifications	
1844.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Astedol Plus 325/37.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Paracetamol…..325mg Tramadol HCl…..37.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6217 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol hydrochloride/Paracetamol 37.5mg/325mg Film-coated Tablets MHRA Approved
	Me-too-status	Distalgesic Tablets by M/s Atco Lab (Reg#73865)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate • The firm revised the weight of Tramadol hydrochloride in master formulation considering the salt factor
	Decision: Approved	
1845.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Astesul 0.4mg Capsule
	Composition	Each Capsule Contains: Tamsulosin HCl (as enteric coated pellets 0.2%).…0.4mg (Source of Pellets: Vision Pharma)
	Dairy No. date of R &I fee	Form-5 Dy.No 6215 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019

	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tamurex 400 micrograms prolonged-release capsules (MHRA approved)
	Me-too-status	Timsol 0.4 mg Capsule by M/s Scilife Pharma (Reg#82094)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate without signature • The undertaking at the end of form 5 signed by technical persons • The firm submitted revised master formulation adjusting the weight of API as per label claim. • The firm submitted valid GMP certificate of vision pharmaceuticals valid upto 10th February 2022.
	Decision: Approved	
1846.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Astedol 50mg Capsule
	Composition	Each Capsule Contains: Tramadol HCl……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6216 dated 13-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Opoid Analgesic
	Type of form	Form 5
	Finished product specifications	BP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol Hydrochloride 50mg Capsules. MHRA approved
	Me-too-status	Antram plus 50mg Capsules by Dr Raza Pharma (Reg# 84244)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate • The undertaking at the end of form 5 signed by technical persons • The firm have sumitted the revised label claim as per reference formulation without considering the salt factor along with submission of Rs. 5000/ on deposite slip No. 1932624 date 14.05.2020 • The firm submitted revised master formulation adjusting the weight of API without considering the salt factor.
	Decision: Approved	
1847.	Name and address of manufacture / Applicant	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name + Dosage Form and Strength	Astedol 100mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Tramadol HCl…..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6212 dated 13-02-2019 Rs.20,000/-

		Dated 11-02-2019
	Pharmacological Group	Opoid Analgesic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	2ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol hydrochloride 50mg/ml solution for Injection MHRA Approved
	Me-too-status	Amadrol Injection 100mg/ 2 ml by M/s Amarant Pharmacetuicals (Reg#83042)
	GMP Status	The firm was inspected on13-11-2018 and conclusion of inspection was: Overall the GMP Compliance of the firm is Good.
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 as per approved formate • The undertaking at the end of form 5 signed by technical persons • The firm have sumitted the revised label claim as per reference formulation without considering the salt factor along with submission of Rs. 5000/ on deposite slip No. 1932625 date 14.05.2020 • The firm submitted revised master formulation adjusting the weight of API without considering the salt factor. • The firm have submitted revised manufacturing outline showing terminal setrilzation of the product. • The firm submitted the use of type I glass ampoule as primary packaging material.
	Decision: Approved as per innovator's specifications	
1848.	Name and address of manufacture / Applicant	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura
	Brand Name + Dosage Form and Strength	Hypersal Eye Drops 5%
	Composition	Each ml contains: Sodium chloride.…5%
	Dairy No. date of R &I fee	Form-5 Dy.No 6342 dated 13-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Other ophthalmologicals
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	5ml; 10ml; 15ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	OPTRINE FORET HYPERTONIC SALINE EYE DROPS sodium chloride 50mg/mL topical liquid bottle (TGA Approved)
	Me-too-status	Sodium Chloride 5% Ophthalmic Solution by M/s Opal Labs (Reg#48483)
	GMP Status	Firm was inspected on 20-12-2017 and Conclusion of inspection was: Based on the areas inspected, the people met and considering the findings of inspection M/s Jaens Pharmaceuticals (pvt.) ltd., is operating satisfactory. Overall hygienic condition of the firm was satisfactory at the time of inspection however, they were advised to continue improvements in production and quality control, they agreed."
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 but not as per approved formate • The firm submitted master formulation of the applied

		product
	Decision: Deferred for submission of application on prescribed Form 5.	
1849.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Valpharm AM 10/160mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate..…10mg Valsartan…..160mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7054 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 10mg/160mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 10/160 of M/s Jupiter Pharma (Reg.#081933)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1850.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Valpharm AM 5/80mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate..…5mg Valsartan…..80mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7052 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/80mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/80 of M/s Jupiter Pharma (Reg.#081931)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1851.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Valpharm AM 5/160mg Tablet

	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate…..5mg Valsartan…..160mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7053 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Calcium channel blockers and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Amlodipine/Valsartan 5mg/160mg film-coated tablets MHRA Approved
	Me-too-status	Amlodine Tablet 5/160 of M/s Jupiter Pharma (Reg.#081932)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1852.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Valpharm H 12.5/160mg Tablet
	Composition	Each Film Coated Tablet Contains: Hydrochlorothiazide…..12.5mg Valsartan…..160mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7051 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Diuretics and Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Diovan 160/12.5 mg film-coated tablets MHRA Approved.
	Me-too-status	Cova-H 160mg/12.5mg Tablet by M/s Getz Pharma (Reg#83311)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1853.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Valpharm H 80/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…..80mg Hydrochlorothiazide..…12.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5734 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and Diuretics

	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Diovan 80/12.5 mg film-coated tablets. (MHRA Approved)
	Me-too-status	Cova-H 80mg/12.5mg Tablet by M/s Getz Pharma (Reg#83314)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1854.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Bizole Cream 1% w/w
	Composition	Each gram contains: Bifonazole…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5738 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Anti-fungal
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	15gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Canesten Bifonazole Cream 1% w/w MHRA Approved
	Me-too-status	Mecze Cream by M/s Epoch Pharmaceuticals (Reg#045341)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1855.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Focin 500mg Capsule
	Composition	Each Capsule Contains: Fosfomycin (as calcium)…..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9077 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Other antibacterials
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FOSFOMICINA CALCICA SOLUFOS 500 mg capsules, Approved in Spain
	Me-too-status	Osfocin Capsule 500mg of Krka Pak Pharmaceuticals (Reg#48611)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of

		inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1856.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Isonin E Gel
	Composition	Each gram contains: Isotretinoin…..0.5mg Erythromycin…..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5736 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Anti-Acne Preparations For Topical Use
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Isotrexin Gel MHRA Approved
	Me-too-status	Vegatrex Gel by M/s Vega Pharmaceuticals (Reg#83841)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 with signature of technical persons on undertaking.
	Decision: Approved as per innovator's specifications	
1857.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Tifmine Syrup 1mg/5ml
	Composition	Each 5ml contains: Ketotifen (as hydrogen fumarate)..…1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9085 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihistamines
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZADITEN 1mg/5ml oral solution (in the form of ketotifen fumarate (as fumarate)) ANSM Approved
	Me-too-status	Asarest Syrup (in the form of ketotifen hydrogen fumarate (as hydrogen fumarate)) by M/s Chas A Mendoza (Reg#34321)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory

	Remark of the Evaluator [XI]	• The firm has applied Ketotifen (as hydrogen fumarate) while the approved product in RRR is in the form of (ketotifen fumarate (as fumarate). • The firm provided the evidence of applied formulation in RRR.
	Decision: Deferred for revision of formulation as per reference formulation	
1858.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Tifmine 1mg Tablet
	Composition	Each Tablet Contains: Ketotifen (as hydrogen fumarate)..…1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9078 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antihistamines
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZADITEN Tablets 1mg MHRA Approved
	Me-too-status	Asarest tablet by M/s Chas A Mendoza (Reg#36226)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1859.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Letrole 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole…..2.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9079 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Aromatase inhibitor
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FEMARA 2.5mg film coated tablet USFDA Approved
	Me-too-status	Letzole 2.5mg Tablet by M/s Opal Labs (Reg#75805)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
1860.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Depride 25mg Tablet

	Composition	Each Uncoated Tablet Contains: Levosulpiride…25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5737 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25mg tablets, AIFA AItaly approved.
	Me-too-status	Sulvoric 25mg Tablet by M/s High-Q (Reg#070484)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1861.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Depride 50mg Tablet
	Composition	Each uncoated tablet contains: Levosulpiride.…50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5740 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Antipsychotics (Benzamides)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 50mg tablets AIFA Italy Approved.
	Me-too-status	Sulvoric 50mg Tablet by M/s High-Q (Reg#070485)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	• The firm submitted revised form 5 with signature of technical persons on undertaking.
	Decision: Approved as per innovator's specifications	
1862.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Nimrest 100mg Tablet
	Composition	Each uncoated Tablet Contains: Nimesulide…….100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5741 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	NSAIDS
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference	ALGIMESIL 100 mg tablets AIFA Italy Approved

	Regulatory Authorities	
	Me-too-status	Nimcid Tablets by Unexolabs (Reg#46336)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	• The firm has submitted revised form 5 revising the formulation from film coated to uncoated tablets along with submission of Rs. 5000/- on deposit slip No.0825546 date 11.05.2020. Moreover the firm also submitted revised master formulation and manufacturing outline
	Decision: Approved as per innovator's specifications	
1863.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Olpine 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine…..5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9084 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antipsychotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Olanzapine 5mg film coated tablets MHRA Approved
	Me-too-status	Olanzpine 5mg tablets Akson Pharmaceuticals (Reg#81660)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1864.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Olpine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9083 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Antipsychotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Olanzapine 10mg film coated tablets MHRA Approved
	Me-too-status	Olanzpine 10mg tablets Akson Pharmaceuticals (Reg#81661)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was:

		Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1865.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Ephagor Syrup 0.25mg/5ml
	Composition	Each 5ml contains: Pizotifen (as Hydrogen Malate)……0.25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9082 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti-migraine
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sanomigran Elixir 0.25mg /5ml (MHRA Approved)
	Me-too-status	Welxofen Syrup 0.25mg/5ml by M/s Welmed Pharmaceutical (Reg#82514)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	
1866.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Cral Suspension 1g/5ml
	Composition	Each 5ml contains: Basic aluminium sucrose sulfate (Sucralfate)…1g
	Dairy No. date of R &I fee	Form-5 Dy.No 7050 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Antepsin 1g/5ml Oral Suspension. MHRA approved
	Me-too-status	Gastromed Oral Suspension 1gm/5ml by M/s Aries Pharmaceuticals (Reg# 82601)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications.	

1867.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Sulmid V Cream
	Composition	Each gram contains: Sulphanilamide…..150mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5735 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Gynaecological anti-infective
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	80gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	AVC (sulfanilamide) Vaginal Cream 15% USFDA Approved
	Me-too-status	Sulphakream-N Cream By M/s Nabiqasim (Reg#012452) as provided by the firm which could not be verified
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	• The firm provided evidence of applied formulation/drug already approved by DRAP which could not be verified
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm	
1868.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Terfine 125mg Tablet
	Composition	Each Tablet Contains: Terbinafine (as HCl)..…125mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5747 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Antifungal
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 125mg tablets MHRA Approved
	Me-too-status	Logirid Tablet 125mg of Lowitt Pharmaceutical (Reg#80846)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1869.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Terfine 250mg Tablet
	Composition	Each Tablet Contains: Terbinafine (as HCl)…..250mg

	Dairy No. date of R &I fee	Form-5 Dy.No 5743 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Antifungal
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 250mg tablets MHRA Approved
	Me-too-status	Logirid Tablet 250mg of Lowitt Pharmaceutical (Reg#80847)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1870.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Terfine Cream 1%
	Composition	Each gram contains: Terbinafine (as HCl).....10mg (1%)
	Dairy No. date of R &I fee	Form-5 Dy.No 5739 dated 08-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Antifungal for topical use
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	10gm; As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine Hydrochloride 1 % Cream MHRA Approved
	Me-too-status	Bina 1% Cream by M/s Linta Pharmaceuticals (Reg#80268)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	• The firm has claimed manufacturer's specifications but the official monograph is available in JP.
	Decision: Approved with JP specifications	
1871.	Name and address of manufacture / Applicant	M/s Epharm Laboratories. A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name + Dosage Form and Strength	Relidol-P 37.5mg/325mg Tablet
	Composition	Each Film Coated Tablet Contains: Tramadol HCl.....37.5mg Paracetamol.....325mg
	Dairy No. date of R &I fee	Form-5 Dy.No 9086 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Tramadol hydrochloride/Paracetamol 37.5mg/325mg Film-coated Tablets MHRA Approved
	Me-too-status	Distalgesic Tablets by M/s Atco Lab., (Reg#73865)
	GMP Status	The firm was inspected on 01/03/18 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management towards the continuous improvements their current level of compliance was noted as satisfactory
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1872.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Azepal Tablet 200mg
	Composition	Each Tablet Contains: Carbamazepine……200mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8478 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Carbagen 200mg tablets MHRA Approved
	Me-too-status	Carbawel 200 mg Tablets by M/s Welmark Pharmaceuticals (Reg#77462)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate • The firm submitted revised/updated monograph of API and state that there is no requirement of XRD for identification of API (identified by FTIR and HPLC)
	Decision: Approved	
1873.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Azepal Tablet 400mg
	Composition	Each Tablet Contains: Carbamazepine…..400mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8479 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Carbagen 400mg tablets MHRA Approved
	Me-too-status	Tegral 400mg Tablet by M/s Novartis (Reg#79918)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.

	Remark of the Evaluator [XI]	• The firm submitted the duly signed 1st page of form 5 as per approved formate • The firm submitted revised/updated monograph of API and state that there is no requirement of XRD for identification of API (identified by FTIR and HPLC)
	Decision: Approved	
1874.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Azepal Oral Suspension 100mg/5ml
	Composition	Each 5ml contains: Carbamazepine……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8489 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiepileptics
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tegretol 100mg/5ml Liquid (Oral suspension) MHRA Approved
	Me-too-status	Tegral 100mg/5ml suspension by M/s Novartis Pharma (Reg#70803)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm submitted the duly signed 1st page of form 5 as per approved formate
	Decision: Approved	
1875.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Flexiban Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Cyclobenzaprine HCl……5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5425 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Skeletal Muscle Relaxant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FLEXERIL 5mg film coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Eumytic 5mg Tablet by M/s Atco Labarotories (Reg#67273)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate
	Decision: Approved	

1876.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Flexiban Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Cyclobenzaprine HCl……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5426 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Skeletal Muscle Relaxant
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FLEXERIL 10mg film coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Eumytic 10mg Tablet by M/s Atco Labarotories (Reg#67274)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate
	Decision: Approved	
1877.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Cyprostol Tablet 200mcg
	Composition	Each Tablet Contains: Misoprostol (as 1% HPMC Dispersion)…200mcg
	Dairy No. date of R &I fee	Form-5 Dy.No 8477 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Prostaglandin
	Type of form	Form 5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec (100 mcg, 200 mcg) tablets (USFDA Approved)
	Me-too-status	Prosotec 200mcg Tablet by Atco Laboratories Limited (Reg#58356)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate • The firm has claimed manufacturer's specifications but the official monograph is available in IP. • Misoprostol is used as 1% dispersion which is an intermediate and not the active substance. Do we need additional documents, source fixation and fee? • Approved with boxed warning of ―misoprostol administration to women who are pregnant can cause birth defects, abortion, premature birth or uterine rupture.
	Decision: Approved with IP specifications and with boxed warning of ―misoprostol	

	administration to women who are pregnant can cause birth defects, abortion, premature birth or uterine rupture.	
1878.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Cyprostol Tablet 100mcg
	Composition	Each Tablet Contains: Misoprostol (as 1% HPMC Dispersion)…100mcg
	Dairy No. date of R &I fee	Form-5 Dy.No 8476 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Prostaglandins
	Type of form	Form 5
	Finished product specifications	IP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cytotec (100 mcg, 200 mcg) tablets (USFDA Approved)
	Me-too-status	Prosotec 100mcg Tablet by Atco Laboratories Limited (Reg#58355)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate • The firm has claimed manufacturer's specifications but the official monograph is available in IP. • Misoprostol is used as 1% dispersion which is an intermediate and not the active substance. Do we need additional documents, source fixation and fee? • Approved with boxed warning of ―misoprostol administration to women who are pregnant can cause birth defects, abortion, premature birth or uterine rupture.
	Decision: Approved with IP specifications and with boxed warning of ―misoprostol administration to women who are pregnant can cause birth defects, abortion, premature birth or uterine rupture.	
1879.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Dolmina P Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…..50mg
	Dairy No. date of R &I fee	Form-5 Dy.No.8485(26-2-2019) Rs.20,000/- 21-2-2019
	Pharmacological Group	NSAID
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac potassium 50mg Film Coated Tablets MHRA Approved.
	Me-too-status	Kalfen 50mg tablets by M/s Candid Pharmaceuticals (Reg#100912)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate
	Decision: Approved	

1880.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Tolezepine Oral Suspension 300mg/5ml
	Composition	Each 5ml contains: Oxcarbazepine.…300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8484 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRILEPTAL 300mg/5mL oral suspension USFDA approved
	Me-too-status	Oxaze 300mg/5mL suspension by M/s Shrooq Pharmaceuticals (Reg#60611)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate • The firm has claimed manufacturer's specifications but the official monograph is available in USP.
	Decision: Approved with USP specifications	
1881.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Tolezepine tablet 600mg
	Composition	Each Film Coated Tablet Contains: Oxcarbazepine…..600mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8483 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRILEPTAL (150 mg, 300 mg, 600 mg) film coated tablets USFDA approved
	Me-too-status	Telox 600mg Tablets of M/S Platinum Pharmaceutical (Reg#44236)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate • The firm has claimed manufacturer's specifications but the official monograph is available in USP.
	Decision: Approved with USP specifications	
1882.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Tolezepine tablet 150mg
	Composition	Each Film Coated Tablet Contains: Oxcarbazepine.…150mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8481 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019

	Pharmacological Group	Antiepileptic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRILEPTAL (150 mg, 300 mg, 600 mg) film coated tablets USFDA approved
	Me-too-status	Telox 150mg Tablets of M/S Platinum Pharmaceutical (Reg#44234)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate duly signed by the signatory • The firm has claimed manufacturer's specifications but the official monograph is available in USP.
	Decision: Approved with USP specifications	
1883.	Name and address of manufacture / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name + Dosage Form and Strength	Tolezepine tablet 300mg
	Composition	Each Film Coated Tablet Contains: Oxcarbazepine.…300mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8482 dated 26-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antiepileptic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRILEPTAL (150 mg, 300 mg, 600 mg) film coated tablets USFDA approved
	Me-too-status	Telox 300mg Tablets of M/S Platinum Pharmaceutical (Reg#44235)
	GMP Status	The firm was inspected on 29-01-2019 and conclusion of inspection was: The firm is overall GMP compliant.
	Remark of the Evaluator [XI]	• The firm revised the 1st page of form 5 as per approved formate duly signed by the signatory • The firm has claimed manufacturer's specifications but the official monograph is available in USP.
	Decision: Approved with USP specifications	
1884.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Max-Cla 500mg XL Tablet
	Composition	Each Film Coated extended release Tablet Contains: Clarithromycin……..500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7566 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Macrolide antibiotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	BIAXIN XL Filmtab film-coated extended-release tablets (500mg) USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety

		or efficacy reasons**
	Me-too-status	Loud XL 500mg Tablet by M/s Sigma Pharma (Reg#090947)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1885.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Max-Cla film coated 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin……500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7572 dated 21-02-2019 Rs.20,000/- Dated 20 -02-2019
	Pharmacological Group	Macrolide antibiotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	BIAXIN Filmtab (250 mg, 500 mg) film-coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Throm 500mg Tablet by M/s Daneen Pharma (Reg#099130)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1886.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Max-Cla 250mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin…..250mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7551 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Macrolide antibiotic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	BIAXIN Filmtab (250 mg, 500 mg) film-coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too-status	Throm 250mg Tablet by M/s Daneen Pharma (Reg#099129)

	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1887.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Mebas 10mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Ebastine……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7565 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antihistamine
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	EBASTINE ARROW 10mg film-coated tablets ANSM Approved
	Me-too-status	Acmin 10mg Tablets by M/s Medpharm Research (Reg#100559)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved with JP specifications	
1888.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Mebas 20mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Ebastine…..20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7557 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antihistamine
	Type of form	Form 5
	Finished product specifications	JP
	Pack size and Demand Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Kestine 20mg film coated tablet Netherlands Approved
	Me-too-status	Acmin 20mg Tablets by M/s Medpharm Research (Reg#100560)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved with JP specifications	

1889.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Glifloz 25mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin… …25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7553 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Blood Glucose Lowering Drugs, Excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	JARDIANCE (10mg, 25mg) film-coated tablets USFDA Approved
	Me-too-status	Empoli 25mg Tablet by M/s Sami Pharmaceuticals (Reg#098701)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.
	Decision: Deferred for submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting	
1890.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Glifloz 10mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin ..…10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8804 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Blood Glucose Lowering Drugs, Excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	JARDIANCE (10mg, 25mg) film-coated tablets USFDA Approved
	Me-too-status	Empoli 10mg Tablet by M/s Sami Pharmaceuticals (Reg#098702)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.
	Decision: Deffered for submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting	
1891.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Glitec 2mg Tablet
	Composition	Each Tablet Contains:

		Glimepiride…2mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7570 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Sulfonylureas
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	AMARYL (1mg, 2mg, 4mg) tablets USFDA Approved
	Me-too-status	Zoryl 2mg tablet by M/s Innvotek Pharmaceuticals (Reg#099262)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1892.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Glitec 1mg Tablet
	Composition	Each Tablet Contains: Glimepiride.….1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7555 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Sulfonylureas
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	AMARYL (1mg, 2mg, 4mg) tablets USFDA Approved
	Me-too-status	Zoryl 1mg tablet by M/s Innvotek Pharmaceuticals (Reg#099261)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1893.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Glitec 3mg Tablet
	Composition	Each Tablet Contains: Glimepiride……3mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7556 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Sulfonylureas
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	20's; 30's; As per SRO
	Approval status of product in Reference	Glimepiride 3mg Tablets MHRA Approved

	Regulatory Authorities	
	Me-too-status	Zoryl 3mg tablet by M/s Innvotek Pharmaceuticals (Reg#099263)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1894.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Glitec 4mg Tablet
	Composition	Each Tablet Contains: Glimepiride……4mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7569 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Sulfonylureas
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	20's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	AMARYL (1mg, 2mg, 4mg) tablets USFDA Approved
	Me-too-status	Zoryl 4mg tablet by M/s Innvotek Pharmaceuticals (Reg#099264)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1895.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Glifloz-M 12.5mg/500mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……12.5mg Metformin HCl.…500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7559 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5 mg/500 mg, 12.5mg/1000 mg) film coated tablets USFDA Approved
	Me-too-status	Jardy-Met 12.5/500 tablet by M/s CCL Pharmaceuticals (Reg#099764)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards

		constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.
	Decision: Deferred for submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting	
1896.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Siga 50mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin (as phospate monohydrate)……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7561 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antidiabetic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Januvia (25mg, 50mg, 100mg) film-coated tablets USFDA Approved.
	Me-too-status	Viasit 50mg tablet by M/s Hiranis Pharmaceuticals (Reg#095915)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1897.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Siga 25mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin (as phospate monohydrate)……25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7568 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antidiabetic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Januvia (25mg, 50mg, 100mg) film-coated tablets USFDA Approved.
	Me-too-status	Viasit 25mg tablet by M/s Hiranis Pharmaceuticals (Reg#095916)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	

1898.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Siga 100mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin (as phospate monohydrate)……100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7562 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antidiabetic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's; 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Januvia (25mg, 50mg, 100mg) film-coated tablets USFDA Approved.
	Me-too-status	Viasit 100mg tablet by M/s Hiranis Pharmaceuticals (Reg#095914)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1899.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Sigamet 50/1000mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phospate monohydrate…..50mg Metformin HCl……1000mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7571 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antidiabetic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) USFDA Approved.
	Me-too-status	Silmax-M 50mg/1000mg Tablet by M/s High-Q Pharmaceuticals (Reg#76400)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1900.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Sigamet 50/500mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phospate monohydrate……50mg Metformin HCl…….500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7567 dated 21-02-2019 Rs.20,000/-

		Dated 11-02-2019
	Pharmacological Group	Antidiabetic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet film coated tablet (50mg/500mg & 50mg/1000mg) USFDA Approved.
	Me-too-status	Silmax-M 50mg/500mg Tablet by M/s High-Q Pharmaceuticals (Reg#76399)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1901.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Sigamet 50/850mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phospate monohydrate…..50mg Metformin HCl……850mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7568 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antidiabetic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet 50/850mg film coated tablets of TGA approved
	Me-too-status	Treviamet 50mg/850mg Tablet by M/s Getz Pharma (Reg#83315)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1902.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Vilda 50mg Tablet
	Composition	Each Tablet Contains: Vildagliptin……50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7563 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Anti-diabetic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's; 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUS vildagliptin 50mg tablets TGA Approved

	Me-too-status	Gevo 50mg Tablets by M/s BJ Pharmaceuticals, (Reg#82780)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1903.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Vilda-M 50mg/1000mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……50mg Metformin HCl……1000mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7554 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50 mg vildagliptin and 1,000 mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/1000mg Tablets by Novartis Pharma (Reg. No. 66107)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1904.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Vilda-M 50mg/850mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……50mg Metformin HCl……850mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7552 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50mg vildagliptin and 850mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/850mg TABLETS by Novartis Pharma (Reg. No. 66106)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the

		attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1905.	Name and address of manufacture / Applicant	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi
	Brand Name + Dosage Form and Strength	Vilda-M 50mg/500mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…..50mg Metformin HCl..…500mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7560 dated 21-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	14's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET® (50mg vildagliptin and 500mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	Tinmet Tablet 50mg/500mg by M/s Bio-Mark Pharmaceuticals (Reg. No.85718)
	GMP Status	The firm was inspected on 21-02-2019 and conclusion of inspection was: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1906.	Name and address of manufacture / Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form and Strength	Baclodex 10mg Tablet
	Composition	Each uncoated tablet contains: Baclofen…..10mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7748 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents M03BX01
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Baclofen 10mg Tablets MHRA Approved
	Me-too-status	Baflex Tablets by M/s Polyfine Chempharma (Reg. No.78458)
	GMP Status	The firm was inspected on 23.07.2018 and conclusion of inspection was; The firm was found in satisfactory compliance with GMP guidelines, documents including SOPs, log books were found intact and implemented. Although firm was directed to shift all the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act 1976/ DRAPAct 2012 and make available all the requisites including columns and certified reference standards.

	Remark of the Evaluator [XI]	•
	Decision: Approved	
1907.	Name and address of manufacture / Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form and Strength	Deslodine Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Desloratadine……5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 7746 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti-histamine
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarinex 5mg film coated tablet USFDA Approved.
	Me-too-status	Desatil Tablets 5mg by Aries Pharma (Reg#84270)
	GMP Status	The firm was inspected on 23.07.2018 and conclusion of inspection was; The firm was found in satisfactory compliance with GMP guidelines, documents including SOPs, log books were found intact and implemented. Although firm was directed to shift all the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act 1976/ DRAPAct 2012 and make available all the requisites including columns and certified reference standards.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1908.	Name and address of manufacture / Applicant	M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad
	Brand Name + Dosage Form and Strength	Rostat 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin (as calcium)……10mg
	Dairy No. date of R &I fee	Form-5 Dy.No.7747(21-2-2019) Rs.20,000/- 21-2-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	CRESTOR (5, 10, 20, or 40 mg) film coated tablets USFDA Approved
	Me-too-status	Apollo 10mg Tablets by M/s Dyson Research Laboratories (Reg#78837)
	GMP Status	The firm was inspected on 23.07.2018 and conclusion of inspection was; The firm was found in satisfactory compliance with GMP guidelines, documents including SOPs, log books were found intact and implemented. Although firm was directed to shift all the existing registered products specifications for testing from in-house to international pharmacopoeias where applicable, as per drug specifications rules of drug act 1976/ DRAPAct 2012 and make available all the requisites including columns and certified reference standards.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications.	

1909.	Name and address of manufacture / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan.
	Brand Name + Dosage Form and Strength	Alpram 1mg Tablet
	Composition	Each Tablet Contains: Alprazolam…..1mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8522 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xanax (0.25mg, 0.5mg, 1mg, 2mg) tablets USFDA Approved
	Me-too-status	Lydia 1mg Tablets by M/s. Wilshire Laboratories (Reg#65699)
	GMP Status	The firm was inspected on 15-03-3018 and conclusion of inspection was: During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remark of the Evaluator [XI]	•
	Decision: Approved	
1910.	Name and address of manufacture / Applicant	M/s Wilshire Laboratories Pvt Ltd 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Glivo-Met Tablet 50mg/1000mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin ……50mg Metformin HCl……1000mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5337 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5's, 7's, 10's, 20's, 30's, 40's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET (50mg vildagliptin and 1,000mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/1000mg Tablets by Novartis Pharma (Reg. No. 66107)
	GMP Status	The firm was inspected on 27-08-2018, 05-10-2018, 06-11-2018 and Recommendations of inspections were: The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1911.	Name and address of manufacture / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Glivo-Met Tablet 50mg/850mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin …..50mg

		Metformin HCl…..850mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5336 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Blood glucose lowering drugs, excl. Insulins
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5's, 7's, 10's, 20's, 30's, 40's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET (50mg vildagliptin and 850mg metformin hydrochloride) film coated tablets of TGA; Australia Approved
	Me-too-status	GALVUS MET 50mg/850mg TABLETS by Novartis Pharma (Reg. No. 66106)
	GMP Status	The firm was inspected on 27-08-2018, 05-10-2018, 06-11-2018 and Recommendations of inspections were: The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1912.	Name and address of manufacture / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Glivo Tablet 50mg
	Composition	Each Tablet Contains: Vildagliptin… …50mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5333 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Anti-diabetic
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5's, 7's, 10's, 20's, 30's, 40's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUS vildagliptin 50mg tablets TGA Approved
	Me-too-status	Gevo 50mg Tablets by M/s BJ Pharmaceuticals, (Reg#82780)
	GMP Status	The firm was inspected on 27-08-2018, 05-10-2018, 06-11-2018 and Recommendations of inspections were: The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1913.	Name and address of manufacture / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Aviga 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Agomelatine……25mg
	Dairy No. date of R &I fee	Form-5 Dy.No 5340 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antidepressant

	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5's, 7's, 10's, 20's, 30's, 40's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Valdoxan (Agomelatine) 25mg Film-Coated Tablets TGA Approved
	Me-too-status	Agoviz 25mg tablet of M/s PharmEvo (Reg#086887)
	GMP Status	The firm was inspected on 27-08-2018, 05-10-2018, 06-11-2018 and Recommendations of inspections were: The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specfications	
1914.	Name and address of manufacture / Applicant	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
	Brand Name + Dosage Form and Strength	Sovevo 400/100/100mg Tablet
	Composition	Each Film Coated Tablet Contains: Sofosbuvir…….400mg Velpatasvir……100mg Voxilaprevir……100mg
	Dairy No. date of R &I fee	Form-5D Dy.No 6950 dated 19-02-2019 Rs.50,000/- Dated 19-02-2019
	Pharmacological Group	HCV NS5B polymerase inhibitor+HCV NS5A inhibitor+HCV NS3/4A protease inhibitor
	Type of form	Form 5D
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	5's, 7's, 10's, 20's, 30's, 40's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	VOSEVI (400mg sofosbuvir, 100mg velpatasvir, 100mg voxilaprevir) film coated tablets USFDA Approved
	Me-too-status	New molecule
	GMP Status	The firm was inspected on 27-08-2018, 05-10-2018, 06-11-2018 and Recommendations of inspections were: The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.
	Remark of the Evaluator [XI]	• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.
	Decision: Deferred for submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting	
1915.	Name and address of manufacture / Applicant	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Brand Name + Dosage Form and Strength	Rivascot Tablet 2.5mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban……2.5mg
	Dairy No. date of R &I fee	Form-5 Dy.No 8161 dated 25-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Antithrombotic Agents
	Type of form	Form 5

	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto film-coated tablets (2.5mg, 10mg, 15mg, 20mg) by USFDA Approved.
	Me-too-status	Xarelto 2.5mg Tablet by M/s. Bayer Pakistan (Reg#074794)
	GMP Status	The firm was inspected on 10-10-2018 & 17-10-2018 and Recommendations of inspection were: Firm has been adhering to GMP guidelines and showing good compliance with quality policy completely implemented. Guidelines, SOP's and written instructions for each and every step in manufacturing testing, and storage ensuring quality products are intact and implemented. Keeping in view the above, the panel unanimously recommends for grant of GMP certificate.
	Remark of the Evaluator [XI]	•
	Decision: Approved as per innovator's specifications	

Deferred Cases (Human):

1916.	Name and address of manufacture / Applicant	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name + Dosage Form and Strength	Davicef 250mg Capsule
	Composition	Each capsule contains Cephradine monohydrate equivalent to Cephradine….250mg
	Dairy No. date of R &I fee	Dy. No. 15882 dated 07-03-19, Rs. 20,000/- 04-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefradine 250mg Capsules (MHRA Approved)
	Me-too-status	Zasinol 250mg capsule by M/s Martin Dow Reg#080643)
	GMP Status	The firm was inspected on 01-10-2019 and conclusion of inspection was: Based on the areas inspected, the people met, documents reviewed and considering the findings especially the efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended: 1- Renewal of DML 2- Grant of additional sections. I- Cephalosporin (capsule) II- Cephalosporin (Dry suspension)
	Previous Remark of the Evaluator [XI]	• The reference formulation contains cephradine anhydrous while applied formulation is cephradine monohydrate.
	Previous Decision	• Deferred in 293rd DRB meeting for revision of formulation as per the reference product.
	Evaluation by PEC	• The firm submitted revised master formulation and form 5 as per reference product. The revised label claim is as under: Each capsule contains: Cephradine Anhydrous….250mg
	Decision: Approved	

1917.	Name and address of manufacture / Applicant	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name dosage and Strength	Distaclor 250mg Capsule
	Composition	Each Capsule Contains: Cefaclor Monohydrate Eq. to Cefaclor…250mg
	Dairy No. date of R &I fee	Dy. No 15857 dated 07-03-2019 Rs. 20,000/- Dated 04-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in reference regulatory Authorities	MHRA Approved
	Me-too-status	Cavalor Capsules 250mg By Barrett Hodgson Pakistan (Pvt) Ltd, (Reg. 30972)
	GMP Status	The firm was inspected on 01-10-2019 and conclusion of inspection was: Based on the areas inspected, the people met, documents reviewed and considering the findings especially the efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended: 1- Renewal of DML 2- Grant of additional sections. I- Cephalosporin (capsule) II- Cephalosporin (Dry suspension)
	Previous Remark of the Evaluator [XI]	• The firm has applied Cefaclor Monohydrate Eq. to Cefaclor…250mg while quantity of API in master formulation is also Cefaclor Monohydrate 250mg, not considering the salt factor. Master formulation not revised.
	Previous Decision	• Deferred in 293rd DRB meeting for revision of master formulation with respect to weight of API considering the monohydrated form.
	Evaluation by PEC	• The firm submitted revised master formulation adjusting the weight of API considering the monohydrate form
	Decision: Approved	
1918.	Name and address of manufacture / Applicant	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name dosage and Strength	Distaclor 500 mg Capsule
	Composition	Each Capsule Contains: Cefaclor Monohydrate Eq. to Cefaclor…500mg
	Dairy No. date of R &I fee	Dy. No 15858 dated 07-03-2019 Rs. 20,000/- Dated 04-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in reference regulatory Authorities	Cefaclor 500mg Capsules (MHRA Approved)
	Me-too-status	Cavalor Capsules 500mg By Barrett Hodgson Pakistan (Pvt) Ltd, (Reg. 30973)
	GMP Status	The firm was inspected on 01-10-2019 and conclusion of inspection was: Based on the areas inspected, the people met, documents reviewed and considering the findings especially the

		efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended: 1- Renewal of DML 2- Grant of additional sections. I- Cephalosporin (capsule) II- Cephalosporin (Dry suspension)
	Previous Remark of the Evaluator [XI]	• The firm has applied Cefaclor Monohydrate Eq. to Cefaclor…500mg while quantity of API in master formulation is also Cefaclor Monohydrate 500mg, not considering the salt factor. Master formulation not revised.
	Previous Decision	• Deferred in 293rd DRB meeting for revision of master formulation with respect to weight of API considering the monohydrated form.
	Evaluation by PEC	• The firm submitted revised master formulation adjusting the weight of API considering the monohydrate form
	Decision: Approved	
1919.	Name and address of manufacture / Applicant	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name dosage and Strength	Davicef 250mg/5ml Dry Powder for Suspension
	Composition	Each 5ml Contains: Cephradine …250mg
	Dairy No. date of R &I fee	Dy. No 15881 dated 07-03-2019 Rs. 20,000/- Dated 04-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in reference regulatory Authorities	Nicef Syrup 250mg/5ml / Cefradine Syrup 250mg/5ml Approved in MHRA as syrup
	Me-too-status	Cephrascot Oral Suspension by Scotmann Pharmaceuticals (Reg. 028221)
	GMP Status	The firm was inspected on 01-10-2019 and conclusion of inspection was: Based on the areas inspected, the people met, documents reviewed and considering the findings especially the efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended: 1- Renewal of DML 2- Grant of additional sections. I- Cephalosporin (capsule) II- Cephalosporin (Dry suspension)
	Previous Remark of the Evaluator [XI]	• MHRA mentions CEFRADINE as powder of syrup (cefradine anhydrous). • The case was evaluated with the reference to AUGMENTIN DUO claims that product is in syrup form, but actually is suspension. In this regard, DRAP has previously sent email to TGA (Therapeutic Goods Administration) Australia. On this behalf TGA (Australia) clarified the situation that AUGMENTIN

		DUO is not syrup, and technically you are right after reconstitution product prepare as suspension.
	Previous Decision	• Deferred in 293rd meeting for further deliberations
	Evaluation by PEC	•
	Decision: Approved	

Deferred Cases (Veterinary):

1920.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber, AJK.
	Brand Name, Dosage Form, Strength	FEN HANS 25 % ORAL LIQUID
	Composition	Each 100ml contains:- Florfenicol …… 25g Colistin Sulphate……50MIU
	Diary No., Date of R & I & Fee	Dy.No 1512 dated 14/02/2020; Rs. 20,000 14/02/2020
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml,150ml, 250ml,500ml,1Litre,2.5Litre Decontrolled
	Me-Too Status	Flocol Liquid by M/s D-Maarson Pharmaceuticals (Reg#074082)
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• The firm has claimed manufacturer's specifications & the product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision	• In 294th meeting of DRB, Deferred for scientific rational for formulation containing 25g/100ml florfenicol, since formulation containing 23g/100ml florfenicol is already approved.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product and stated that this product is manufactured by other veterinary firms on the basis of registration granted by DRAP and also strength of formulation different from our other applied formulations
	Decision: Registration Board referred the case regarding the composition/strength to the expert working group on veterinary drugs.	
1921.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	FEN HANS 11% ORAL LIQUID
	Composition	Each 100ml contains:- Florfenicol …… 11g Colistin Sulphate……50MIU
	Diary No., Date of R & I & Fee	Dy.No 1513 dated 14/02/2020; Rs. 20,000 14/02/2020
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml,150ml, 250ml, 500ml, 1Litre, 2.5Litre Decontrolled
	Me-Too Status	Flo Raft Oral Liquid by M/s Nawal Pharmaceuticals (Reg#078252)
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	The firm has claimed manufacturer's specifications & the product is not present in available pharmacopoeia (USP, BP,

		IP, JP)
	Previous Decision	• In 294th meeting of DRB, Deferred for scientific rational for formulation containing 11g/100ml florfenicol, since formulation containing 10g/100ml florfenicol is already approved.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product and stated that this product is manufactured by other veterinary firms on the basis of registration granted by DRAP and also strength of formulation different from our other applied formulations
	Decision: Registration Board referred the case regarding the composition/strength to the expert working group on veterinary drugs.	
1922.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	FLOHANS-25 % ORAL LIQUID
	Composition	Each 100ml contains:- Florfenicol …… 25g
	Diary No., Date of R & I & Fee	Dy.No 1516 dated 14/02/2020; Rs. 20,000 14/02/2020
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml,150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	Wal-Fen 25% Oral Liquid by M/s Nawal Pharmaceuticals (Reg#099438)…could not be confirmed
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator [XI]	• Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm could not be confirmed • The firm has claimed manufacturer's specifications & product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision	In 294th meeting of DRB, Deferred for following: • Scientific rational for formulation containing 25g/100ml florfenicol, since formulation containing 23g/100ml florfenicol is already approved. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product and stated that this product is manufactured by other veterinary firms on the basis of registration granted by DRAP and also strength of formulation different from our other applied formulations • The firm has submitted mee-too of the applied product Fenster-25 Oral Liquid by M/s Amster Laboratories (Reg#099481)
	Decision: Registration Board referred the case regarding the composition/strength to the expert working group on veterinary drugs.	
1923.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	TIMBER-PL ORAL LIQUID
	Composition	Each ml contains:- Tilmicosin…… 250mg
	Diary No., Date of R & I & Fee	Dy.No 1520 dated 14/02/2020; Rs. 20,000 14/02/2020
	Pharmacological Group	Antibiotic

	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml,150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	Tilconoor 2.5% Oral Liquid by M/s Kohinoor Industries (Reg#081312)
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• The firm has already applied the same product, in same strength and same dosage form with salt form. • The firm has claimed manufacturer's specifications & product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision	• In 294th meeting of DRB, Deferred for clarification since the same product in same strength and dosage form (with salt form) is also applied.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product and stated that this product is manufactured by other veterinary firms on the basis of registration granted by DRAP
	Decision: Registration Board referred the case regarding the composition to the expert working group on veterinary drugs.	
1924.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	COBAZASOL DS ORAL SUSPENSION
	Composition	Each 100ml contains:- Oxyclozanide …… 6% Levamisole HCl …… 3% Cobalt Chloride……. 0.15% Sodium selenite …….. 0.07%
	Diary No., Date of R & I & Fee	Dy.No 2031 dated 19/02/2020; Rs. 20,000 19/02/2020
	Pharmacological Group	Anthelmintic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• Evidence of applied formulation already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm not available • The firm has claimed manufacturer's specifications & the product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision	• In 294th meeting of DRB, Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product Stezole DS Oral suspension by M/s Amster Laboratories (Reg#101435)
	Decision: Approved as per innovator's specifications	
1925.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	LEVA BALT ORAL SUSPENSION
	Composition	Each 100ml contains:- Triclabendazole …… 5g Levamisole HCl …… 3.75g

		Cobalt sulphate ……. 0.075g Sodium selenite ……. 0.035g
	Diary No., Date of R & I & Fee	Dy.No 2033 dated 19/02/2020; Rs. 20,000 19/02/2020
	Pharmacological Group	Anthelmintic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	Tenex plus 8.75 Drench by M/s Breeze Pharma (Reg#059107)
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• Mee-Too of applied product shows the base form of Levamisole while the applied formulation contains the hydrochloride salt of Levamisole. Moreover Mee-Too of applied product shows the chloride salt of cobalt while the applied formulation contains the sulphate salt of cobalt. Clarify or revise the salt form of Levamisole and cobalt in the label claim and master formulation along with submission of applicable fee. • The firm has claimed manufacturer's specifications & the product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision	• In 294th meeting of DRB, Deferred for revision of formulation as per DRAP approved me-too / generic product along with submission of requisite fee.
	Evaluation by PEC	• The firm has corrected formulation as per DRAP me-too product alongwith submission of Rs 5000/- on deposite slip No.1927792 date 03.06.2020. The correct label claim is as under; Each 100ml contains:- Triclabendazole …… 5g Levamisole ……..…… 3.75g Cobalt Chloride ……. 0.075g Sodium selenite ……. 0.035g
	Decision: Approved as per innovator's specifications with following label claim: **Each 100ml contains:-** **Triclabendazole …… 5g** **Levamisole ……..…… 3.75g** **Cobalt Chloride ……. 0.075g** **Sodium selenite ……. 0.035g**	
1926.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	HANSENID–PL ORAL SUSPENSION
	Composition	Each ml contains:- Oxfendazole……...25mg
	Diary No., Date of R & I & Fee	Dy.No 2037 dated 19/02/2020; Rs. 20,000 19/02/2020
	Pharmacological Group	Anthelmintic
	Type Of Form	Form 5
	Finished product Specification	USP
	Pack Size and Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	Arox Drench by M/s Leads Pharma (Reg#046670)
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• The firm has submitted revised form 5 correcting the strength in label claim as per Mee-Too product along with submission of Rs. 5000/- on deposit slip No. 1927782 date 06.04.2020 • The firm has claimed BP specifications (product not

		available) but the product is in available US pharmacopoeia.
	Previous Decision	• In 294th meeting of DRB, Deferred for submission of fee Rs 15,000/- for revision of formulation.
	Evaluation by PEC	• The firm has further submitted Rs. 15000/- for revision of formulation/strength in label claim as per Mee-Too product on deposite slip No. 1927791 dated 03.06.2020
	Decision: Approved	
1927.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	HANZOLE 12.5% ORAL SUSPENSION
	Composition	Each 100ml contains:- Albendazole……12.5g
	Diary No., Date of R & I & Fee	Dy.No 2023 dated 19/02/2020; Rs. 20,000 19/02/2020
	Pharmacological Group	Anthelmintic
	Type Of Form	Form 5
	Finished product Specification	USP
	Pack Size and Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	Albadec Super Oral Suspension by M/s Decent Pharma (R#079838)
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• The firm has claimed for manufacturer's specifications but the product is present in USP as oral suspension
	Previous Decision	• In 294th meeting of DRB, Deferred for scientific rational for formulation containing 12.5g/100ml albendazole, since formulation containing 10g/100ml albendazole is already approved.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product and stated that this product is manufactured by other veterinary firms on the basis of registration granted by DRAP and also strength of formulation different from our other applied formulations
	Decision: Registration Board referred the case regarding the composition/strength to the expert working group on veterinary drugs.	
1928.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	HANZOLE-11.25% ORAL SUSPENSION
	Composition	Each 100ml contains:- Albendazole……11.25g.
	Diary No., Date of R & I & Fee	Dy.No 2024 dated 19/02/2020; Rs. 20,000 19/02/2020
	Pharmacological Group	Anthelmintic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	Albensure Drench by M/s Biogen Pharma (Reg#069609)
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• The firm has claimed for manufacturer's specifications but the product is present in USP as oral suspension
	Previous Decision	• In 294th meeting of DRB, Deferred for scientific rational for formulation containing 11.25g/100ml albendazole, since formulation containing 10g/100ml albendazole is already approved.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product and stated that this product is manufactured by other veterinary firms on the basis of registration granted by DRAP and also

		strength of formulation different from our other applied formulations
	Decision: Registration Board referred the case regarding the composition/strength to the expert working group on veterinary drugs.	
1929.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	ALBAHANS-10% ORAL SUSPENSION
	Composition	Each 100ml contains:- Albendazole……10g Cobalt Sulphate…….0.075g Sodium Selenite……..0.035g
	Diary No., Date of R & I & Fee	Dy.No 2026 dated 19/02/2020; Rs. 20,000 19/02/2020
	Pharmacological Group	Anthelmintic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• Evidence of applied formulation already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm not available • The firm has claimed manufacturer's specifications & the product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision	• In 294th meeting of DRB, Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product Alba 10 Suspension by M/s Breeze Pharma. (Reg#075666). • Moreover the firm revise the label claim as per available mee-too product correcting the salt form of cobalt along with submission of Rs 5000/- on deposite slip No. 1927793 dated 03.06.2020. The correct label claim is as under; Each 100ml contains:- Albendazole……10g Cobalt Chloride…….0.075g Sodium Selenite……..0.035g
	Decision: Approved as per innovator's specifications with the following label claim: **Each 100ml contains:-** **Albendazole……10g** **Cobalt Chloride…….0.075g** **Sodium Selenite……..0.035g**	
1930.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	HISO-VIT LIQUID
	Composition	Each ml contains:- Sulphadiazine……. 35.50 gm Sulphadimidine…….. 28.40 gm Neomycin Sulphate…….. 1.80 gm Hysocine Methylbromide…. 0.04 gm Pectin…….. 7.10 gm Kaoline…….. 103.30 gm Vitamin B1…… 0.15 gm Vitamin B2……. 0.22 gm
	Diary No., Date of R & I & Fee	Dy.No 2029 dated 19/02/2020; Rs. 20,000 19/02/2020

	Pharmacological Group	Antibiotics, Anti-diarrheal, Vitamins
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 150ml, 250ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• Evidence of applied formulation already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm is not available • The firm has claimed manufacturer's specifications & the product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision	• In 294th meeting of DRB, Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product Minizine Oral Liquid by M/s D-Maarson Pharma. (Reg#097908).
	Decision: Approved as per innovator's specifications	
1931.	Name and address of Manufacturer / Applicant	D-Haans Pharma (Pvt) Ltd. Plot No. 9/A, Industrial Estate, Bhimber. AJK.
	Brand Name, Dosage Form, Strength	PEFROX-BH ORAL LIQUID
	Composition	Each Litre contains:- Pefloxacin methanesulfonate equ. to Pefloxacin…….... 100 gm
	Diary No., Date of R & I & Fee	Dy.No 2030 dated 19/02/2020; Rs. 20,000 19/02/2020
	Pharmacological Group	Fluoroquinolones
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	150ml, 250ml, 450ml, 500ml, 1Litre, 2.5Litre; Decontrolled
	Me-Too Status	
	GMP Status	New DML (No. 000912) issued on 11-02-2020 on the basis of inspection conducted on 12-12-2019.
	Previous Remarks of Evaluator XI	• Evidence of applied formulation already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm is no available • The firm has claimed manufacturer's specifications & the product is not present in available pharmacopoeia (USP, BP, IP, JP)
	Previous Decision	• In 294th meeting of DRB, Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	• The firm has submitted mee-too of the applied product Peperoxin solution by M/s Hassan Brothers (Reg#082807).
	Decision: Approved as per innovator's specifications.	

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

a. New cases

1932.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.
	Brand Name +Dosage Form + Strength	Gepride Tablet 50mg
	Composition	Each Film coated tablet contains: Itopride hydrochloride……..50mg
	Diary No. Date of R& I & fee	34879, 19-10-2018, 20,000/- 12-10-2018
	Pharmacological Group	Gastroprokinetic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 240 per 10 tablet Rs. 24 per tablet
	Approval status of product in Reference Regulatory Authorities.	Ganaton 50mg Tablet by Abbott (PMDA approved)
	Me-too status	Itoguard Tablet of M/s Macter International (Reg.#055753)
	GMP status	The firm was granted GMP certificate based on inspection dated 19-09-2019.
	Remarks of the Evaluator.(VI)	
	Decision: Approved with innovator's specification.	
1933.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.
	Brand Name +Dosage Form + Strength	Gepride Tablet 150mg
	Composition	Each Film coated tablet contains: Itopride hydrochloride……..150mg
	Diary No. Date of R& I & fee	34882, 19-10-2018, 20,000/- 12-10-2018
	Pharmacological Group	Gastroprokinetic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 330 per 10 tablet Rs. 33 per tablet
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Itoride tablet of amarant pharma
	GMP status	The firm was granted GMP certificate based on inspection dated 19-09-2019.
	Remarks of the Evaluator.(VI)	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1934.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.
	Brand Name +Dosage Form + Strength	SOFSPA Capsules 200mg
	Composition	Each Capsule contains: Mebeverine hydrochloride (as SR pellets)…….200mg
	Diary No. Date of R& I & fee	34875, 19-10-2018, 20,000/- 12-10-2018
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 300 per 10 Capsules Rs. 30 per Capsule
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Berrin 200 mg Capsules of M/s Focus &Rulz Pharmaceuticals, (Reg#066660)
	GMP status	The firm was granted GMP certificate based on inspection

		dated 19-09-2019.
	Remarks of the Evaluator.(VI) (VI)	Source of pellets: M/s Vision pharma
	Decision: Approved with innovator's specification.	
1935.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.
	Brand Name +Dosage Form + Strength	Aloran syrup 0.5mg/ml
	Composition	Each ml contains: Desloratadine……..0.5mg
	Diary No. Date of R& I & fee	34885, 19-10-2018, 20,000/- 12-10-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 90 per 30 ml bottle
	Approval status of product in Reference Regulatory Authorities.	Aerius For Children Syrup Desloratadine 2.5mg/5mL oralliquid bottle by M/s Bayer Australia Ltd (TGA Approved)
	Me-too status	Desora 0.5mg/ml syrup by M/s Continental Pharma. (Reg.#055192)
	GMP status	The firm was granted GMP certificate based on inspection dated 19-09-2019.
	Remarks of the Evaluator.(VI)	
	Decision: Approved with innovator's specification.	
1936.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.
	Brand Name +Dosage Form + Strength	Aloran Tablet
	Composition	Each Film coated Tablet contains: Desloratadine……..5mg
	Diary No. Date of R& I & fee	34876, 19-10-2018, 20,000/- 12-10-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 17.5 per tablet Rs. 175 per 10 tablets
	Approval status of product in Reference Regulatory Authorities.	Desloratadine film-coated tablet 5mg of M/s Lupin Healthcare (UK) Limited (MHRA Approved)
	Me-too status	Destina tablet 5mg of M/s Hilton Pharma (Reg. # 039364)
	GMP status	The firm was granted GMP certificate based on inspection dated 19-09-2019.
	Remarks of the Evaluator.(VI)	
	Decision: Approved with innovator's specification.	
1937.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.
	Brand Name +Dosage Form + Strength	Obesinil Capsules 120mg
	Composition	Each Capsule contains: Orlistat……120mg
	Diary No. Date of R& I & fee	34881, 19-10-2018, 20,000/- 12-10-2018
	Pharmacological Group	Lipase inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 60 per Capsule Rs. 600 per 10 capsules
	Approval status of product in Reference Regulatory Authorities.	Beacita 120mg Capsules of (MHRA approved)
	Me-too status	Orlisat 120mg Capsules by M/s Merck Sharp & Dhome
	GMP status	The firm was granted GMP certificate based on inspection

		dated 19-09-2019.
	Remarks of the Evaluator.(VI)	Source of pellets: M/s Vision Pharma
	Decision: Deferred for further deliberation upon stability data requirement for orlistat pellets.	
1938.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.
	Brand Name +Dosage Form + Strength	Dexaprufen Tablet 400mg
	Composition	Each tablet contains: Dexibuprofen……400mg
	Diary No. Date of R& I & fee	34889, 19-10-2018, 20,000/- 12-10-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 10.93 per Tablet Rs. 328 per 30 Tablets
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Dexwel Tablets of M/s Welwrd Pharmaceutical. (Reg.#076813)
	GMP status	The firm was granted GMP certificate based on inspection dated 19-09-2019.
	Remarks of the Evaluator.(VI)	
	Decision: Approved with innovator's specification.	
1939.	Name and address of manufacturer / Applicant	M/s Lahore Chemical & Pharmaceutical works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.
	Brand Name +Dosage Form + Strength	Arthrofen Tablet
	Composition	Each tablet contains: Diclofenac sodium……50mg Misoprostol……..200mcg
	Diary No. Date of R& I & fee	34877, 19-10-2018, 20,000/- 12-10-2018
	Pharmacological Group	Non-steroidal anti-inflammatory drug
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 13.55 per Tablet Rs. 271 per 20 Tablets
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Tector Plus 50 Tablet of Macter International
	GMP status	The firm was granted GMP certificate based on inspection dated 19-09-2019.
	Remarks of the Evaluator.(VI)	The reference formulation contains Misoprostol in 1% HPMC dispersion surrounded by diclofenac sodium enteric coated core. Revised master formulation is required. Evidence of bilayer compression machine is required.
	Decision: Deferred for following observations: • **Revise master formulation in-line with the reference product formulation with the submission of requisite fee.** • **Evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.**	
1940.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd, 124/1 Industrial Estate, Kotlakhpat, Lahore
	Brand Name +Dosage Form + Strength	Agitanil 10mg Injection
	Composition	Each vial contains: Olanzapine…..10mg
	Diary No. Date of R& I & fee	0987, 6-06-2011, 8,000/- 6-6-2011, Rs. 12,000, 14-1-2015 (Duplicate Dossier)

	Pharmacological Group	Atypical Antipsychotic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	A per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confimed.
	GMP status	cGMP certificate is granted based on inspection dated 26-9-2017.
	Remarks of the Evaluator.(VI)	Fee challan photocopy attached.
	Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
1941.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd, 124/1 Industrial Estate, Kotlakhpat, Lahore
	Brand Name +Dosage Form + Strength	Zyqro Forte 500mg/5ml Suspension
	Composition	Each 5mlcontains: Cefadroxil as monohydrate…..500mg
	Diary No. Date of R& I & fee	0564, 20-10-2008, 8,000/- 20-10-2008, Rs. 12,000, 16-12-2014 (Duplicate Dossier)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	A per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefadroxil Biochemie 500 mg/5ml - Pulver zur Herstellung einer Suspension zur Einnahme. EMA approved
	Me-too status	Could not be confirmed
	GMP status	cGMP certificate is granted based on inspection dated 26-9-2017.
	Remarks of the Evaluator.(VI)	Fee challan photocopy attached.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along-with registration number, brand name and name of firm	
1942.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt Ltd, 124/1 Industrial Estate, Kotlakhpat, Lahore
	Brand Name +Dosage Form + Strength	Artane 20mg Injection
	Composition	Each ml ampoule contains: Artemether….20mg
	Diary No. Date of R& I & fee	0875, 3-6-2011, 8,000/- 20-10-2008, Rs. 12,000, 14-1-2015 (Duplicate Dossier)
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	A per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	cGMP certificate is granted based on inspection dated 26-9-2017.
	Remarks of the Evaluator.(VI)	Fee challan photocopy attached.
	Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	

1943.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals, Pvt Ltd 21Km Ferozpur road, lahore
	Brand Name +Dosage Form + Strength	Torvast tablet 20mg
	Composition	Each tablet contains: Atorvastatin as calcium….20mg
	Diary No. Date of R& I & fee	952, 16-12-2009, 8,000/- 16-12-2009, Rs. 12,000, 25-6-2014 (Duplicate Dossier)
	Pharmacological Group	Cardiovascular drug
	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	A per SRO
	Approval status of product in Reference Regulatory Authorities.	Lipitor Tablet 20mg
	Me-too status	Dublin Ireland Pfizer
	GMP status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the Evaluator.(VI)	Fee challan photocopy attached.
	Decision: Approved with innovator's specification. Fee shall be verified as per procedure adopted by Registration Board.	
1944.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals, Pvt Ltd 21Km Ferozpur road, lahore
	Brand Name +Dosage Form + Strength	Torvast tablet 10mg
	Composition	Each tablet contains: Atorvastatin as calcium….10mg
	Diary No. Date of R& I & fee	954, 16-12-2009, 8,000/- 16-12-2009, Rs. 12,000, 25-6-2014 (Duplicate Dossier)
	Pharmacological Group	Cardiovascular drug
	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	A per SRO
	Approval status of product in Reference Regulatory Authorities.	Lipitor Tablet 10mg
	Me-too status	Dublin Ireland Pfizer
	GMP status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the Evaluator.(VI)	Fee challan photocopy attached.
	Decision: Approved with innovator's specification. Fee shall be verified as per procedure adopted by Registration Board .	
1945.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals, Pvt Ltd 21Km Ferozpur road, lahore
	Brand Name +Dosage Form + Strength	Losart tablet 50mg
	Composition	Each tablet contains: Losartan as potassium….50mg
	Diary No. Date of R& I & fee	955, 16-12-2009, 8,000/- 16-12-2009, Rs. 12,000, 25-6-2014 (Duplicate Dossier)
	Pharmacological Group	Cardiovascular drug
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	A per SRO
	Approval status of product in Reference Regulatory Authorities.	Cozaar Tablet 50mg
	Me-too status	USA Approved
	GMP status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the Evaluator.(VI)	Fee challan photocopy attached.
	Decision: Approved with innovator's specification. Fee shall be verified as per procedure	

	adopted by Registration Board .	
1946.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals, Pvt Ltd 21Km Ferozpur road, lahore
	Brand Name +Dosage Form + Strength	Losart tablet 25mg
	Composition	Each tablet contains: Losartan as potassium…25mg
	Diary No. Date of R& I & fee	955, 16-12-2009, 8,000/- 16-12-2009, Rs. 12,000, 25-6-2014 (Duplicate Dossier)
	Pharmacological Group	Cardiovascular drug
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	A per SRO
	Approval status of product in Reference Regulatory Authorities.	Cozaar Tablet 25mg
	Me-too status	USA Approved
	GMP status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the Evaluator.(VI)	Fee challan photocopy attached.
	Decision: Approved with innovator's specification. Fee shall be verified as per procedure adopted by Registration Board.	
1947.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate, Lahore Contract manufacturing by M/s Nicholas Pharmaceuticals Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Ncopenem 500mg IV Injection
	Composition	"Each Vial Contains: Meropenem as trihydrate …….. 500mg"
	Diary No. Date of R& I & fee	Dy. No 40327 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Meropenem 500 mg powder for solution for injection or infusion of (UK)
	Me-too status (with strength and dosage form)	Mopen 500mg Injection of M/s Hilton Pharma
	GMP status	Inspection of M/s Nicholas Pharma dated 03-08-2018 recommended grant of DML. Bio-Mark is granted GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator.(VI)	
	Decision: Approved	
1948.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate, Lahore Contract manufacturing by M/s Nicholas Pharmaceuticals Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Ncopenem 1gm Injection
	Composition	"Each Vial Contains: Meropenem as trihydrate …….. 1gm"
	Diary No. Date of R& I & fee	Dy. No 40328 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Meropenem 1 g powder for solution for injection or infusion (MHRA)
	Me-too status (with strength and dosage form)	Mopen 1gm Injection of M/s Hilton Pharma
	GMP status	Inspection of M/s Nicholas Pharma dated 03-08-2018 recommended grant of DML. Bio-Mark is granted GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator.(VI)	
	Decision: Approved.	
1949.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate, Lahore Contract manufacturing by M/s Nicholas Pharmaceuticals Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Ertapem 1gm Injection
	Composition	"Each Vial Contains: Ertapenem sodium eq. to Ertapenem…1gm"
	Diary No. Date of R& I & fee	Dy. No 40329 dated 05-12-2018 Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's sepcifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Ernem Injection of Genix Pharma
	GMP status	Inspection of M/s Nicholas Pharma dated 03-08-2018 recommended grant of DML. Bio-Mark is granted GMP certificate based on evaluation conducted in February 2020.
	Remarks of the Evaluator.(VI)	
	Decision: Approved with innovator's specification.	
1950.	Name and address of Manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name+DosageForm+Strength	Parkofen Syrup 200mg/5ml
	Composition	Each 5ml Contains: Ibuprofen…200mg
	Diary No. Date of R&I & fee	Dy No.24906; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti-Pyretic, Analgesic & Anti-Inflammatory
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	90ml
	Approval status of product in Reference Regulatory Authorities	Ibuprofen 200 mg/ 5ml oral suspension by M/s Aspire Pharma Ltd, MHRA approved.
	Me-too status	Brufen DS Oral Suspension
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of Evaluator (VI)	Ibuprofen suspension monograph is available but not of syrup. The firm has deposited Rs.5,000 and Rs. 15,000 dated 3-12-2020 Deposit slip No. 2021336 and changed the formulation as : Revised Formulation:

		Each 5ml suspension contains: Ibuprofen……200mg
	Decision: Approved the revised formulation.	
1951.	Name and address of Manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name+DosageForm+Strength	Parkofen Syrup 100mg/5ml
	Composition	Each 5ml Contains: Ibuprofen…100mg
	Diary No. Date of R&I & fee	Dy No.24912; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti Pyretic, Analgesic & Anti-Inflammatory
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Burfen Syrup MHRA Approved
	Me-too status	041735 Adfin Syrup by Vision Pharmaceuticals, Plot No.224, Street No.1, I-10/3, Islamabad.
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of Evaluator (VI)	Ibuprofen suspension monograph is available but not of syrup. The firm has deposited Rs.5,000 and Rs. 15,000 dated 3-12-2020 Deposit slip No. 2021335 and changed the formulation as : **Revised Formulation:** Each 5ml suspension contains: Ibuprofen……**100mg**
	Decision: Approved the revised formulation.	

b. Deferred cases

1952.	**Name and address of manufacturer / Applicant**	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Diary No. Date of R& I & fee	Diary No: 24179 , 13-12-2017 , Rs: 20,000/-
	Brand Name +Dosage Form + Strength	Prodiol Tablets
	Composition	Each film coated tablet contains: Ethinyl Estradiol…….0.035mg Cyproterone Acetate…….2mg
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form-5
	Finished product Specification	Innovators
	Pack size & Demanded Price	21`s / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dermapil film coated tablet, TGA Approved.
	Me-too status	DIANE-35 by Bayer Health care (Reg. No. 011467), Eva-35 tablet by M/s Hansel (Reg#064796)
	GMP status	New License (Inspection Date: 29-05- 2017, 30-05-2017, 13-07-2017, 03-10-17 and 04-10-2017
	Remarks of the Evaluator.(VI)	Firm has given undertaking that we shall only manufacture steroidal hormonal drug/products in our hormone section
	Previous Decision:	**Previous Decision:** The Board deferred product and advised the firm to get approval from Licensing Division particularly for either Tablet (Steroidal Hormone) or Tablet (Non-steroidal Horomone) for further processing by Registration Board. **Decision of 286th :**

		Deferred for further deliberation upon requirements of manufacturing facility for applied formulation.
	Evaluation of PEC (VI)	The firm has submitted a letter form CLB stating that your request for the change in nomenclature from Tablet Hormone Human into Tablet Steroid Hormone Human is approved.
	Decision: Approved with innovator's specification.	
1953.	Name and address of manufacturer / Applicant	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:2736, 19/01/2018, Rs: 20,000/- Dated 17/01/2018
	Brand Name +Dosage Form + Strength	Rivar G Tablets 10mg
	Composition	Each film coated contains: Rivaroxaban…..10mg
	Pharmacological Group	Antithrombotic (B01AF01)
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Xeralto Tablets USFDA Approved
	Me-too status	080789; Rivaxo 10mg Tablet M/s Getz Karachi
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	Approved in USFDA with box warning.
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved with innovator's specification.	
1954.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:2737, 19/01/2018, Rs: 20,000/- Dated 17/01/2018
	Brand Name +Dosage Form + Strength	Rivar G Tablets 15mg
	Composition	Each film coated contains: Rivaroxaban…..15mg
	Pharmacological Group	Antithrombotic (B01AF01)
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Xeralto Tablets USFDA Approved
	Me-too status	080790; Rivaxo 15mg Tablet M/s Getz Karachi

	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	Approved in USFDA with box warning.
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved with innovator's specification.	
1955.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:2734, 19/01/2018, Rs: 20,000/- Dated 17/01/2018
	Brand Name +Dosage Form + Strength	Basinol Tablets 5mg
	Composition	Each film coated contains: Bisoprolol fumarate…..5mg
	Pharmacological Group	Beta blocking agents, selective (C07AB07)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 28's, 30's, 50's, 100's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zebeta Tablet 5mg Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons. USFDA Approved
	Me-too status	079558; Bisolol 5mg M/s Paramount Pharmaceuticals, Islamabad
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved with innovator's specification.	
1956.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:2735, 19/01/2018, Rs: 20,000/- Dated

		17/01/2018
	Brand Name +Dosage Form + Strength	Basinol Tablets 10mg
	Composition	Each film coated contains: Bisoprolol fumarate…..10mg
	Pharmacological Group	Beta blocking agents, selective (C07AB07)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 28's, 30's, 50's, 100's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zebeta Tablet 5mg Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons. USFDA Approved
	Me-too status	079559; Bisolol 10mg M/s Paramount Pharmaceuticals, Islamabad
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved	
1957.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:2729, 19/01/2018, Rs: 20,000/- 17/01/2018
	Brand Name +Dosage Form + Strength	Atom Capsules 10mg
	Composition	Each capsule Contains: Atomoxetine Hydrochloride eq. to Atomoxetine…10mg
	Pharmacological Group	Psychostimulants, Agents Used for ADHD and Nootropics Centrally acting sympathomimetics (N06BA09)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,28's,42's,50's,100's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	STRATTERA® USFDA Approved
	Me-too status	079955; Autis 10mg Capsule M/s Amarant Karachi . .
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	Approved in USFDA with box warning.
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate

		till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved	
1958.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:2729, 19/01/2018, Rs: 20,000/- 17/01/2018
	Brand Name +Dosage Form + Strength	Atom Capsules 18mg
	Composition	Each capsule Contains: Atomoxetine Hydrochloride eq. to Atomoxetine…18mg
	Pharmacological Group	Psychostimulants, Agents Used for ADHD and Nootropics Centrally acting sympathomimetics (N06BA09)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,28's,42's,50's,100's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	STRATTERA® USFDA Approved
	Me-too status	079956; Autis 18mg Capsule M/s Amarant Karachi . .
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	Approved in USFDA with box warning.
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved	
1959.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:2731 , 19/01/2018, Rs: 20,000/- 17/01/2018
	Brand Name +Dosage Form + Strength	Atom Capsules 25mg
	Composition	Each capsule Contains: Atomoxetine Hydrochloride eq. to Atomoxetine…25mg
	Pharmacological Group	Psychostimulants, Agents Used for ADHD and Nootropics Centrally acting sympathomimetics (N06BA09)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,28's,42's,50's,100's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	STRATTERA® USFDA Approved

	Me-too status	079957; Autis 25mg Capsule M/s Amarant Karachi.
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	Approved in USFDA with box warning.
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved	
1960.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Dy.No.26527; 29-12-2017; Rs.20,000/- (28-12-2017)
	Brand Name +Dosage Form + Strength	Trimet tablet 35mg
	Composition	Each film-coated tablet contains: Trimetazidine Dihydrochloride……..35mg
	Pharmacological Group	Anti- anginal
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	30's & as per policy of DRAP
	Approval status of product in Reference Regulatory Authorities.	Vastarel MR of M/s Servier Laboratories, France (ANSM)
	Me-too status	Vastarel-MR tablet of M/s Servier Research & Pharmaceuticals
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved	
1961.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Dy. No.26529; 29-12-2017; Rs.20,000/- (28-12-2017)
	Brand Name +Dosage Form + Strength	Alizole tablet 500mg

	Composition	Each chewable tablet contains: Mebendazole ……...500mg
	Pharmacological Group	Anti-infective/ Anthelmintic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & as per policy of DRAP
	Approval status of product in Reference Regulatory Authorities.	Vermox 500mg chewable tablet of M/s Janssen Pharms (**Discontinued in USFDA**)
	Me-too status	Nemazole tablet 500mg of M/s GSK Pharmaceuticals
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	In master formulation, coating is involved while the applied formulation is a chewable tablet.
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved	
1962.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Dy.No.26530; 29-12-2017; Rs.20,000/- (28-12-2017)
	Brand Name +Dosage Form + Strength	Zeocit syrup 2.5mg/ 5ml (60ml)
	Composition	Each 5ml contains: Mebendazole ……...2.5mg
	Pharmacological Group	Antiallergic/ Anti-histamines
	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	60ml, 90ml, 120ml & 240ml & as per policy of DRAP
	Approval status of product in Reference Regulatory Authorities.	Xyzal 0.5mg/ml oral solution of M/s UCB Pharma Limited (MHRA Approved)
	Me-too status	Ocitra Syrup of M/s Searle Pakistan (Pvt.) Limited (Reg. # 054519)
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the

		verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved with innovator's specification.	
1963.	**Name and address of manufacturer / Applicant**	M/s Glitz Pharma , Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Dy. No.26528; 29-12-2017; Rs.20,000/- (28-12-2017)
	Brand Name +Dosage Form + Strength	Glif Na-SR tablet 100mg
	Composition	Each enteric-coated tablet contains: Diclofenac Sodium ……..…100mg
	Pharmacological Group	Analgesics, antipyretics, NSAIDs, anti-gout, and antirheumatic , non-opioid analgesics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & as per policy of DRAP
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dicloran tablet 100mg of M/s Sami Pharma
	GMP status	5-10-2018 Conclusion: Keeping in view the observations noted during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations.
	Remarks of the Evaluator.(VI)	
	Previous Decision:	**Decision of 287th :** Deferred for updated GMP status of the firm since last inspection report does not recommend the GMP certificate till the rectification of said observations.
	Evaluation of PEC (VI)	Reference to the QA&LT Division Letter No.4-3/2008-QA dated 16th Jan 2019, an inspection of the firm has been carried out by the panel on 16th Jan 2019 for the verification of the improvements:-The panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection report and decided to recommend the issuance of GMP certificate.
	Decision: Approved	
1964.	Name and address of manufacturer / Applicant	"M/s Sante Pvt Ltd . 245/2-Z, Block 6, PECHS, Karachi 75400"
	Diary No. Date of R& I & fee	Dy.No 22190 dated 26-06-2018 Rs.20,000/- Dated 26-06-2018 Duplicate
	Brand Name +Dosage Form + Strength	Terbison Tablets 250mg
	Composition	"Each Tablet Contains: Terbinafine HCL…250mg"
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 1121 packof 10 Tab.
	Approval status of product in Reference Regulatory Authorities.	TGA Approved.
	Me-too status	080847; Logirid Tablet 250mg Lowitt Pharmaceutical (Pvt) Ltd, Industrial estate,Peshawar
	GMP status	02-07-2019 Conclusion:

		Based on the current practices and keeping in view the attitude of the management towards better compliance of GMP their overall compliance level for the said dosage form is rated as Good.
	Remarks of the Evaluator.(VI)	3 % overage has been added without justification.
	Previous Decision:	Decision of 291st : Deferred for revision of formulation as per innovator i.e. "Terbinafine as HCL…250mg", whereas, the applied formulation is "Terbinafine HCL…250mg" and justification of 3% overage on the basis of scientific data.
	Evaluation of PEC (VI)	Firm has revised formulation as per innovator's and eliminated the overage from the master formulation.
	Decision: Approved the revised formulation.	
1965.	Name and address of manufacturer / Applicant	M/s Efroze chemical Industries ,Korangi Industrial Are, Karachi
	Diary No. Date of R& I & fee	Dy. No.51; 21-12-2016; Rs.20,000/- (21-12-2016)
	Brand Name +Dosage Form + Strength	Trisil Plus Tablet (Sugar -Free)
	Composition	Each chewable tablet contains: Aluminium Hydroxide dried gel….200mg Magnesium Hydroxide……..200mg Simethicone….25mg
	Pharmacological Group	Antacid,Antiflatulence
	Type of Form	Form 5
	Finished product Specification	In-House
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	USfda Gelusil tablet by Wellspring pharma as an OTC drug (Could not be confirmed as sugar -free)
	Me-too status	Gelusil tablet by Johnson and Johnson(Could not be confirmed)
	GMP status	19-3-2018, panel recommends the grant of renewal of the DML by way of formulation
	Remarks of the Evaluator.(VI)	Fee challan photocopy attached. Me-too status could not be confirmed.
	Previous Decision:	Decision of 284th : Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation of PEC (VI)	The firm has submitted that our this product is line extension or the sugar free version of the already registered product Trisil Plus Tablet Reg No 006993.We want to launch this product for the diabetics. They also want for the chance of personal hearing. The reference product Gelusil is not sugar-free.
	Decision: Deferred for confirmation of excipients in comparison to innovator's product	
1966.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals Pvt. Ltd. Plot 129 Sunder Industrial Estate Raiwind Lahore
	Brand Name + Dosage Form + Strength	SOLFENA Tablet 10mg
	Composition	Each film-coated tablet contains: Solifenacin Succinate …..10mg
	Diary No. Date of R& I & fee	Dy.No 6255 dated 20-02-2018 Rs. 20,000/- Dated 20-02-2018
	Pharmacological Group	Muscarinic Antagonists, Urological Agents
	Type of Form	Form 5

	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	Pack Size:10's Price: As per SRO
	Approval status of product in Reference Regulatory Authorities.	VESIcare USFDA Approved.
	Me-too status	081959 Solfine Tablet 10 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Last GMP inspection is conducted on 08/11/2018 and The report concludes that firm was found to be operating at good level of GMP compliance.
	Remarks of the Evaluator.(VI)	
	Previous Decision:	Decision of 288th : Deferred for submission of revised label claim in terms of equivalency of Solifenacin as per reference product.
	Evaluation of PEC (VI)	The composition of reference product is same as of applied composition: Each film-coated tablet contains: Solifenacin Succinate …..10mg
	Decision: Approved with innovator's specification.	
1967.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Road Post Office Daghal, Rawalpindi
	Brand Name + Dosage Form + Strength	Dobesil 500mg Capsule Varilate 500mg Capsules
	Composition	Each Capsule Contains: Calcium Dobesilate as Monohydrate…500mg"
	Diary No. Date of R& I & fee	Dy.No 32075 dated 26-09-2018 Rs.20,000/- Dated 26-09-2018
	Pharmacological Group	Antivaricose Therapy C05BX01
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	Alu-Alu/Alu-PVC Blister Strip of 10's, pack of 3x10's. Rs. 990.00/-.
	Approval status of product in Reference Regulatory Authorities.	Doxium® 500 Regulatory Authorities. Swissmedic Approved.
	Me-too status	023199\ Doxium Capsule 500mg M/s Anglo French Drug Co Karachi Haroon Brothers Karachi
	GMP status	25-9-2019 Panel recommended the renewal of DML
	Remarks of the Evaluator.(VI)	The master formulation mentions Calcium Dobesilate as Monohydrate…526mg, whereas, label claim is Calcium Dobesilate as Monohydrate…500mg. Firm has revised the master formulation as per the label claim without submitting fee.
	Previous Decision:	Decision of 293rd : Deferred for submission of fee for revision of formulation
	Evaluation of PEC (VI)	The firm has submitted Rs.5,000 dated 27-2-2020. Deposit No 1981051
	Decision: Approved the revised formulation with innovator's specification.	
1968.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Road Post Office Daghal, Rawalpindi
	Brand Name + Dosage Form +	Co-Press Opthalmic Solution

	Strength	Iopex Opress
	Composition	Each ml Contains: Brimonidine Tartrate…2mg Timolol as Maleate…5mg"
	Diary No. Date of R& I & fee	Dy.No 32078 dated 26-09-2018 Rs.20,000/- Dated 26-09-2018
	Pharmacological Group	Antiglaucoma Preparations And Miotics S01EA05 Sympathomimetics in glaucoma therapy Beta blocking agents
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	5ml white LDPE vial with 5ml.Rs. 490.00/-.
	Approval status of product in Reference Regulatory Authorities.	Combigan Brimonidine Tartrate; Timolol Maleate Solution/Drops;Ophthalmic
	Me-too status	061145 Brimonol Ophthalmic Solution M/s Atco Laboratories Karachi
	GMP status	25-9-2019 Panel recommended the renewal of DML
	Remarks of the Evaluator.(VI)	The master formulation mentions Calcium Dobesilate as Monohydrate…526mg, whereas, label claim is Calcium Dobesilate as Monohydrate…500mg. Firm has revised the master formulation as per the label claim without submitting fee.
	Previous Decision:	Decision of 293rd : Deferred for submission of fee for revision of formulation
	Evaluation of PEC (VI)	The firm has submitted Rs.5,000 dated 27-2-2020. Deposit No 1981052
	Decision: Approved the revised master formulation with innovator's specification.	
1969.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Altraz 1mg Tablet
	Composition	Each Tablet Contains: Anastrozole…1mg
	Diary No. Date of R& I & fee	Dy.No 6197 dated 22-01-2019 Rs. 20,000/- Dated 22-01-2019
	Pharmacological Group	Anti-neoplastic agent
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 28's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANASTROZOLE FBM anastrozole 1mg film coated tablet by Southern Cross Pharma Pty Ltd (TGA Approved)
	Me-too status	Anastrozole 1mg Tablet by Novartis (Reg# 066179)
	GMP status	13-11-2018, The panel recommended the grant of DML.
	Remarks of the Evaluator.(VI)	Present as film coated tablet in RRA
	Previous Decision:	Decision of 293rd : Deferred for revision of master formulation as per the innovator's with the submission of requisite fee.
	Evaluation of PEC (VI)	The firm has submitted Rs.5,000 dated 24-2-2020. Deposit No 0849787 and corrected the formulation as per the reference product i.e.

		Each film coated tablet contains: Anastrazole……1mg
	Decision: Approved with protective measures for workers	
1970.	Name and address of manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name + Dosage Form + Strength	Parkomef 50mg/5ml Syrup
	Composition	Each 5ml Contains: Mefenamic Acid…50mg
	Diary No. Date of R& I & fee	Dy No.24908; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti Pyretic, Analgesic & Anti-Inflammatory
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	60ml, , As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	077426 "Constel 50 mg Suspension by Hicon Pharma.
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of the Evaluator.(VI)	Approval of applied formulation in reference regulatory authorities/ agencies which were declared/ approved by the Registration Board in its 275th meeting could not be confirmed. Applied formulation/drug me-too status could not be confirmed.
	Previous Decision:	Decision of 287th : • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along-with registration number, brand name and name of firm.
	Evaluation of PEC (VI)	The firm has submitted Rs.5,000 and Rs.15,000 dated 09-01-2020. Deposit No 2021337 and corrected the formulation as per the reference product i.e. Revised Formulation: Each 5ml suspension contains: Mefenamic Acid…50mg
	Decision: Approved the revised formulation with innovator's specification.	
1971.	Name and address of manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name + Dosage Form + Strength	Parkomef DS 100mg/5ml Syrup
	Composition	Each 5ml Contains: Mefenamic Acid…100mg
	Diary No. Date of R& I & fee	Dy No.24907; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti Pyretic, Analgesic & Anti-Inflammatory
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	60ml, , As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	039179 Deemac Forte Suspension by Delux Chemical, Karachi.
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of the Evaluator.(VI)	Approval of applied formulation in reference regulatory

		authorities/ agencies which were declared/ approved by the Registration Board in its 275th meeting could not be confirmed. □ Applied formulation/drug me-too status could not be confirmed.
	Previous Decision:	Decision of 287th : • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation of PEC (VI)	The firm has submitted Rs.5,000 and Rs.15,000 dated 09-01-2020. Deposit No 2021338 and corrected the formulation as per the reference product i.e. Revised Formulation: Each 5ml suspension contains: Mefenamic Acid…100mg
	Decision: Approved thr revised master formulation with innovator's specification.	
1972.	Name and address of manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name + Dosage Form + Strength	Bactran Syrup (40/200 mg)/5ml
	Composition	Each 5ml Contains: Trimethoprim…40mg Sulphamethoxazole…200mg
	Diary No. Date of R& I & fee	Dy No.24903; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti bacterial
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	50ml, , As per SRO
	Approval status of product in Reference Regulatory Authorities.	Trimethoprim+Sulphamethoxazole 40+200mg By Teva , USA
	Me-too status	002322 "Lobact Paed Suspension By" " Leama Chemi Pharma (Pvt) Ltd,
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of the Evaluator.(VI)	□ Sulfamethoxazole And Trimethoprim Oral Suspension is present in IP2018 and USP 2017. □ International availability and Me too could not be confirmed.
	Previous Decision:	Decision of 287th : • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation of PEC (VI)	The firm has submitted Rs.5,000 and Rs.15,000 dated 09-01-2020. Deposit No 2021340 and corrected the formulation as per the reference product i.e. Revised Formulation:

		Each 5ml suspension contains: Trimethoprim…40mg Sulphamethoxazole…200mg
	Decision: Approved the revised formulation.	
1973.	Name and address of manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name + Dosage Form + Strength	Bactran Syrup (80/400 mg)/5ml
	Composition	Each 5ml Contains: Trimethoprim…80mg Sulphamethoxazole…400mg
	Diary No. Date of R& I & fee	Dy No.24902; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti bacterial
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	50ml, , As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulfatrim Pediatri Sulfamethoxazole; Trimethoprim 200mg/5ml;40mg/5ml Suspension;Oral
	Me-too status	068292 "tran DS Suspension by "Imco Pharmaceutical Labs.,
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of the Evaluator.(VI)	Sulfamethoxazole And Trimethoprim Oral Suspension is present in IP2018 and USP 2017. International availability and Me too could not be confirmed.
	Previous Decision:	Decision of 287th : • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation of PEC (VI)	The firm has submitted Rs.5,000 and Rs.15,000 dated 09-01-2020. Deposit No 2021339 and corrected the formulation as per the reference product i.e. Revised Formulation: Each 5ml suspension contains: Trimethoprim…80mg Sulphamethoxazole…400mg
	Decision: Approved the revised formulation.	
1974.	**Name and address of manufacturer / Applicant**	**M/s. Wilshire Laboratories Pvt Ltd, Lahore.**
	Diary No. Date of R& I & fee	Dy. No.11249; 27-8-2017; Rs.20,000/- (7-8-2017)
	Brand Name +Dosage Form + Strength	Nolazin 500mg tablet
	Composition	Each tablet contains: Ranolazine……..500mg
	Pharmacological Group	Antianginal
	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	10's, 14's, 20's, 30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed

	GMP status	GMP certificate issued on the basis of inspection conducted on 26-9-2017
	Remarks of the Evaluator.(VI)	Approval in RRA and me-too status could not be confirmed
	Previous Decision:	**Decision of 283rd** : Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**.**
	Evaluation of PEC (VI)	Firm has provided original fee Rs.5,000/- deposit slip No. 1955743 dated 27-09-2019 and change the formulation to Revised Formulation: Each extended release tablet contains: Ranolazine…500mg Me-too status:- Rancard XR 500mg Tablet of M/s Searle Reference in RRA contries :- Ranolazine 500mg Tablet of Dreden Germany
	Previous Decision: Deferred for the submission of differential fee of Rs.15,000/-	
	Evaluation by PEC: Firm has deposited Rs. 15000 dated 16-3-2020 Deposit Slip NO. 1984851	
	Decision: Approved the revised formulation with innovator's specification.	
1975.	**Name and address of manufacturer / Applicant**	**M/s. Wilshire Laboratories Pvt Ltd, Lahore.**
	Diary No. Date of R& I & fee	Dy. No.11256; 7-8-2017; Rs.20,000/- (2-8-2017)
	Brand Name +Dosage Form + Strength	Nolazin 1000mg tablet
	Composition	Each tablet contains: Ranolazine……..1000mg
	Pharmacological Group	Antianginal
	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	10's, 14's, 20's, 30's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on the basis of inspection conducted on 26-9-2017
	Remarks of the Evaluator.(VI)	Clarification is required since reference product is extended release whereas applied formulation is immediate release film coated tablet.
	Previous Decision:	**Decision of 284th** : Deferred for clarification of dosage form since reference product is extended release whereas applied formulation is immediate release film coated tablet.
	Evaluation of PEC(VI)	Firm has provided original fee Rs.5,000/- deposit slip No. 1955744 dated 27-09-2019 and change the formulation to Revised Formulation: Each extended release tablet contains: Ranolazine…1000mg **Me-too :-** Ranzol-XR 1000mg Tablet. Reg. No. 61010 **RRA :-** RANEXA® (ranolazine) 1000mg extended-release tablets, filmcoated. **USFDA** approved
	Previous Decision: Deferred for the submission of differential fee of Rs.15,000/-	

	Evaluation by PEC: Firm has deposited Rs. 15000 dated 16-3-2020 Deposit Slip NO. 1984852.	
	Decision: Approved the revised formulation with innovator's specification.	
1976.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt ltd, 124/1 Industrial Estate, KOt Lakhpat Lahore
	Diary No. Date of R& I & fee	Dy.No 324 dated 6-07-2011 Rs.8,000/- Dated 6-07-2011, Rs. 12,000 dated 9-01-2015 (Duplicated fee Chalan)
	Brand Name +Dosage Form + Strength	Zimid 30mg Injection Vial
	Composition	Each vial contains: Lansoprazole….30mg
	Pharmacological Group	PPI
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	1's vial, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	20-7-2020, Firm is operating at satisfactory level of GMP.
	Remarks of the Evaluator.(VI)	Both fee challan are photocopy, Product in RRA nd me-too status could not be confirmed.
	Previous Decision: Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firmEvidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Evaluation by PEC: The firm has submitted RRA product approved in USFDA "Prevacid 30mg lsterile lyophilized powder for injection" and me-too product is Qipro 30mg injection Reg. 015133 by Bosch. Lyophilized section of the firm is not confirmed.	
	Decision: Deferred for the confirmation of manufacturing facility of the applied product.	
1977.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	GALV-MET Tablet 50mg/500mg
	Composition	Each film Coated tablet contains: Vildagliptin…… 50mg Metfromin…….. 500mg
	Diary No. Date of R&I & fee	Dy. No.8811 dated 27/02/2019 Rs 20,000/- 27/02/2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet (50/500, 50/850, 50/1000 mg) film coated tablet by M/s Novartis, TAG Australia Approved
	Me-too status	Galmet 50mg/500mg Tablet by M/S Vision (Reg. No.81905)
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator (VI)	Shelf Life: 18 months The firm has applied for Manufacturer specifications and the product is Not PRESENT in available pharmacopoeia (USP, BP, JP).
	Previous Decision: Deferred for the following:	

	Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee.	
	Evaluation by PEC: The firm has adjusted the weigh of API as :- Metformin Hydrochloride……500mg along with the Rs.5,000.	
	Decision: Approved with innovator's specification.	
1978.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	GALV-MET Tablet 50mg/1000mg
	Composition	Each film Coated tablet contains: Vildagliptin…… 50mg Metfromin…….. 1000mg
	Diary No. Date of R&I & fee	Dy. No.8812 dated 27/02/2019 Rs 20,000/- 27/02/2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet (50/500, 50/850, 50/1000 mg) film coated tablet by M/s Novartis, TAG Australia Approved
	Me-too status	Galmet 50mg/1000mg Tablet by M/S Vision (Reg. No.81907)
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator(VI)	Shelf Life: 18 months The firm has applied for Manufacturer specifications and the product is Not PRESENT in available pharmacopoeia (USP, BP, JP).
	Previous Decision: Deferred for the following: Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee.	
	Evaluation by PEC: The firm has adjusted the weigh of API as :- Metformin Hcl……1000mg along with the Rs.5,000	
	Decision: Approved with innovator's specification.	

1979.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad Contract Manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Form-5 Dy.No 31745 dated 24-09-2018 Rs.50,000/- Dated 24-09-2018
	Brand Name +Dosage Form + Strength	Sonnet 250mg IV Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IV) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Ceftirains 250mg (ceftriaxone Sodium) I.V Injection by Sunrise Pharma (Pvt) Ltd. Reg. No. 78655
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.(VI)	
	Decision of 293rd Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore	
	Decision: Approved	
1980.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad Contract Manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Form-5 Dy.No 31749 dated 24-09-2018 Rs.50,000/- Dated 24-09-2018
	Brand Name +Dosage Form + Strength	Sonnet 1gm IV Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…1gm
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 1 g (IV) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Martixon 1gm (Ceftriaxone sodium) I.V Dry powder Injection by Alkemy Pharma. Reg. No. 70663
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.(VI)	
	Decision of 293rd Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.	
	Decision: Approved	

1981.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad Contract Manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Form-5 Dy.No 31748 dated 24-09-2018 Rs.50,000/- Dated 24-09-2018
	Brand Name +Dosage Form + Strength	Sonnet 500mg IM Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 500mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IM injection by Wnsfeild Pharmaceuticals. Reg. No. 68371
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.(VI)	
	Decision of 293rd Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.	
	Decision: Approved	
1982.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad Contract Manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Form-5 Dy.No 31747 dated 24-09-2018 Rs.50,000/- Dated 24-09-2018
	Brand Name +Dosage Form + Strength	Sonnet 500mg IV Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 500mg (IV) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IV by Wel Wink Pharmaceuticals. Reg. No. 78097
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.(VI)	
	Decision of 293rd Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore	
	Decision: Approved	

1983.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Form-5 Dy.No 32329 dated 27-09-2018 Rs.50,000/- Dated 27-09-2018
	Brand Name +Dosage Form + Strength	Ironofer 20mg/ml Injection
	Composition	Each ml Ampoule Contains: Iron Sucrose complex eq. to elemental Iron.…20mg
	Pharmacological Group	Iron preparation
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	5's x 5ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.(VI)	
	Decision of 293rd Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore	
	Decision: Approved	
1984.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Form-5 Dy.No 32328 dated 27-09-2018 Rs.50,000/- Dated 27-09-2018
	Brand Name +Dosage Form + Strength	Kerol 30mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Ketorolac Tromethamine….30mg
	Pharmacological Group	Iron preparation
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5's x 1ml, 10's x 1ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ketorolac Tromethamine Injection 30mg/ml by M/s Hospira Pharmaceuticals, USFDA approved.
	Me-too status	Toralac Injection 30mg/ml by M/s Vision Pharmaceuticals
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.(VI)	
	Previous Decision of 293rd :Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore	
	Decision: Approved	

1985.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad Contract Manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Diary No. Date of R& I & fee	Form-5 Dy.No 31746 dated 24-09-2018 Rs.50,000/- Dated 24-09-2018
	Brand Name +Dosage Form + Strength	Sonnet 250mg IM Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Unixone Injection (ceftriaxone Sodium) 250mg IM by Caliph Pharmaceuticals (Pvt.) Ltd. Reg. No. 82556
	GMP status	NovaMed: 5th and 27th December 2017, Firm is compliant to good cGMP guidelines. Firm has Cephalosporin injectable section according to this report.
	Remarks of the Evaluator.(VI)	
	Decision of 293rd : Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore	
	Decision: Approved	
1986.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	FINA-GROW Tablet 5mg
	Composition	Each film coated tablet contains: Finasteride…… 5mg
	Diary No. Date of R&I & fee	Dy. No.30422 dated 10/09/2018 Rs 20,000/- 10/09/2018
	Pharmacological Group	Testosterone-5-alpha reductase inhibitor
	Type of Form	From 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×10's , 2×7's price as per SRO
	Approval status of product in Reference Regulatory Authorities	Proscar tablet 5mg by M/s Merck, USFDA approved
	Me-too status	Fenstar tabket 5mg by M/s Hansel Pharma, reg # 64798
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator(VI)	The firm was granted the Tablet (hormone) section vide letter No.F.1-9/89-Lic (Vol-IV) dated 22nd Feb, 2018.
	Decision of 291st : Deferred for followings: • **Clarification required whether the applied product is steroidal hormone or otherwise.** • **Evidence of manufacturing facility of applied product.**	

	Evaluation by PEC: The firm has submitted that the applied drug is synthetic 4-azasteroid compound and is analogue of androgen steroid hormone. Furthermore, it will be manufactured in steroidal hormone section tablet approved by CLB in its 269th meeting
	Decision: Approved with protection facility for workers.

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

b. Deferred Cases

1987.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Diary No. Date of R& I & fee	Dy No. 26848; 06-08-2018 ; Rs.20,000
	Brand Name +Dosage Form + Strength	Vetamec Plus Injection 10ml
	Composition	Each ml Contains: Ivermectin…10mg Vitamin A…250,000 IU Vitamin D3…37500 IU Vitamin E……..25mg
	Pharmacological Group	Anthelmintic + Vitamin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10ml / De-Controlled
	Me-too status	046563 Bovimec Injection By Leads Pharma
	GMP status	26 & 27-7-2019 Conclusion: Based on the above observations their current GMP compliance level is rated as good.
	Remarks of the Evaluator.(VI)	The Me too provided for applied formulation has different strength.
	Previous Decision:	Decision of 292nd Deferred for evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation of PEC	Firm has revised composition as that of me-too : Each ml Contains: Ivermectin…10mg Vitamin A…25,000 IU Vitamin D3…3750 IU Vitamin E……..25mg The firm has submitted Fee Rs.5,000 + Rs.15,000 dated 4-2-2020 Deposit Slip No. 0727578
	Decision: Approved the revised formulation with innovator's specification.	
1988.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Diary No. Date of R& I & fee	Dy No. 26849; 06-08-2018 ; Rs.20,000
	Brand Name +Dosage Form + Strength	Vetamec Plus Injection 50ml
	Composition	Each ml Contains: Ivermectin…10mg Vitamin A…250,000 IU Vitamin D3…37500 IU Vitamin E……..25mg
	Pharmacological Group	Anthelmintic + Vitamin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	50ml / De-Controlled
	Me-too status	046563 Bovimec Injection By Leads Pharma
	GMP status	26 & 27-7-2019 Conclusion: Based on the above observations their current GMP compliance level is rated as good.

	Remarks of the Evaluator.(VI)	The Me too provided for applied formulation has different strength.
	Previous Decision:	Decision of 292nd □ Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation of PEC	Firm has revised composition as that of me-too : Each ml Contains: Ivermectin…10mg Vitamin A…25,000 IU Vitamin D3…3750 IU Vitamin E……..25mg The firm has submitted Fee Rs.5,000 + Rs.15,000 dated 4-2-2020 Deposit Slip No. 0727577
	Decision: Approved the revised formulation with innovator's specification.	
1989.	Name and address of manufacturer / Applicant	M/s Biorific Pharma.Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Diary No. Date of R& I & fee	Dy.No 23248 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Brand Name +Dosage Form + Strength	Enrofic-C Oral Solution
	Composition	Each 1000ml contains: Enrofloxacin……20% Colistin Sulphate……3%
	Pharmacological Group	Antibiotic, Flouroquinolone
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	100ml, 500ml, 1000ml, Plastic Container, As per SRO.
	Me-too status	Could not be confirmed.
	GMP status	31-10-2019, Firm may be considered to be operating at a reasonable level of compliance with GMP guidelines.
	Remarks of the Evaluator.(VI)	Firm has dry powder and liquid syrup section.
	Previous Decision:	Decision of 291st : Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Moreover, the Registration Board referred the case to QA & LT to update GMP status of the firm on priority. Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm (M-293).
	Evaluation of PEC	The firm has submitted me-too reference Enrofic C Oral Liquid (Vet) (Reg # 087965) by M/s FarmAid Group which has been verified.
	Decision: Approved with innovator's specification.	

Case no. 03 Registration applications of newly granted DML or New section (Human)

a. New DML /section

1990.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24691 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	CLARI 125 mg/5 ml Dry Susp
	Composition	Each 5 ml after reconstitution contains: Clarithromycin …….125mg
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60 ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Biaxin granules for oral suspension 125mg/5ml by M/s Abbvie, USFDA approved
	Me-too status	Rethro 125mg/5ml Dry Suspension by M/s Regal Pharmaceutical
	GMP status	New License (Inspection Date: 29-05- 2017, 30-05-2017, 13-07-2017, 03-10-17 and 04-10-2017
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the source of granules used in the formulation.
	Evaluation of PEC	The firm has submitted that the source of granules will be vision pharmaceuticals, Islamabad
	Decision: Approved	
1991.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No.26410 ;(09-12-2019);Rs.20,000/-(09-12-2019)
	Brand Name +Dosage Form + Strength	Clinda 1 % gel
	Composition	Each tube contains Clindamycin (as phosphate) …10 mg (1%w/w)
	Pharmacological Group	Anti-infectives for treatment of acne
	Type of Form	Form-5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	10gm /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duac Once Daily 10mg/g + 50mg/g Gel by M/s GlaxoSmithKline UK Limited (MHRA Approved)
	Me-too status	Clingard- Gel by M/s Hoover Pharmaceuticals (Reg#064533
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator’s.
	Evaluation of PEC	The firm has revised the label claim as : “Each gm contains: Clindamycin as phosphate…..10mg”
	Decision: Deferred for the submission of requisite fee as the label claim has been changed.	
1992.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24697 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	ENCH CREAM 1% w/w
	Composition	Each tube contains: Silver sulfadiazine (USP)….1.0 % w/w
	Pharmacological Group	Antibacterial

	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	50gm / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Silvadene Cream USFDA approved
	Me-too status	Quench 1% Cream by Ferozsons (Reg. No. 013090)
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Silver sulfadiazine …..10mg"
	Decision: Approved	
1993.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24700 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	FUDIC CREAM 2% w/w
	Composition	Each tube contains: Fusidic Acid (BP)…….(2% w/w)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	15gm, 5gm /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fucidin of MHRA Approved
	Me-too status	Ucid 2% Cream by Ciba Pharma (Reg. No. 081566)
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Fusidic acid …..20mg"
	Decision: Approved	
1994.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24703 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	ISOT CREAM 0.05%w/w
	Composition	Each tube contains: Isotretinoin…0.05%
	Pharmacological Group	Retinoid for treatment of acne D10BA01
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	10g, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Isotrex 0.05% Cream by GSK (MHRA Approved)
	Me-too status	Acnecid Creamby Reko Pharmacal
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd :

		Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Isotretinoin …..0.5mg"
	Decision: Approved with innovator's specification.	
1995.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24675;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	PERMETH Cream 5%w/w
	Composition	Each tube contains: Permethrin… (5 %w/w)
	Pharmacological Group	Ectoparasiticides, incl. Scabicides
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30gm, as per SRO
	Approval status of product in Reference Regulatory Authorities.	Permethrin Lotion 5% w/w by M/s GlaxoSmithKline Consumer Healthcare (UK) Trading Limited (MHRA Approved)
	Me-too status	Permilot 5% by M/s Semos
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: permethrin …..50mg"
	Decision: Approved with innovator's specification.	
1996.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No 23164 dated 08-11-2019 Rs. 20,000 Dated 07-11-2019
	Brand Name +Dosage Form + Strength	Terbina 1% Cream
	Composition	Each Tube Contains: Terbinafine Hcl…1%
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO, as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Bina 1.0% Cream by M/s Linta pharmaceuticals (Pvt) Limited , Islamabad (Reg.# 080268)
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Terbinafine HCl …..10mg"
	Decision: Approved with innovator's specification.	
1997.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24677;(22-11-2019);Rs.20,000/-(19-11-2019)

	Brand Name +Dosage Form + Strength	XYLO Gel 2%w/w
	Composition	Each tube contains: Lignocaine HCl 2%
	Pharmacological Group	Local anaesthetic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	15gm, 30gm, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	XYLO CAIN GEL BARRETT HODGSON
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Lignocaine HCl …..20mg"
	Decision: Approved	
1998.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 26404 ;(09-12- 2019);Rs.20,000/-(09 -12-2019)
	Brand Name +Dosage Form + Strength	Lobeta ointment
	Composition	Each tube contains: Clobetasol Propionate…0.05%
	Pharmacological Group	Topical Corticosteroid
	Type of Form	Form-5
	Finished product Specification	Mfg Specs
	Pack size & Demanded Price	15gm; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Dermovate 0.05% W/W ointment of (MHRA approved)
	Me-too status	Primovate ointment Pearl Pharmaceuticals, Islamabad
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Clobetasol Propionate …..0.5mg"
	Decision: Approved with innovator's specification.	
1999.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No.26403 ;(09-12-2019);Rs.20,000/-(09-12-2019)
	Brand Name +Dosage Form + Strength	Lobeta Cream
	Composition	Each tube contains: Clobetasol Propionate…0.05%
	Pharmacological Group	Topical Corticosteroid
	Type of Form	Form-5
	Finished product Specification	Mfg Specs
	Pack size & Demanded Price	10gm; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Dermovate 0.05% W/W Cream of (MHRA approved)
	Me-too status	Primovate Cream Pearl Pharmaceuticals, Islamabad

	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Clobetasol Propionate …..0.5mg"
	Decision: Approved with innovator's specification.	
2000.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24672 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	MYCO Gel 2%w/w
	Composition	Each tube contains: Miconazole Nitrate……..2%
	Pharmacological Group	Antiinfective/ Antiseptic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	20g tube & as per SRO
	Approval status of product in Reference Regulatory Authorities.	(MHRA Approved)
	Me-too status	Miconit Oral Gel 2% of M/s Bio-Labs (Reg. # 054776)
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Miconazole Nitrate …..20mg"
	Decision: Approved	
2001.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24670;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	MYCO-V vaginal Cream 2%w/w
	Composition	Each tube contains: Miconazole Nitrate……..2%
	Pharmacological Group	Anti-infective/ Antiseptic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	20g tube & as per SRO
	Approval status of product in Reference Regulatory Authorities.	(MHRA Approved)
	Me-too status	GYNO DAKTARIN cream 2% of M/s JANSSENCILAG
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Miconazole Nitrate …..20mg"
	Decision: Approved	

2002.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24671 ;(22-11-2019);Rs.20,000/-(19-11-2019))
	Brand Name +Dosage Form + Strength	MYCO Cream 2%w/w
	Composition	Each tube contains: Miconazole Nitrate……..20mg
	Pharmacological Group	Anti-infective/ Antiseptic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10g tube & as per SRO
	Approval status of product in Reference Regulatory Authorities.	(MHRA Approved)
	Me-too status	DAKTARIN cream 2% of M/s JANSSEN-CILAG
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the revision of label claim as per innovator's.
	Evaluation of PEC	The firm has revised the label claim as : "Each gm contains: Miconazole Nitrate …..20mg"
	Decision: Approved	
2003.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24689 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	CIPOSE 125 mg/5 ml Dry Susp
	Composition	After reconstitution Each 5ml contains: Ciprofloxacin hydrochloride eq.to ciprofloxacin….125mg
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	60 ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available as 125mg/5ml suspension but already approved by Registration Board based on domestic needs, dosage for children and its stated quantitative composition in SmPC.
	Me-too status	Novidat 125mg/5ml of Sami Pharmaceuticals
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the source of granules used in the formulation.
	Evaluation of PEC	The firm has submitted that our source of granules will be M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved with innovator's specification.	
2004.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24690 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	CIPOSE 250 mg/5 ml Dry Susp
	Composition	After reconstitution Each 5ml contains: Ciprofloxacin hydrochloride eq.to ciprofloxacin….250mg

	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	60 ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipro 250mg/5ml of Bayer Healthcare,(USFDA)
	Me-too status	Novidat of Sami Pharmaceuticals
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the source of granules used in the formulation.
	Evaluation of PEC	The firm has submitted that our source of granules will be M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved with innovator's specification.	
2005.	Name and address of manufacturer / Applicant	M/S Health Care Pharmaceuticals 40-Km,Lahore Road Multan
	Diary No. Date of R& I & fee	Dy.No. 24692 ;(22-11-2019);Rs.20,000/-(19-11-2019)
	Brand Name +Dosage Form + Strength	CLARI 250 mg/5 ml Dry Susp
	Composition	Each 5 ml after reconstitution contains: Clarithromycin …….250mg
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60 ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Biaxin granules for oral suspension 125mg/5ml by M/s Abbvie, USFDA approved
	Me-too status	Rethro 250mg/5ml Dry Suspension by M/s Regal Pharmaceutical
	GMP status	New License (DML 000905) (Inspection Date: 28/06/2019)
	Remarks of the Evaluator.(VI)	New DML 000905 28/06/2019
	Previous Decision:	Decision of 293rd : Deferred for the source of granules used in the formulation.
	Evaluation of PEC	The firm has submitted that our source of granules will be M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved	

Case no. 06 Registration applications of import cases

b. New Cases (Veterinary)

2006.	**Name and address of Applicant**	**M/s SCHIWO PAKISTAN** **Previous Head Office Address:-**Off. No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad , Multan, Punjab, Pakistan **New Address:-** 11 G, Shah Rukn e Alam Colony, District Multan. The firm has deposited Fee of Rs.5,000/- dated 29-1-2020 for the change in Head office address
	Detail of Drug Sale License	**M/s Schiwo Pakistan** **Address:** 11 G, Shah Rukn e Alam Colony, District Multan. Address of Go-Down:- House no. 24/C, Loha Market, Vehari Road, Near Metro Station, Peoples Colony, District Multan. The license is valid upto 26-Aug-2021
	Name and address of manufacturer	Thinh A Trading and Manufacturing Veterinary Medicine Co (ASIFAC), Road No 5, Giang Dien Industrial park, Trang Bom district, Dong Nai Province, Viet Nam
	Name of exporting country	Viet Nam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 23254 Dated : 05-07-2018
	Fee including differential fee	Rs : 1,00,000 Dated : 05-07-2018
	Brand Name +Dosage Form + Strength	**ASI-FLORFENICOL 20% Liquid (Oral Solution)**
	Composition	Each 1000ml contains: Florfenicol……..200g
	Finished Product Specification	Manufacturer
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Demanded Price	Rs. 9,000/-
	Pack size	1 liter
	International availability	
	Me-too status	Floricol by Inshal Pharma Reg no 073936
	Remarks of the Evaluator.(VI)	• Certificate of free sale is submitted that is valid upto 25-9-2021issued from department of AnimalHealth of Vietnam • Attested GMP certificate of manufacturer issued from Department of animal health and valid upto 2022 is submitted. • Authorization letter from the manufacturer is submitted. • Stability data as per zone 4-A is submitted
	Decision: Approved with innovator's specification and as per import policy for finished product.	

c. Deferred cases

2007.	**Name and address of Applicant**	**M/s The Searle Company Limited, 1st floor, NICL building Abbasi Shaheed Road, karachi**
	Detail of Drug Sale License	**Adress:** M/s The Searle Company Limited, F-319, SITE Karachi **Validity:** 15th May 2021 **Status:** Drug License by wayof Wholesale
	Name and address of manufacturer	M/s BIOLAB Co.Ltd, 625 SOI 7A BANGPOO Industrial Estate, Sukhumvit Road, MOO 4, Prakasa, Muang, Samutprakarn 10280, Thailand **Repacking and Addition of Solvent:** The Searle Company Limited, F-319, SITE, Karachi
	Name and address of marketing authorization holder	M/s BIOLAB Co.Ltd, 625 SOI 7A BANGPOO Industrial Estate, Sukhumvit Road, MOO 4, Prakasa, Muang, Samutprakarn 10280, Thailand
	Name of exporting country	**Thailand**
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.4785 Dated 5/06/2017
	Fee including differential fee	Rs. 100,000/- Dated 5/06/2017
	Brand Name +Dosage Form + Strength	**Dorimax (Doripenem) 500mg Injection (IV infusion)**
	Composition	Each pack contains: Each vial contains: Doripenem monohydrate, sterile powder equivalent to Doripenem…….500mg Solvent: Sterile water for Injection 1ampoule of 10ml
	Finished Product Specification	Manufacturer's
	Pharmacological Group	Antibacterial
	Shelf life	36months
	Demanded Price	As per SRO
	Pack size	A pack of 01 colorless Type I glass vial and 1 sterile water for injection ampoules of 10ml
	International availability	USFDA Approved bur Discontinued. EMA Approved
	Me-too status	Not confirmed
	Detail of certificates attached	Original legalized CoPP Certificate No. 4-2-10-03-20-00220 Certificate Issuing date: 20 March 2020 Certifying Authority: Bureau of Drug Control Food and Drug Administration, Ministry of Public Health, Thailand. Free sale: confirms the free sale of the product in exporting country.
	Remarks of the Evaluator.(VI) Stability studies of 3 batches are conducted at : Accelerated: 6months at 40+-2'C/75+-5%RH Real: 0,3,6,9,12,18,24,30,36 Months at 30+_2'C/75+_5%RH The firm has elaborated complete details of import , re-packing & batch release of finished product Step # 1: Bulk labeled vials of Doripenem injection will be imported from M/s Biolab Co. Ltd. Thailand Step # 2: Purchase of registered solvent (Sterile water for injection 2 ampoules of 10ml) Step # 3: Complete testing will be performed on the vials of Doripenem and solvent. Step # 4: Bulk labeled vials of Doripenem injection and solvent will be re-packed in final unit dose carton. This re-packing activity will be performed in GMP compliant facility located at F-319, S.I.T.E, Karachi havinf DML No. 000016	

	Step #5 QC release & batch release of the final dosage form will be done by the Searle Company limited	
	Previous Decision:	**Decision of 282nd :** • **Deferred for further deliberation.**
	Evaluation by PEC	
	Decision: Approved with innovator's specification and as per import policy for finished product.	

ii. Veterinary

2008.	**Name and address of manufacturer / Applicant**	M/s ICI Pakistan Ltd, ICI House , 5 West Wharf, Karachi
	Detail of Drug Sale License	**Address:** 5 West Wharf, Karachi **Validity:** 19-02-2020 **Status:** Drug License by way of Wholesale.
	Name and address of manufacturer	M/s Intervet Productions SA Rue De Lyons, 27460 Igoville, France
	Name and address of marketing authorization holder	M/s Intervet International BV Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No Dated 26/05/2017
	Fee including differential fee	Rs. 100,000/- Dated 23/02/2018
	Brand Name +Dosage Form + Strength	Exzolt Solution 10mg/ml for use in Drinking Water
	Composition	Each ml contains: Fluralaner…10mg
	Target Specificationie	Chickens (pullets, breeders, layer hen)
	Finished Product Specification	In-House
	Pharmacological Group	Ectoparasitcides
	Shelf life	3 years
	Demanded Price	As per SRO
	Pack size	Bottle of 1 L, 4 L
	International availability	Approved in ANSM
	Me-too status	N/A
	Detail of certificates attached	**Original Legalized COPP** Certificate No. 06/17/113733 Certified by: EMA Free sale: Yes GMP : GMP Complaint Issue Date: 12-10-2017 **Letter of Authorization** M/s Intervet International BV Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands & M/s ICI Pakistan LTD ICI House , 5 West Wharf, Karachi Dated: Nov, 2017
	Remarks of the Evaluator.(VI)	Withdrawal Period Meat and Offal: 14 days

		Eggs: Zero days □ In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing.
	Evaluation by PEC:	Decision of 291st :- Deferred for further deliberation regarding use of applied formulation in chickens. Firm has submitted EPAR stating that Exzolt is a veterinary medicine used to treat poultry red mite (Dermanyssus gallinae) infestation in pullets (Young female chickens), breeders and layer hens.
	Decision of 293rd : Deferred for further deliberation regarding use of applied formulation in chickens	
	Evaluation by PEC:	
	Decision: Deferred for the justification of safety parameters in accordance with the withdrawl period.	

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

a. New cases

b. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2009.	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.	Diamant 25 mg tablet Each film coated tablet contain: Empagliflozin …25mg (Sodium-glucose co-transporter 2 (SGLT2) inhibitors) Manufacturer's Specifications.	Form-5-D Dy. No: 1362 Dated. 10/3/2016 Rs.50,000/- (10/March/2016) 1's.., As per SRO 5's.. As per SRO 10's. As per SRO 20's.., As per SRO 30's.. As per SRO 50's. As per SRO	Jardiance tablet 25 mg by M/s Boehringer Ingelheim (USFDA Approved). GMP inspection report conducted on Last inspection was conducted on 27-08-2018, 05-10-2018, 06-11-2018 Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.

STABILITY STUDY DATA (AD-PEC-VI)	
Drug	Diamant 25 mg tablet
Name of Manufacturer	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore
Manufacturer of API	**Empagliflozin :** M/s Zhejing materials industry chemical group co. Ltd. 25 floor tower A, Zhongda plaza, Zhongshan road, Hangzhou china
API Lot No.	**Empagliflozin:** 20170401

Description of Pack (Container closure system)	Al foil 2x10's		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)		
Batch No.	**T#001**	**T#002**	**T#003**
Batch Size	0.45 kg	0.45 kg	0.45 kg
Manufacturing Date	3-2018	3-2018	3-2018
Date of Initiation	10-3-18	10-3-18	10-3-18
No. of Batches	03		
Date of Submission	13/12/18 (Dy. No. 12527)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate issued to MSN M/s Zhejing Hongyun pharmaceuticals co. Ltd, The said certificate has been issued by Taizhou city no Zhejiang province
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Empagliflozin:** Copy of commercial invoice has been submitted but it is not attested by ADC, DRAP.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Following short comings were convey to the firm via letter No. F.1-1/2018 / PEC- DRAP (AD PEC-VII)

Sr.#	**Deficiency/Observation** (AD-PEC-VI)	**Response by Pharma.**
i.	Submitted GMP certificate of supplier of API was issued by Taizhou city. Provide GMP certificate of the relevant Drug regulatory authority i.e. provincial or federal authority is needed.	New GMP certificate provided, authorized by FDA
ii.	Invoice for importing API is not ADC attested. Clarify	Firm responded that the material was received by the courier but no tracking ID was provided

iii.	In the dossier, in many points e.g. in point 28, velbuvir is mentioned instead of Diamant 25.Clarify.	It's a typo mistaken rectified by the firm
iv.	The commercial invoice is from M/s Zhejing materials industry chemical group co. Ltd. and mentions manufacturer as Zheijiang Hongyuan Pharmaceutical Co. Ltd. Provide the relationship.	Firm provide the statement from the manufacturer that Zhejiang Hongyuan pharmaceuticals Co., Ltd is one of the sub companies of Zheijang Material industry chemical group (ZMICHEM)all the export business would be through ZMICHEM or from Honygyuan
v.	The API quantity imported as per commercial invoice is 0.535 kg. Justify the quantity of API imported which is less than the total of API dispensed for all the three batches (0.45 Kg per batch).	The firm clarify that they had imported 0.535 kg but the overall batch size of diamant 25 mg is 0.45 kg along with excipient and 0.063 kg is the weight of the active for one trial batch.
vi.	Provide reference for assay calculation formula i.e. Assay= Sample Area / Standard Area x Weight of Standard /Weight of Sample x P x 100	Firm claims that they have taken equivalent weight of standard and sample in same dilution that's why concentrations was not mentioned but we have revised complete formula for assay in test method.
vii.	Submit raw data sheets and system suitability sheets of each time point.	For system suitability the tailing factor and theoretical plates are already mentioned in all chromatograms
viii.	The injection volume mentioned in test method of assay and dissolution is 10 µl whereas, in the chromatograms is 20 µl. Justify.	It's a typo error in test method. Correction has been made in test methods and reference was provided.
ix.	The innovators finished product release specifications tests for this dosage form including uniformity of dosage unit. Justify the exemption of these tests.	Firm claim that we have performed the uniformity of dosage unit on all 3 trial batches with previously validated method and results found satisfactory (85%-115%). Documents and chromatograms are provided. Microbial test are also performed on 3 trial batches and results found satisfactory. COA of trail batches are provided.
x.	1st month assay chromatograms for accelerated stability not provided for all the three batches.	**Not provided**
xi.	Stability data sheets of real time analysis not provided.	Provided

(AD-PEC-VI)

Registration Board was approised that the firm has also submitted data for exemption from onsite inspection of submitted stability study data.

Decision: Registration Board decided to defer the case for evaluation of data submitted for exemption from onsite inspection of submitted stability study data.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
2010.	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.	Diamant 10 mg tablet Each film coated tablet contain: Empagliflozin …10 mg	Form-5-D Dy. No: 1363 Dated. 10/3/2016 Rs.50,000/- (10/March/2016)	Jardiance tablet 10 mg by M/s Boehringer Ingelheim (USFDA Approved).

		(Sodium-glucose co-transporter 2 (SGLT2) inhibitors) Manufacturer's Specifications.	1's.., As per SRO 5's.. As per SRO 10's. As per SRO 20's.., As per SRO 30's.. As per SRO 50's. As per SRO	GMP inspection report conducted on Last inspection was conducted on 27-08-2018, 05-10-2018, 06-11-2018 Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.

STABILITY STUDY DATA (AD-PEC-VI)			
Drug	Diamant 10 mg tablet		
Name of Manufacturer	M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore		
Manufacturer of API	**Empagliflozin :** Zheijiang Hongyuan Pharmaceutical Co. Ltd, Chem and API Industrial Zone, Linhai, Zhejiang, China		
API Lot No.	**Empagliflozin:** 20170401		
Description of Pack (Container closure system)	Al-alu foil 2x10's		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.	T001	T002	T003
Batch Size	0.45 kg	0.45 kg	0.45 kg
Manufacturing Date	3-2018	3-2018	3-2018
Date of Initiation	10-3-18	10-3-18	10-3-18
No. of Batches	03		
Date of Submission	13/12/18 (Dy. No. 12526)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes Lot no. 20170401 DOM:12-04-2017 Assay(anhy.): 99.8%
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Empagliflozin: Copy of GMP certificate issued to MSN M/s Zhejing Hongyun pharmaceuticals co. Ltd, The said certificate has been issued by Taizhou city no Zhejiang province. Firm has submitted copy of GMP certificate

		of M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd. Issued by China Food and Drug Administration China. Firm has copy of a statement that Zhejiang Hongyuan Pharmaceutical Co. Ltd., is sub company of Zhejiang Material industry chemical group Co. Ltd. The GMP certificate bearing number ZJ20130070 has been verified from CFDA database that mentions bulk material; atorvastatin.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	
5.	Documents confirming import of API etc.	Empagliflozin alon with working standard and all impurity standards: Copy of commercial invoice has been submitted but it is not attested by ADC, DRAP. Invoice No. 30178567 Dated: 18-05-2017 Quantity: 0.535 Kg DOM: 12-04-2017
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Justify the dissolution specification NLT= Q in 30 minutes. Since dissolution acceptance criteria of innovators product (Jardiance) is NLT Q in 15minutes. (The value of Q in USP general chapters and FDA guideline is 75-80%).

Decision of 293rd meeting: Registration Board decided to defer the cases of Diamant 25 mg tablet & Diamant 10 mg tablet and directed the firm to submit dissolution testing data with specifications of "NLT Q within 15 minutes" at initial and one month time point at both accelerated and real time stability conditions for 2 batches of both Diamant 25 mg tablet & Diamant 10 mg tablet.

Evaluation by PEC (AD-PEC-VI)
: The firm has submitted dissolution testing data of two batches with specification NLQ within 15minutes at initial and one month time point at both accelerated and real time stability conditions.

Registration Board was approised that the firm has also submitted data for exemption from onsite inspection of submitted stability study data.

Decision: Registration Board decided to defer the case for evaluation of data submitted for exemption from onsite inspection of submitted stability study data.

c. Verification of stability study data

d. Exemption from onsite verification of stability data

2011.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	LAGITA Chewable Tablets
	Composition	Each chewable tablet contains: Sodium Alginate BP ……..250mg Sodium Bicarbonate BP ……133.5mg Calcium Carbonate BP ……80mg
	Diary No. Date of R& I & fee	Dy No….50,000/- (04-03-2019)
	Pharmacological Group	Antacid
	Type of Form	Form-5D
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	48's
	Approval status of product in Reference Regulatory Authorities.	Approved in UK Gaviscon Peppermint Flavour Tablets M/s.Reckitt Benckiser Healthcare United Kingdom
	Me-too status	N/A
	GMP status	-

STABILITY STUDY DATA (AD-PEC-VI)

Drug	LAGITA Chewable Tablets		
Name of Manufacturer	M/s SAMI Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.		
Manufacturer of API	**Sodium Alginate:** M/s. Qingdao Bright Moon Seaweed Group Co., Ltd. **Calcium Carbonate:** Sudeep Pharma Pvt. Ltd **Sodium Bicarbonate:** TATA Chemicals Europe Ltd.		
API Lot No.	**Sodium Alginate:** Lot#: H051707038 , Qty. 5000kg **Calcium Carbonate:** Lot#: 18C/CP/080 Qty. 12kg **Sodium Bicarbonate:** Lot#: 0000044143, Qty. 25kg		
Description of Pack (Container closure system)	ALU/PVC		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Lab#01	Lab#02	Lab#03
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	August - 2018	August - 2018	August - 2018
Date of Initiation	September - 2018	September - 2018	September - 2018
No. of Batches	03		
Date of Submission	--		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Yes **Sodium Alginate:** • Lot#: H051707038 **Calcium Carbonate:** • Lot#: 18C/CP/080 **Sodium Bicarbonate:** • Lot#: 0000044143
2.	Approval of API by regulatory authority of	**Sodium Alginate:**

	country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin	M/s. Qingdao Bright Moon Seaweed Group Co., Ltd. **Calcium Carbonate:** Sudeep Pharma Pvt. Ltd **Sodium Bicarbonate:** TATA Chemicals Europe Ltd.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Yes **Sodium Alginate:** Invoice No. BMM17152 Quantity: 5000Kg **Calcium Carbonate:** Invoice No. SPPL/EX021/18-19 Quantity: 12kg **Sodium Bicarbonate:** Invoice No. PM070318 Quantity: 25kg
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATORS

The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administration portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years **TEFOD** *(Tenofovir Alafenamide)* **25mg Tablets** on 28th January, 2019 by following panel: 1. Dr. Rafeeq Alam Khan, Meritorious Professor, Member Registration Board 2. Mr. Aslam Shah, Member Registration Board. 3. Mr. Affan Ali Qureshi, Assistant Director (CDL), DRAP, Karachi.

<table>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>
<table>
<tr><th>API</th><th>Source</th><th>Batch No</th><th>Invoice No</th><th>Received Qty.</th></tr>
<tr><td>Sodium Alginate</td><td>M/s. Qingdao Bright Moon Seaweed Group Co., Ld.</td><td>H051707038</td><td>BMM17152</td><td>5000 Kg</td></tr>
<tr><td>Calcium Carbonate</td><td>M/s. Sudeep Pharma Pvt. Ltd</td><td>18C/CP/080</td><td>SPPL/EX021/18-19</td><td>12Kg</td></tr>
<tr><td>Sodium Bicarbonate</td><td>M/s. TATA Chemicals Europe Ltd.</td><td>0000044143</td><td>PM070318</td><td>25kg</td></tr>
</table>
All above mentioned APIs' documents are cleared by ADC
</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted COAs of Working /reference standard as under:
<table>
<tr><th>API</th><th>Source</th><th>Batch No</th><th>Received Qty.</th></tr>
<tr><td>Sodium Alginate</td><td>M/s. Qingdao Bright Moon Seaweed Group Co., Ld.</td><td>H051707038</td><td>5000 Kg</td></tr>
<tr><td>Calcium Carbonate</td><td>M/s. Sudeep Pharma Pvt. Ltd</td><td>18C/CP/080</td><td>12Kg</td></tr>
<tr><td>Sodium Bicarbonate</td><td>M/s. TATA Chemicals Europe Ltd.</td><td>0000044143</td><td>25kg</td></tr>
</table>
</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP has been submitted issued by regulatory authority of country of origin as under:

<u>Sodium Alginate:</u>
M/s. Qingdao Bright Moon Seaweed Group Co., Ltd.
<u>Calcium Carbonate:</u>
M/s. Sudeep Pharma Pvt. Ltd
<u>Sodium Bicarbonate:</u>
M/s. TATA Chemicals Europe Ltd.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Work instruction for Evaluation of Suppliers and vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Copies of COAs of API have been submitted, detailed as under:
<table>
<tr><th>API</th><th>Batch No</th><th>Received Qty.</th></tr>
<tr><td>Sodium Alginate</td><td>H051707038</td><td>5000Kg</td></tr>
<tr><td>Calcium Carbonate</td><td>18C/CP/080</td><td>12Kg</td></tr>
<tr><td>Sodium Bicarbonate</td><td>0000044143</td><td>25kg</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Firm has been submitted COAs of working /reference standards</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted commercial invoices & COAs of all the excipients used in formulation of LAGITA Chewable Tablets, from relevant manufacturers</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted copy of List of qualified staff their involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of SOP for development of LAGITA Chewable Tablets Stability protocol.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Batch manufacturing Record of the following 3 batches Three stability batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Lab-01</td><td>2500 Tablets</td><td>August 2018</td></tr>
<tr><td>Lab-02</td><td>2500 Tablets</td><td>August 2018</td></tr>
<tr><td>Lab-03</td><td>2500 Tablets</td><td>August 2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has been submitted reconciliation sheet mentioning that 1330 Tablets of each of three batches are remaining</td></tr>
<tr><td colspan="3">QA/QC Data</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts for Real Time and Accelerated Conditions for complete stability Studies of applied formulations.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has applied supplier’s method for analysis of API and has submitted analytical reports, raw data sheets & relevant chromatograms.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product specification & Test method along with analytical method validation report.
Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copies of reports of 06 Months Accelerated and 12 Months Real Time Stability Study (30°C+2 °C, 75+5%) Data of 03 Batches</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of its own Analytical reports for all excipients used in product development of LAGITA Chewable Tablets</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Compatibility study report along with raw data sheets and relevant chromatograms.
It is pertinent to mention here that compatibility studies have been performed after the initiation of stability studies</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data</td><td>Firm has submitted the details of reference product & Sample product are as follows:</td></tr>
</table>

		<table><tr><th>Feature</th><th>Reference Product</th><th>Product of M/s SAMI</th></tr><tr><td>Brand Name</td><td>GAVISCON Tablets</td><td>LAGITA Chewable Tablets</td></tr><tr><td>Batch No.</td><td>617201</td><td>LAB-01</td></tr><tr><td>Exp. Date</td><td>June- 2019</td><td>July 2020</td></tr></table>
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches.

Remarks of Evaluator: (AD-PEC-VI)

Shortcomings communicated	**Response by the firm**
Please clarify the dissolution of Calcium Carbonate & Sodium Bicarbonate in LAGITA Chewable Tablet	As the sodium bicarbonate and Calcium carbonate used to neutralize the gastric acid. In addition, the dissolution test is not available in product specific monograph of antacid tablet (Reference provided)
Submit method of analysis of API along with certificates of analysis generated after receiving the material instead of submitting copies of BP monograph	Method of analysis from vendor and in-house method attached. Certificate of analysis also provided previously but we again attached for reference
Justify why palatability and hardness tests are not performed	Palatability and Hardness testing was performed during stability studies but not incorporated in stability summary Revised stability studies summary and initial test response attached for reference
Documents for procurement of calcium carbonate and sodium bicarbonate are not ADC attested. Clarify please	ADC endorsed invoice of Calcium carbonate and sodium bicarbonate ultra-coarse attached again for your reference. In addition, Sodium bicarbonate Form-7 and Form -3 also attached
Batch no. of sodium alginate not mentioned on commercial invoices. Submit Form 7	Form 3,7 and 5 provided
The batch no. of sodium alginate on COA H051707038 whereas on stability data sheet is 171106-R02. Justify	171106-R02 is the SAMI lab generated batch number, while the H051707038 is the batch number of manufacturer
The date of analysis of sodium alginate and sodium bicarbonate is 30-Aug-2018 and 31-Aug-2018 respectively. Whereas initial testing date mentioned on stability data sheet is 17-09-2018. Clarify the difference of dates. Moreover final date of analysis is 31-Aug-2018 whereas placement of samples in chamber is 22-09-2018. Justify the time gap between initial analysis and date of placement in chamber.	Batch testing has been completed on 03.09.2018 and the date is mentioned on the stability report i.e. 17.09.2018 is the date of reporting, and batch was kept in stability on 22.09.2018 which is in the acceptable time limit of one month, and revised stability
The retention time of initial analysis of sodium alginate in 1.603 min whereas the retention time for 1st month analysis and 6 month analysis is 1.046 min and 0.973 min respectively. Justify	The retention time can be slightly vary in different analysis at different time point but the retention of sample and standard should be same in each analysis which is same in our case.
Dissolution test for chewable table has not been performed. Justify	Dissolution test is not applicable on this formulation because it acts only physical way and have no systemic absorption sodium alginate acts in a physical way forming a raft that folates on the stomach contents and exert a demulcent effect Calcium carbonate and sodium bi carbonate only neutralize the gastric acid
In Product Development master formulation you have submitted that quantity of each API is	Attached

calculated as per their potencies. Submit calculation for potency adjustment of APIs per in house assay	
Provide target weight of tablet	Attached
Justify why impurities has not been performed	Method of analysis used to conduct the stability studies of sodium alginate is on HPLC and there is no additional peak is observed throughout accelerated stability studies
At 6 month time point accelerated stability studies, the tailing factor of sodium alginate standard is greater than 2. Justify	It is in-house developed method and the limit of tailing factor was set to NMT 3.0
The data sheet of Lab-02 mentions initial analysis date 16-07-2018, however batch has been manufactured in August 2018	Typographical error in stability summary of Lab -02 the actual initial date is 03-9-2018. Revised stability summary is attached
Approval of API by regulatory authority of country of origin or GMP certificate of all API's manufacturer issued by regulatory authority of country of origin	GMP attached
In the specification of sodium alginate API you have claimed SAMI's specification, whereas the attached monograph is of BP. Moreover the tests are not similar to the BP. You have exempted the tests of chloride, calcium and changed the specs. of sulphated ash i.e. 30% - 36% and your specs. are 19% - 37%. Justify	Material specifications is BP, which was written with every test and the specification has been revised and shared. Chlorides and Calcium tests performed and included in the specifications, while the test for sulphated Ash was the part of specification as per BP i.e. 30 % to 36 %, revised specifications is submitted
In the specification of sodium bicarbonate you have claimed SAMI's specification, whereas the attached monograph is of BP. You have not included assay of sodium bicarbonate. Justify	RM Material specification is BP and in the specifications lower limit was mentioned and upper specification was missed, specifications has been revised and submitted
In the specification of calcium carbonate, you have claimed SAMI's specification, whereas the attached monograph is of BP. The claimed specifications of assay are NLT 98.5% whereas BP specs. are 98.5% - 100.5%. Justify	RM Material specification is BP and in the specifications lower limit was mentioned and upper specification was missed, specifications has been revised and submitted
Decision: Registration Board decided to approve registration of "LAGITA Chewable Tablet " by M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi. Manufacturer will place first three commercial batches of product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.	

Case no. 08 CTD cases

a) Deferred cases

2012.	**Name, address of Applicant / Marketing Authorization Holder**	M/s The Searle Company Limited., F-319, S.I.T.E, Karachi, Pakistan 75530
	Name, address of Manufacturing site.	**Applicant is Contract manufacturing from** **Name:** M/s NabiQasim Industries (PVT) Limited **Address:** 17/24, Korangi Industrial Area, Korangi, Karachi-Pakistan
	Status of the applicant	□ Manufacturer □ Importer ☑ **Is involved in none of the above (contract giver)**
	Dy No. and date of submission	Dy No. 12686 , : 22-07-2019
	Details of fee submitted	PKR 50,000/-: 22-07-2019
	The proposed proprietary name / brand name	Ezium IV 40mg Lyophilized Powder for Solution for Injection / Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole Sodium eq to Esomeprazole……. 40mg
	Dosage form of applied drug	Injection

	Route of administration	Intravenous
	Pharmacotherapeutic Group of (API)	Proton pump Inhibitor
	Pharmacopoeial reference	Firm has submitted:- "Innovators Specifications"
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Nexium IV 40mg by AstraZeneca LP, USA
	For generic drugs (me-too status)	Nexum 40mg IV infusion
	Valid drug manufacturing license/Drug Sale License	Firm has submitted DML of NabiQasim (DML # 000015)
	Evidence of approval of manufacturing facility / approved section from licensing authority	Firm has submitted a approval letter from CLB of lyophilized/vial General section
	Type of Application	☐ New Drug Product (NDP) ☑ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☑ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	For imported products, please specify one of following:	Not Applicable
	Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976	Domestic Manufacturing
	List of registered products	Not Applicable
	Manufacturer's site master file and credentials (for importers)	Yes
	Identification of signature of authorized persons, Incharge Production, Quality Control & Quality Assurance of manufacturer.	Yes
	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens	Yes
	Description of Batch numbering system	No
	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).	We have a well experienced technical team in our tableting section. We are manufacturing more than 40 products in tablets dosage form in this section.
	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).	Yes
	Commitments	Firm has submitted undertaking/commitments on its letter head
	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.	Yes
	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.	Yes
	Information on Prior-related Applications	Not Applicable
	Electronic Review Package	Yes
	QIS (Quality Information Summary)	Yes
	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	M/s Metrochem API Private Limited, Hyderabad
	b. Approval of manufacturing facility of API by regulatory body of country and validity.	Firm has Submitted GMP certificate of M/s Metrochem API pvt Ltd and it

		is valid till 12-3-2020
	c. Vendor qualification / audit is	☑ **Document based** ☑ Site inspection based
	d. Reason for above point (c)	Already approved vendor for other API's
	MODULE 2: OVERVIEWS & SUMMARIES	
	Drug Substance	Firm has submitted overall summary of drug substance including general information, Manufacture, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, control of Drug Product, Reference standards or materials, container closure system and stability studies.
	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	General information on Structure, Nomenclature are provided
	Manufacture	M/s Metrochem API Private Limited, Unit-I Plot No. 62/C/6, Pipeline Road, Phase-I, IDA, Jeedimetla, Quthbullapur (M), Medchal (Dist) - 500 055 Talangana State, India.
	Characterization	Firm has submitted data.
	Control of drug substance	Firm has submitted data.
	Reference standards or materials	Firm has submitted data.
	Container closure system	Firm has submitted data.
	Stability	Firm has submitted data of 7 batches.
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of Pharmaceutical development, Components of the FPP, formulation development, overages, physicochemical and biological properties.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.
	Control of excipients	Firm has submitted Control of excipients, Specifications, Analytical Procedures, Validation of analytical procedures, Justification of specifications, Excipients of Human or animal origin and Novel excipients
	Control of drug product	Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification.
	Reference standard or materials	Firm has submitted certificate of analysis of reference standards and impurity standards
	Container closure system	TUBULAR GLASS VIAL USP TYPE 1 OUTER DIA 22mm

	Stability	Firm has provided stability study data of 3 batches as per Zone IV-A
	Comparative dissolution profile	Not Applicable
	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Firm has submitted Pharmacology.
	Pharmacokinetics	Firm has submitted Pharmacokinetics.
	Toxicology	Firm has submitted Toxicology.
	MODULE 5: CLINICAL / EFFICACY	

Remarks of the Evaluator.(VI):	**Response of Applicant:**
● Valid GMP certificate of API manufacturer (i.e., Metrochem API Private Ltd.) as mentioned in subsection 1.6.5 is required to be submitted.	● The valid GMP of API manufacturer (i.e. Metrochem API Private Ltd) is submitted it is valid till 12-3-2020
● You have referred various sections of QOS to module 3. It is required that you should summarize all the information as specified in section 2.3.P.3 to 2.3.P.8 of module II.	● The summarize all the information a specified in Section 2.3.P.3 to 2.3.P.8 Module II is submitted.
● The applied formulation contains Mannitol. However reference product in MHRA does not mention such excipient.	● Mintakenly the tentative formulation contains mannitol. Therefore we are enclosing Blank BMR for review purpose.
● Finished pharmaceutical product manufacturer's certificate of analysis of API with API lot numbers is required to be submitted.	● Finished Pharmaceutical product Manufacturer's Certificate of Analysis of API with API Lot Numbers is submitted
● Although you have used overkill cycle for sterilization and de-pyrogenation process, studies are required for the heat distribution and penetration and submit the data.	● The Studies for heat distribution and Penetration alongwith required data is submitted.
● Since this product is going to be diluted with various IV solutions, it is therefore very important to have compatibility studies upto the recommended time periods.	● The Compatibility studies upto recommended time period with diluents are provided.
● You have not submitted process validation data by referring that it is a me-too product. Relevant data is required as specified I 3.2.P.3.5 of Module 3.	● The Process Validation alongwith required data is provided.
● You have not submitted validation of analytical procedures under control of drug product. It is very important to submit the data as specified in 3.2.P.5.3 especially where in-house method is developed.	● Validation of Analytical Procedure under control of Drug is submitted.
● You have not submitted supporting documents like raw data sheets and chromatograms against submitted stability summary sheets of applied formulation.	● The Stability studies along with supporting documents and Chromatograms has been submitted

Decision of 293rd:: Deferred for panel verification of mannitol in formulation or otherwise.

Evaluation by PEC:
Verification of Authenticity of formulation of Esomax (Esomeprazole) 40mg IV Injection by M/s. Martin Dow Limited, K.I.A. Karachi.

Reference No: F.1-2/2020-PEC dated 02nd January, 2020.
Investigation Date and Time: 6th January, 2020. (Afternoon)
Investigation Site: Factory premises of M/s. Nabi Qasim Industries Pvt. Ltd. Karachi.

Background:
The Pharmaceutical Evaluation and Registration Division considered the application of M/s Martin Dow Limited for registration of Esomax (Esomeprazole) 40mg IV Injection manufactured by M/s Nabi Qasim

Industries on contract manufacturing basis. The Chairman Registration Board constituted a two member panel for investigation of the query mentioned in the scope of investigation:

Composition of Panel:

1. Ms. Hira Bhutto, Assistant Director, CDL, DRAP, Karachi
2. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

On Site Investigation/verification of the following point:

1. Verification of formulation for use of mannitol as the firm initially submitted the formulation containing mannitol and upon query for justification they replied that their formulation do not contain mannitol and their formulation is as per innovator's product.

Details of Investigation:

1. The panel visited the firm, reviewed the batch records including dispensing, production records, log books, the available software (ERP), audit trail for the ERP on the system and found that mannitol was never dispensed for the manufacturing of any batch of the said product:
2. As per record available with the firm the formulation of product is as under:
    a. Esomeprazole Sodium (Pyrogen Free) 42.5mg/vial
    b. Di Sodium EDETATE (Injectable Grade) 1mg/vial
    c. Sodium Hydroxide (Injectable Grade) 0.7mg/vial
    d. Water for injection q.s. 2.1ml

Conclusion & Recommendation:

1. On the basis of the site visit, documents reviewed and personnel inquired the panel reached on conclusion that the firm has not used mannitol in their formulation and their formulation is as per innovator product.

Therefore, in opinion of the panel the firm may kindly be granted registration of the product with current formulation if there is no more query.

(AD-PEC-VI)

Decision: Registration Board decided to approve registration of Ezium IV 40mg Lyophilized Powder for Solution for Injection / Infusion with Innovator's specifications by The Searle Company Limited Karachi.

2013.	Name, address of Applicant / Marketing Authorization Holder	M/s The Searle Company Limited., F-319, S.I.T.E, Karachi, Pakistan
	Name, address of Manufacturing site.	Applicant is Contract manufacturing from Name: NabiQasim Industries (PVT) Limited Address: 17/24, Korangi Industrial Area, Korangi, Karachi-Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☑ Is involved in none of the above (contract giver)
	Dy No. and date of submission	Dy No. 12685 , : 22-07-2019
	Details of fee submitted	PKR 50,000/-: 22-07-2019
	The proposed proprietary name / brand name	Lovanzo IV 40mg Lyophilized Powder for Solution for Injection / Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole sodium eq to Omeprazole…… 40mg Injection
	Dosage form of applied drug	Injection
	Route of administration	Intravenous
	Pharmacotherapeutic Group of (API)	Proton pump Inhibitor
	Pharmacopoeial reference	Firm has submitted:- "Innovators Specifications"
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Omeprazole IV 40mg by AstraZeneca LP, USA
	For generic drugs (me-too status)	Risek 40mg IV Infusion
	Valid drug manufacturing license/Drug Sale License	Firm has submitted DML of NabiQasim (DML # 000015)

	Evidence of approval of manufacturing facility / approved section from licensing authority	Firm has submitted
	Type of Application	□ New Drug Product (NDP) ☑ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☑ **Domestic sale** □ Export sale □ Domestic and Export sales
	For imported products, please specify one of following:	Not Applicable
	Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976	Domestic Manufacturing
	List of registered products	Not Applicable
	Manufacturer's site master file and credentials (for importers)	Yes
	Identification of signature of authorized persons, Incharge Production, Quality Control & Quality Assurance of manufacturer.	Yes
	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens	Yes
	Description of Batch numbering system	No
	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).	We have a well experienced technical team in our tableting section. We are manufacturing more than 40 products in tablets dosage form in this section.
	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).	Yes
	Commitments	Firm has submitted undertaking/commitments on its letter head
	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.	Yes
	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.	Yes
	Information on Prior-related Applications	Not Applicable
	Electronic Review Package	Yes
	QIS (Quality Information Summary)	Yes
	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	● The valid GMP of API manufacturer (i.e. Metrochem API Private Ltd) is submitted it is valid till 12-3-2020
	b. Approval of manufacturing facility of API by regulatory body of country and validity.	Firm has Submitted
	c. Vendor qualification / audit is	☑ **Document based** ☑ Site inspection based
	d. Reason for above point (c)	Already approved vendor for other API's
	MODULE 2: OVERVIEWS & SUMMARIES	
	Drug Substance	Firm has submitted overall summary of drug substance including general information,

		Manufacture, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, control of Drug Product, Reference standards or materials, container closure system and stability studies.
	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	General information on Structure, Nomenclature are provided
	Manufacture	M/s Metrochem API Private Limited, Unit-I Plot No. 62/C/6, Pipeline Road, Phase-I, IDA, Jeedimetla, Quthbullapur (M), Medchal (Dist) - 500 055 Talangana State, India.
	Characterization	Firm has submitted data.
	Control of drug substance	Firm has submitted data.
	Reference standards or materials	Firm has submitted data.
	Container closure system	Firm has submitted data.
	Stability	Firm has submitted data of 7 batches.
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of Pharmaceutical development, Components of the FPP, formulation development, overages, physicochemical and biological properties.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.
	Control of excipients	Firm has submitted Control of excipients, Specifications, Analytical Procedures, Validation of analytical procedures, Justification of specifications, Excipients of Human or animal origin and Novel excipients
	Control of drug product	Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification.
	Reference standard or materials	Firm has submitted certificate of analysis of reference standards and impurity standards
	Container closure system	TUBULAR GLASS VIAl USP TYPE 1 OUTER DIA 22mm
	Stability	Firm has provided stability study data of 3 batches as per Zone IV-A
	Comparative dissolution profile	Not Applicable
	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Firm has submitted Pharmacology.
	Pharmacokinetics	Firm has submitted Pharmacokinetics.
	Toxicology	Firm has submitted Toxicology.
	MODULE 5: CLINICAL / EFFICACY	

Remarks of the Evaluator.(VI):	Response of Applicant:
● Valid GMP certificate of API manufacturer (i.e., Metrochem APJ Private Ltd.) as mentioned in subsection 1.6.5 is required to be submitted.	● The valid GMP of API manufacturer (i.e. Metrochem API Private Ltd) is submitted it is valid till 12-3-2020
● You have referred various sections of QOS to module 3. lt is required that you should summarize all the information as specified in section 2.3.P.3 to 2.3.P.8 of module 11.	● The summarize all the information as specified in section 2.3.P.3 to 2.3.P.8 , Module II is enclosed as Annexure-B
● Finished pharmaceutical product manufacturer's certificate of analysis of API with API lot numbers is required to be submitted.	● Finished Pharmaceutical product Manufacturer's Certificate of Analysis of API with API Lot Numbers is submitted
● Although you have used overkill cycle for sterilization and de-pyrogenation process, studies are required for the heat distribution and penetration and submit the data.	● The Studies for heat distribution and Penetration alongwith required data is submitted.
● Since this product is going to be diluted with various IV solutions, it is therefore very important to have compatibility studies upto the recommended time periods.	● The Compatibility studies upto recommended time period with diluents are provided.
● You have not submitted process validation data by referring that it is a me-too product. Relevant data is required as specified I 3.2.P.3.5 of Module 3.	● The Process Validation alongwith required data is provided.
● You have not submitted validation of analytical procedures under control of drug product. It is very important to submit the data as specified in 3.2.P.5.3 especially where in-house method is developed.	● Validation of Analytical Procedure under control of Drug is submitted.
● You have not submitted supporting documents like raw data sheets and chromatograms against submitted stability summary sheets of applied formulation.	● The Stability studies along with supporting documents and Chromatograms has been submitted

Decision of 293rd : The Board deferred the case for further deliberation regarding clarification of the reference product's composition**.**

Evaluation by PEC:

Composition of Reference Product PAR MHRA

Ingredient	Function
Omeprazole	Active
Sodium hydroxide 1N	Excipient
Disodium edetate	Excipient

Decision: Registration Board decided to approve registration of Lovanzo IV 40mg Lyophilized Powder for Solution for Injection / Infusion with Innovator's specifications by The Searle Company Limited Karachi.

2014.	**Name, address of Applicant / Marketing Authorization Holder**	M/s The Searle Company Limited., F-319, S.I.T.E, Karachi, Pakistan
	Name, address of Manufacturing site.	**Applicant is Contract manufacturing from** **Name:** NabiQasim Industries (PVT) Limited **Address:** 17/24, Korangi Industrial Area, Korangi, Karachi-Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☑ **Is involved in none of the above (contract giver)**
	Dy No. and date of submission	Dy No. 12684 , : 22-07-2019
	Details of fee submitted	PKR 50,000/-: 22-07-2019
	The proposed proprietary name / brand name	Panzium IV 40mg Lyophilized Powder for Solution for Injection / Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Pantoprazole sodium eq to Pantoprazole …..40mg
	Dosage form of applied drug	Injection

	Route of administration	Intravenous
	Pharmacotherapeutic Group of (API)	Proton pump Inhibitor
	Pharmacopoeial reference	Firm has submitted:- "Innovators Specifications"
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Protonix IV 40mg by Wyeth Pharmaceutical LLC
	For generic drugs (me-too status)	Zotonix 40mg IV Infusion
	Valid drug manufacturing license/Drug Sale License	Firm has submitted DML of NabiQasim (DML # 000015)
	Evidence of approval of manufacturing facility / approved section from licensing authority	Firm has submitted
	Type of Application	☐ New Drug Product (NDP) ☑ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☑ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, please specify one of following:	Not Applicable
	Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976	Domestic Manufacturing
	List of registered products	Not Applicable
	Manufacturer's site master file and credentials (for importers)	Yes
	Identification of signature of authorized persons, Incharge Production, Quality Control & Quality Assurance of manufacturer.	Yes
	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens	Yes
	Description of Batch numbering system	No
	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).	We have a well experienced technical team in our tableting section. We are manufacturing more than 40 products in tablets dosage form in this section.
	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).	Yes
	Commitments	Firm has submitted undertaking/commitments on its letter head
	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.	Yes
	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.	Yes
	Information on Prior-related Applications	Not Applicable
	Electronic Review Package	Yes
	QIS (Quality Information Summary)	Yes
	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	M/s Metrochem API Private Limited, Hyderabad
	b. Approval of manufacturing facility of API by regulatory body	Firm has Submitted

	of country and validity.	
	c. Vendor qualification / audit is	☑ Document based ☑ Site inspection based
	d. Reason for above point (c)	Already approved vendor for other API's
	MODULE 2: OVERVIEWS & SUMMARIES	
	Drug Substance	Firm has submitted overall summary of drug substance including general information, Manufacture, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, control of Drug Product, Reference standards or materials, container closure system and stability studies.
	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	General information on Structure, Nomenclature are provided
	Manufacture	M/s Metrochem API Private Limited, Unit-I Plot No. 62/C/6, Pipeline Road, Phase-I, IDA, Jeedimetla, Quthbullapur (M), Medchal (Dist) - 500 055 Talangana State, India.
	Characterization	Firm has submitted data.
	Control of drug substance	Firm has submitted data.
	Reference standards or materials	Firm has submitted data.
	Container closure system	Firm has submitted data.
	Stability	Firm has submitted data of 7 batches.
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of Pharmaceutical development, Components of the FPP, formulation development, overages, physicochemical and biological properties.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.
	Control of excipients	Firm has submitted Control of excipients, Specifications, Analytical Procedures, Validation of analytical procedures, Justification of specifications, Excipients of Human or animal origin and Novel excipients
	Control of drug product	Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification.
	Reference standard or materials	Firm has submitted certificate of analysis of reference standards and impurity standards
	Container closure system	TUBULAR GLASS VIAL L0ml USP TYPE 1 OUTER DIA 22mm

	Stability	Firm has provided stability study data of 3 batches as per Zone IV-A
	Comparative dissolution profile	Not Applicable
	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Firm has submitted Pharmacology.
	Pharmacokinetics	Firm has submitted Pharmacokinetics.
	Toxicology	Firm has submitted Toxicology.
	MODULE 5: CLINICAL / EFFICACY	

Remarks of the Evaluator.(VI):	**Response of Applicant:**
● Quantitative composition of applied formulation contains Mannitol as mentioned in 2.3.P.3.2. However, reference product Protium i.v 40mg lnjection approved in MHRA does not mention such excipient. Justification / Clarification is required and also the compatibility studies of APl with this excipient is required. ● Valid GMP certificate of API manufacturer (i.e., Metrochem API Private Ltd.) as mentioned in subsection 1.6.5 is required to be submitted. ● You have referred various sections of QOS to module 3. It is required that you should summarize all the information as specified in section 2.3.P.3 to 2.3.P.8 of module 11. ● Finished pharmaceutical product manufacturer's certificate of analysis of AP! with API lot numbers is required to be submitted. ● You have not submitted process validation data by referring that it is a me-too product. Relevant data is required as specified in 3.2.P.3.5 of Module 3. ● You have not submitted validation of analytical procedures under control of drug product. It is very important to submit the data as specified 111 3.2.P.5.3 especially where in-house method is developed. ● You have not submitted supporting documents like raw data sheets and chromatograms against submitted stability summary sheets of applied formulation.	● Pantoprazole 40mg Powder for Solution for Injection which is approved in MHRA by Ms. Accord HealthCare, UK also contains Mannitol as an excipients. Copy form Internet is enclosed as Annexure – A. In Lyophilized preparations, Mannitol (20-90% w/w) has been included as a carrier to produce a stiff, homogenous cake that improves the appearance of the lyophilized plug in a vial. A pyrogen free form is available specifically for this use. ● The Valid GMP of API manufacturer (i.e. Metrochem API Private Limited) is valid up to 3/2020 ● This summarize all the information as specified in Section 2.3.P.3 to 2.3.P.8 Module II is enclosed as Annexure – C. ● Finished pharmaceutical product manufacturer's Certificate of Analysis of AP! with AP! Lot umbers is enclosed as Annexure - '·E'· ● The process validation alongwith required data is enclosed a Annexure - "G". • Validation of Analytical procedure under control of drug is enclosed as Annexure - "I". ● The stability studies alongwith supporting documents and chromatograms is enclosed as Annexure - "J"

Decision: The Board deferred the case for further deliberation regarding clarification of the reference product's composition.

Evaluation by PEC:

https://mhraproductsproduction.blob.core.windows.net/docs/b9c20f692c254952e6127d1d9067d06ff17e2561

PAR of MHRA of Pantaprozole 40mg powder for solution for injection has excipients as below:

Ingredients	**Function**
Pantoprazole Sodium sesquihydrate	Active
Sodium Citrate Dihydrate	Excipient
Sodium Hydroxide	Excipient (For pH adjustment)
Mannitol	Excipient

Decision: Registration Board decided to approve registration of Panzium IV 40mg Lyophilized Powder for Solution for Injection / Infusion with Innovator's specifications by The Searle Company Limited Karachi.

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

a. New cases

2015.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Roflu 500 µg Tablet
	Composition	"Each Film Coated Tablet Contains: Roflumilast…500 µg "
	Diary No. Date of R& I & fee	Dy.No 40345 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Other systemic drugs for obstructive airway diseases R03DX07
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, 14's, 28's, 30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Daxas Tablet EMA Approved
	Me-too status	NA
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic hence, stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.	
2016.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Canmet 150/500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Canagliflozin as Hemihydrate…150mg Metformin HCl…500mg"
	Diary No. Date of R& I & fee	Dy.No 40336 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD16
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x30's,As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	INVOKAMET® (canagliflozin and metformin hydrochloride tablet USFDA Approved with boxwarning.
	Me-too status	NA
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• The signature of applicant is missing on Form 5. • It is a new molecule/subsequent generic hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for the following: • **Submit stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submit signed application alongwith signed undertakings.**	
2017.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Pirfen 801mg Tablet

	Composition	"Each film coated tablet Contains: Pirfenidone…801mg"
	Diary No. Date of R& I & fee	Dy.No 40338 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Immunosuppressants L04AX05
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	4x21's 1 bottle containing 90 tablets, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	ESBRIET® (pirfenidone) capsules and film-coated tablets USFDA Approved.
	Me-too status	NA
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• Belongs to L4.Hence, separate section is required. • It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.	
2018.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	AVN-Plus 10/10mg Tablet
	Composition	"Each delayed release film coated tablet contains: Doxylamine Succinate…10mg Pyridoxine HCL…10mg"
	Diary No. Date of R& I & fee	Dy.No 40343 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Antihistamines for Systemic Use, Vitamin
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x30, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Xonvea 10 mg/10 mg gastro-resistant (film coated) MHRA Approved.
	Me-too status	75838 Brand Name: Vomipreg Tablet Manufacturer Name : Nexus Pharma,
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• Evidence of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Firms Response Firm has revised their formulation from immediate release to delayed release tablet with submission of Rs, 5000/-. Shortcoming • The form 5 refers to Annexure A to D but the relevant data has not been submitted. Firms Response Annexure A to D has not been provided by the firm.
	Decision: Deferred for submission of application with all its annexure.	

2019.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Tapen 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Tapentadol HCl eq to Tapentadol…50mg"
	Diary No. Date of R& I & fee	Dy.No 40333 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Opioid Analgesic N02AX06
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	TRADENAME™ (tapentadol) immediate release oral tablets USFDA Approved
	Me-too status	Couldnot be confirmed.
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• Signature of applicant missing on Form 5. • The master formulation mentions" Canagliflozain" instead of "Tapentadol". • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.** • **Submit signed application on Form 5 alongwith master formulation of applied formulation.**	
2020.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Ketero 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ketorolac Tromethamine…10mg"
	Diary No. Date of R& I & fee	Dy.No 40344 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Acetic acid derivatives and related substances,NSAID M01AB15
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Toradol oral tablets (ketorolac tromethamine tablets) USFDA Approved.
	Me-too status	060804 Brand Name: Kelac Manufacturer Name: Rotex Pharma (Pvt.) Ltd. (Formerly Rotex Medica)
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• The signature of applicant is missing on Form 5.
	Decision: Deferred for submission of signed application on Form 5.	

2021.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Nife 10mg Capsule
	Composition	"Each Capsule Contains: Nifedipine…10mg"
	Diary No. Date of R& I & fee	Dy.No 40339 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Selective Calcium Channel Blockers With Mainly Vascular Effects Dihydropyridine derivatives C08CA05
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	004162 Brand Name:ADALAT 10MG CAP Manufacturer Name:BAYER
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• Signature of applicant missing on Form 5. • Evidence of international availability as immediate release capsule in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for the following: • **Submission of signed application of applied formulation on Form 5.** • **Evidence of international availability of applied formulation i.e. "Nifedipine 10mg immediate release capsule" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
2022.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Canglf 300mg Tablet
	Composition	"Each Film Coated Tablet Contains: Canagliflozin as Hemihydrate…300mg"
	Diary No. Date of R& I & fee	Dy.No 40335 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK02
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	7's,14's,28's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Invokana USFDA Approved.
	Me-too status	NA
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic hence, stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	

2023.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Enox Tablet 400mcg
	Composition	"Each Film Coated Tablet Contains: Enoxacin Sesquihydrate…400mcg"
	Diary No. Date of R& I & fee	Dy.No 40334 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Fluoroquinolones J01MA04
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	20's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA.
	Me-too status	010174; Enoxabid 400mg Tab M/s Abbott
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• The signature of applicant is missing on Form 5. • Initially firm has applied for "Each Film Coated Tablet Contains: Enoxacin Sesquihydrate…400µg". Now, firm has submitted "Each Film Coated Tablet contains: Enoxacin Sesquihydrate…400mg" and the master formulation mentions :"Each Film Coated Tablet contains: Enoxacin Sesquihydrate…400mcg".
	Decision: Deferred for the following: • **Submission of signed application of applied formulation on Form 5.**	
2024.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Telam Tablet 5/40mg
	Composition	"Each Tablet Contains: Amlodipine as besylate…5mg Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy.No 40330 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers C09DB01
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use USFDA Approved with box warning.
	Me-too status	66946; Brand Name: AM-Telsan Manufacturer Name:Hilton Pharma (Pvt.) Ltd.
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• The form 5 refers to Annexure A to D but the relevant data has not been provided. • Revision of formulation to bilayer tablet as per the reference product along with submission of fee for the revision of formulation and evidence of bilayer tablet machine. Firms Response We are working to collect data as required by your good

		office to fulfill the requirement for registration.
	Decision: Deferred for the following: • **Submit evidence of approval of applied formulation in reference regulatory agencies as single layer tablet or otherwise revision of applied formulation to bilayer tablet in line with reference product alongwith submission of requisite fee and also evidence of availability of tablet bilayer machine.** • **Submit complete application alongwith all its annxure.**	
2025.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Telam Tablet 10/40mg
	Composition	"Each Tablet Contains: Amlodipine as besylate…10mg Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy.No 40332 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers C09DB01
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use USFDA Approved with box warning.
	Me-too status	066945 Brand Name: Amtas 10mg +40mg Tablet Manufacturer Name: Getz Pharma (Pvt) Ltd.
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• The form 5 refers to Annexure A to D but the relevant data has not been provided. • Revision of formulation to bilayer tablet as per the reference product along with submission of fee for the revision of formulation and evidence of bilayer tablet machine. Firms Response We are working to collect data as required by your good office to fulfill the requirement for registration.
	Decision: Deferred for the following: • **Submit evidence of approval of applied formulation in reference regulatory agencies as single layer tablet or otherwise revision of applied formulation to bilayer tablet in line with reference product alongwith submission of requisite fee and also evidence of availability of tablet bilayer machine.** • **Submit complete application alongwith all its annxure.**	
2026.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Telam Tablet 5/80mg
	Composition	"Each Tablet Contains: Amlodipine as besylate…5mg Telmisartan…80mg"
	Diary No. Date of R& I & fee	Dy.No 40331 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers C09DB01
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use USFDA Approved with box warning.
	Me-too status	066944 Brand Name: Amtas 5mg +80mg Tablet Manufacturer Name: Getz Pharma (Pvt) Ltd.
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• The form 5 refers to Annexure A to D but the relevant data has not been provided. • Revision of formulation to bilayer tablet as per the reference product along with submission of fee for the revision of formulation and evidence of bilayer tablet machine. Firms Response We are working to collect data as required by your good office to fulfill the requirement for registration.
	Decision: Deferred for the following: • **Submit evidence of approval of applied formulation in reference regulatory agencies as single layer tablet or otherwise revision of applied formulation to bilayer tablet in line with reference product alongwith submission of requisite fee and also evidence of availability of tablet bilayer machine.** • **Submit complete application alongwith all its annxure.**	
2027.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Coblmn 500mcg Tablet
	Composition	"Each sugar coated tablet contains: Mecobalamin…500mcg"
	Diary No. Date of R& I & fee	Dy.No 40341 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Vitamin B12.
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	30's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	PMDA Approved sugar coated
	Me-too status	081876; Brand Name: Heam 500 mcg Tablet Manufacturer Name: Linear Parma,
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• The signature of applicant is missing on Form 5. • The applied formulation is sugar coated tablet whereas, master formulation and manufacturing method is of film coated tablet.
	Decision: Deferred for the following: • **Submit master formulation & manufacturing method of relevant formulation which is mecobalamin 500mcg sugar coated tablet.** • **Submit signed application on Form 5.**	
2028.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Nimo 30mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nimodipine…30mg"

	Diary No. Date of R& I & fee	Dy.No 40337 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Selective Calcium Channel Blockers With Mainly Vascular Effects C08CA06 Dihydropyridine derivatives
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	30's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Nimotop MHRA Approved
	Me-too status	046975 "Nimopro Tablets 30mg. "M/s. Pulse Pharmaceutical,Mozay Badoke, Raiwind Road,Lahore.
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2029.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Lisin-H Tablet 20/12.5mg
	Composition	"Each Tablet Contains: Lisinopril as dihydrate…20mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 40342 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	C09BA03 ACE inhibitors and diuretics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	28's, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Zestoretic uncoated tablets. USFDA Approved with box warning.
	Me-too status	081496 Co-Zairl 20mg Tablet M/s PPP Karachi . .
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	The signature of applicant missing on Form 5.
	Decision: Approved.	
2030.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore"
	Brand Name +Dosage Form + Strength	Cinit Syrup 1mg/5ml
	Composition	"Each 5ml contains: Cinitapride as hydrogen tartrate…1mg"
	Diary No. Date of R& I & fee	Dy.No 40340 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Propulsives A03FA08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	120ml amber glass/plastic bottle, As per SRO,10% less then brand leader.
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg / 5 ml Oral solution by ALMIRALL, SA (Spain Approved)

	Me-too status	073656 Brand Name:Cinipride 1mg/5ml Syrup Manufacturer Name: Kaizen Pharmaceuticals .
	GMP status	13-02-2020 Firm was GMP Compliant on the day of inspection.
	Remarks of the Evaluator (V)	• Oral Syrup Section is present.
	Decision: Approved as per innovator's specification.	
2031.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Clomi Capsules 50mg
	Composition	"Each Capsule Contains: Clomiphene Citrate…50mg"
	Diary No. Date of R& I & fee	Dy.No 41723 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Ovulation stimulants, synthetic ATC code: G03BG02
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Clomid™ 50mg Tablets MHRA Approved.
	Me-too status	010250 Brand Name: PROLIFEN CAP Manufacturer Name: (CHIESI ITALY) al-markaz
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as submitted evidence is of tablet while applied formulation is capsule.	
2032.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Tamso Capsules 0.4mg
	Composition	"Each Capsule Contains: Tamsulosin HCL…0.4mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 41715 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Alpha-adrenoreceptor antagonists. ATC code: G04C A02. Preparations for the exclusive treatment of prostatic disease.
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	050392: Brand Name: Tamsolin 0.4mg Capsule Manufacturer Name: Getz Pharma, Karachi
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of

		today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	• The strength on Form 5 mentions "Each tablet Contains:Tamsulosin 0.4mg" whereas, rest of the dossier mentions capsule. • Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.
	Decision: Deferred for the following: • **Submit COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.** • **Submit fee challan for relevant formulation.**	
2033.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Maritrax Capsule 250mg
	Composition	"Each Tablet Contains: Tranexamic Acid…250mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 41713 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antifibrinolytics B02AA02
	Type of Form	Form 5
	Finished product Specification	JP Specs
	Pack size & Demanded Price	2x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Tranex Company: MALESCI ISTITUTO FARMACOBIOLOGICO SPA AIFA Approved.
	Me-too status	020510 Brand Name :Aneptil Capsules Manufacturer Name:Alina Combine Pakistan (Pvt) Ltd,
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	• The strength mentioned on Form 5 is "Each tablet Contains: Tranexamic acid 250mg" whereas, rest of the dossier mentions capsule and composition mentions "Each delayed release capsule mentions Tranexamic acid…250mg"
	Decision: Deferred for clarification of dosage form of applied form & submission of all relevant documents accordingly.	
2034.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Maritrax Capsule 500mg
	Composition	"Each Tablet Contains: Tranexamic Acid…500mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 41713 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antifibrinolytics B02AA02
	Type of Form	Form 5
	Finished product Specification	JP Specs

	Pack size & Demanded Price	2x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Tranex Company: MALESCI ISTITUTO FARMACOBIOLOGICO SPA AIFA Approved.
	Me-too status	020511 Brand Name :Aneptil Capsules Manufacturer Name:Alina Combine Pakistan (Pvt) Ltd,
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	• The strength mentioned on Form 5 is "Each tablet Contains: Tranexamic acid 500mg" whereas, rest of the dossier mentions capsule and composition mentions "Each delayed release capsule mentions Tranexamic acid…500mg".
	Decision: Deferred for clarification of dosage form of applied form & submission of all relevant documents accordingly.	
2035.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Desimax Tablets 5mg
	Composition	"Each film coated tablet Contains: Desloratadine…5mg"
	Diary No. Date of R& I & fee	Dy.No 41721 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antihistamines for systemic use R06AX27
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	CLARINEX® (desloratadine) Tablets USFDA Approved.
	Me-too status	073609 Brand Name: D-Jardin 5mg Tablet Manufacturer Name: High-Q, .
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for submission of justification for use of methylene chloride in applied formulation.	
2036.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Glimaryl Tablets 2mg
	Composition	"Each film coated tablet contains:

		Glimepiride…2mg"
	Diary No. Date of R& I & fee	Dy.No 41718 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x10's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	AMARYL (glimepiride) tablets, USFDA Approved
	Me-too status	048408 Brand Name: Glimepiride-Sandoz 2mg Tablets Manufacturer Name: Novartis Pharma
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	• Evidence of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Submission of justification for use of methylene chloride in applied formulation.** • **Submission of either evidence of approval of reference product as film coated tablet or otherwise for revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.**	
2037.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Glimaryl Tablets 4mg
	Composition	Each film coated tablet contains: Glimepiride…4mg"
	Diary No. Date of R& I & fee	Dy.No 41719 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x10's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	AMARYL (glimepiride) tablets, USFDA Approved
	Me-too status	048408 Brand Name: Glimepiride-Sandoz 2mg Tablets Manufacturer Name: Novartis Pharma
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.

	Remarks of the Evaluator (V)	• Evidence of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Submission of justification for use of methylene chloride in applied formulation.** • **Submission of either evidence of approval of reference product as film coated tablet or otherwise for revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.**	
2038.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Dexifen Suspension 100mg/5ml
	Composition	"Each 5ml contains: Dexibuprofen…100mg"
	Diary No. Date of R& I & fee	Dy.No 41720 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Propionic acid derivatives M01AE14
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	120ml, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	061206 Brand Name: Tercica 100mg/5ml Suspension Manufacturer Name: Sami
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	• The Brand name mentioned on Form 5 is Maxigar Syrup whereas rest of the dossier mentions Dexifen Suspension 100mg/5ml. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML. • The master formulation doesn't mention suspending agent. • Evidence of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for the following: • **Evidence of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Mention suspending agent in the master formulation.** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML.**	

	• **Submit fee challan for applied formulation.**	
2039.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Maxigar Suspension 0.5mg/5ml
	Composition	"Each 5ml contains: Pizotifen…0.5mg"
	Diary No. Date of R& I & fee	Dy.No 41716 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antimigraine preparations N02CX01
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	120ml, As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in applied strength.
	Me-too status	020337 Brand Name: Pizo Syrup (Pizotifen as Hydrogen Maleate) Manufacturer Name: English Pharmaceutical Industries
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	• In dossier some places syrup is mentioned and at some places suspension. Clarify your applied formulation and resubmit accordingly. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML. • The Master formulation doesn't mention suspending agent. • Evidence of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • The master formulation mentions Pizotifen maleate 100mg whereas, the applied formulation is "Each 5ml contains: Pizotifen…0.5mg"
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML.** • **Clarification regarding physical form of applied formulation whether it is syrup or suspension is required, moreover submit Composition, master formulation & manufacturing method accordingly.**	
2040.	Name and address of manufacturer / Applicant	"M/s Max Pharmaceuticals,Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Maxivate Cream 0.1/3%
	Composition	"Each tube contains: Betamethasone…0.1% Neomycin sulphate…3%"
	Diary No. Date of R& I & fee	Dy.No 41717 dated 07-12-2018 Rs.20,000/- Dated 06-12-2018

	Pharmacological Group	Corticosteroids, Combinations With Antibiotics D07CC01
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	15g, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Could not be confirmed.
	GMP status	26-06-2019 Conclusion: The company is working at good level of GMP and record of raw material was found maintained along with SOP's the clearance of API's for imported sources are attached as of today. GMP is a continuous process of up gradation, the firm the advise to continue with up gradation and purchase the desired equipments are advised.
	Remarks of the Evaluator (V)	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML. • Evidence of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.** • **Evidence of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML.** • **Clarification regarding physical form of applied formulation whether it is syrup or suspension is required, moreover submit Composition, master formulation & manufacturing method accordingly.**	
2041.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Cerophen 50mg tablet
	Composition	"Each Tablet Contains: Clomiphene Citrate…50mg"
	Diary No. Date of R& I & fee	Dy.No 44553 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Non aromatase inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	GENRX CLOMIPHENE clomifene citrate 50mg uncoated TGA Approved. USFDA Discontinued
	Me-too status	075806 Florid 50mg Tablet M/s Opal Labs, Karachi .
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled

		yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	Registration Board in its 277th meeting approved registration of the above applied product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.
	Decision: Approved.	
2042.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Clopid 75mg tablet
	Composition	"Each Film Coated Tablet Contains: Clopidogrel bisulfate Eq. to Clopidogrel…75mg"
	Diary No. Date of R& I & fee	Dy.No 44554 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PLAVIX® (clopidogrel bisulfate) tablets USFDA Approved with box warning.
	Me-too status	035608 Brand Name: Clopido Tablet 75mg Manufacturer Name:Platinum Pharmaceuticals (Pvt) Ltd
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2043.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Clopid Plus 75/75 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clopidogrel bisulfate Eq. to Clopidogrel…75mg Aspirin…75mg"
	Diary No. Date of R& I & fee	Dy.No 44555 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antithrombotic Agents
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	DuoCover EMA Approved
	Me-too status	056986 Clopido Plus Tablets of WerrickPharmaceuticals

	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	EPAR of DuoCover(Innovator product) Quality aspects DuoCover is presented as film-coated tablets containing two active substances. Tablets are bilayer: clopidogrel and acetylsalicylic acid (ASA). Clopidogrel (Active Substance) It is a chiral substance due to presence of one chiral centre. Three positional isomers and one optical isomer exist. The substance used in the manufacture of DuoCover is the (S) enantiomer. Two polymorphic forms (form I and II) of clopidogrel hydrogen sulphate are known. The substance used in the manufacture of the medicinal product is clopidogrel hydrogen sulphate form II which is thermodynamically more stable than form I. Evaluation Tablets should be bilayer. The (S) enantiomer should be used. The polymorphic form II is more stable than one. Reference EMA
	Decision: Approved.	
2044.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Esitopram 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Escitalopram Oxalate Eq. to Escitalopram…10mg"
	Diary No. Date of R& I & fee	Dy.No 44533 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lexapro® (escitalopram) Tablets, for oral use USFDA Approved with box warning.
	Me-too status	067362 ; Precipra 10mg Tablet by M/s Parke Davis
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2045.	Name and address of manufacturer /	"M/s MKB Pharmaceuticals pvt Ltd

	Applicant	Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Esitopram 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Escitalopram Oxalate Eq. to Escitalopram…20mg"
	Diary No. Date of R& I & fee	Dy.No 44534 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lexapro® (escitalopram) Tablets, for oral use USFDA Approved with box warning.
	Me-too status	057821 Espram 20mg Tablet PharmatecPakistan(Pvt)Ltd
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2046.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Esitopram 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Escitalopram Oxalate Eq. to Escitalopram…5mg"
	Diary No. Date of R& I & fee	Dy.No 44532 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lexapro® (escitalopram) Tablets, for oral use USFDA Approved with box warning.
	Me-too status	067361; Precipra 5mg Tablet Parke Davis
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	

2047.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Lornox 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lornoxicam…4mg"
	Diary No. Date of R& I & fee	Dy.No 44540 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAID, M01AC05
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	10's,20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Xefo 4mg Tablet Swissmedic Approved
	Me-too status	074896 Orno 4mg Tablet Sami Karachi . .
	GMP status	Last GMP inspection dated 01-02-2018 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2048.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Lornox 8mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lornoxicam…8mg"
	Diary No. Date of R& I & fee	Dy.No 44541 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAID, M01AC05
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	10's, 20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	NOXON AIFA Approved
	Me-too status	075824 Xoni-Fast 8mg Tablet M/s Macter International, F-216, Karachi .
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2049.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	NT-Tox 500mg Tablets
	Composition	"Each Film Coated Tablet Contains: Nitazoxanide…500mg"
	Diary No. Date of R& I & fee	Dy.No 44556 Dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antiprotozoals
	Type of Form	Form-5

	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ALINIA® (nitazoxanide) tablets, for oral use USFDA Approved.
	Me-too status	076308 Izato 500 mg tablet Sami Pharmacetuicals, kar.
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2050.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Peptidon 10mg Tablet
	Composition	"Each Tablet Contains: Domperidone as maleate…10mg"
	Diary No. Date of R& I & fee	Dy.No 44543 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Propulsives
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Domperidone 10mg Tablets MHRA Approved.
	Me-too status	60060 Domwis 10mg Tablet WisePharmaceuticals
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2051.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Ramipral 1.25mg Tablet
	Composition	"Each Tablet Contains: Ramipril…1.25mg"
	Diary No. Date of R& I & fee	Dy.No 44558 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form-5
	Finished product Specification	USP

	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Tritace 1.25 mg Tablets or Ramipril 1.25mg Tablets MHRA Approved
	Me-too status	055424 Ramy 1.25mg Tablet GetzPharma
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved with BP Specifications.	
2052.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Ramipral 2.5mg Tablet
	Composition	"Each Tablet Contains: Ramipril…2.5mg"
	Diary No. Date of R& I & fee	Dy.No 44559 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Tritace 2.5 mg Tablets or Ramipril 2.5mg Tablets MHRA Approved
	Me-too status	055425 Ramy 2.5mg Tablet GetzPharma
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved with BP Specifications.	
2053.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Ramipral 5mg Tablet
	Composition	"Each Tablet Contains: Ramipril…5mg"
	Diary No. Date of R& I & fee	Dy.No 44560 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018

	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Tritace 5 mg Tablets or Ramipril 5mg Tablets MHRA Approved
	Me-too status	055426 Ramy 5mg Tablet GetzPharma
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved with BP Specifications.	
2054.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Serlox 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sertraline as Hydrochloride…50mg"
	Diary No. Date of R& I & fee	Dy.No 44544 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZOLOFT (sertraline hydrochloride) tablets, USFDA Approved with box warning.
	Me-too status	042842 Serlin Tablets Shrooq Pharmaceuticals (Pvt) Ltd,
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2055.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Sitamet 50/1000mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate…50mg Metformin HCL …1000mg"

	Diary No. Date of R& I & fee	Dy.No 44545 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs
	Pack size & Demanded Price	14',As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin hydrochloride) tablets, for oral use USFDA Approved.
	Me-too status	055444 Treviamet 50mg + 1000mg Tablet GetzPharma
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2056.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Sitamet 50/500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin phosphate monohydrate…50mg Metformin HCL …500mg"
	Diary No. Date of R& I & fee	Dy.No 44546 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs
	Pack size & Demanded Price	14',As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin hydrochloride) tablets, for oral use USFDA Approved.
	Me-too status	055443 Treviamet 50mg + 500mg Tablet GetzPharma
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2057.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Trajenta 5mg Tablet

	Composition	"Each Film Coated Tablet Contains: Linagliptin…5mg"
	Diary No. Date of R& I & fee	Dy.No 44563 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specification	Innovator Specs.
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TRADJENTA® (linagliptin) tablets USFDA Approved.
	Me-too status	--
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	Registration Board in its 289th DRB meeting decided to refer the case to the Legal affairs Division on the issue of its patent rights.
	Decision: Deferred as the case has been forwarded to Legal Affairs Division for its patent rights.	
2058.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Triforge HCT 5/160/12.5 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 44550 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations C09DX01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® (amlodipine, valsartan, hydrochlorothiazide) tablets, for oral use USFDA Approved.
	Me-too status	067438 Brand Name Tri-Valsan 5/160/12.5mg Tablet Hilton Pharma (Pvt.) Limited
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held

		on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2059.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Triforge HCT 10/160/12.5 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besylate…10mg Valsartan…160mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 44551 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations C09DX01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® (amlodipine, valsartan, hydrochlorothiazide) tablets, for oral use USFDA Approved.
	Me-too status	067438 Tri-Valsan 10/160/12.5mg Tablet Hilton Pharma (Pvt.) Limited
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2060.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Triforge HCT 10/320/25 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besylate…10mg Valsartan…320mg Hydrochlorothiazide…25mg"
	Diary No. Date of R& I & fee	Dy.No 44552 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations C09DX01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® (amlodipine, valsartan, hydrochlorothiazide) tablets, for oral use USFDA Approved.
	Me-too status	067441

		Tri-Valsan 10/320/25mg Tablet Hilton Pharma (Pvt.) Limited
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2061.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Gabalin 50mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…50mg"
	Diary No. Date of R& I & fee	Dy.No 44536 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antiepileptics
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	LYRICA (pregabalin) Capsules USFDA Approved
	Me-too status	048725 Gabica 50mg Capsules Getz Pharma
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2062.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Gabalin 75mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…75mg"
	Diary No. Date of R& I & fee	Dy.No 44537 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antiepileptics
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	LYRICA (pregabalin) Capsules USFDA Approved
	Me-too status	047365 Gabica 75mg Capsules Getz Pharma (Pvt) Ltd;

	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2063.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals Pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Gabalin 150mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…150 mg"
	Diary No. Date of R& I & fee	Dy.No 44538 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antiepileptics
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	LYRICA (pregabalin) Capsules USFDA Approved
	Me-too status	048724 Gabica 150mg Capsules Getz Pharma,
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2064.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals Pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Tamsolin 0.2mg Capsule
	Composition	"Each Capsule Contains: Tamsulosin HCL sustained release pellets …0.2mg"
	Diary No. Date of R& I & fee	Dy.No 44561 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PMDA Approved
	Me-too status	070691 Uroflo Capsule of M/s Novartis, .
	GMP status	Last GMP inspection dated 01-02-2018 concludes

		satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	Source of pellets:M/s Vision Pharmaceuticals
	Decision: Approved.	
2065.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals Pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Tamsolin 0.4mg Capsule
	Composition	"Each Capsule Contains: Tamsulosin HCL sustained release pellets …0.4mg"
	Diary No. Date of R& I & fee	Dy.No 44562 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PMDA Approved
	Me-too status	050392 Tamsolin 0.4mg Capsule Getz Pharma, Karachi
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	Source of pellets:M/s Vision Pharmaceuticals
	Decision: Approved.	
2066.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals Pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Ibru Sachet
	Composition	"Each Sachet Contains: Ibuprofen as Effervescent Granules…600mg"
	Diary No. Date of R& I & fee	Dy.No 44564 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Propionic acid derivatives M01AE01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Brufen Granules MHRA Approved.
	Me-too status	044414 Brufen 600mg Sachet of M/s Abbott Labs
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held

		on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2067.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals Pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Score 10mg Sachet
	Composition	"Each Sachet Contains: Esomeprazole as Magnesium Trihydrate 10mg"
	Diary No. Date of R& I & fee	Dy.No 44565 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Proton pump inhibitors A02BC05
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Nexium 10 mg gastro-resistant granules for oral suspension, sachet. MHRA Approved.
	Me-too status	Could not be confirmed.
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	• Firm has sachet section. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Clarification of formulation whether immediate release or enteric coated formulation.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2068.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals Pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Minicol 40mg/ml Oral Drops
	Composition	"Each ml Suspension Contains: Simethicone…40mg"
	Diary No. Date of R& I & fee	Dy.No 44542 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti-Flatulent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	INFACOL MHRA Approved.
	Me-too status	067454 Infacol Drops Spencer

	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	Liquid syrup section is present.
	Decision: Approved as per innovator's specification.	
2069.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals Pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	NT-Tox 100mg/5ml Dry Powder Suspension
	Composition	"Each 5ml reconstituted suspension contains: Nitazoxanide…100mg"
	Diary No. Date of R& I & fee	Dy.No 44557 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	30ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ALINIA® (nitazoxanide) for oral suspension USFDA Approved.
	Me-too status	076309 Izato 100 mg/5ml Suspension Sami Pharmaceuticals, kar.
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	Oral dry powder suspension section is present.
	Decision: **Approved as per innovator's specification.**	
2070.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Emplan 10/5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…10mg Linagliptin…5mg"
	Diary No. Date of R& I & fee	Dy.No 44528 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Innovator Specs.
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Glyxambi 10/5 mg USFDA Approved.
	Me-too status	--

	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	Deferred for submission of stability studies data as per directions of 278th meeting of Registration Board. Moreover the Board was also apprised that the case of applied formulation has been forwarded to Legal Affairs Division in light of comments of IP.(RB-293)
	Decision: Deferred as the case has been forwarded to Legal Affairs Division for its patent rights.	
2071.	Name and address of manufacturer / Applicant	"M/s MKB Pharmaceuticals pvt Ltd Plot-66, Hayatabad Industrial Estate Peshawar"
	Brand Name +Dosage Form + Strength	Cefispec Capsules 200mg
	Composition	"Each Capsule Contains: Cefixime as trihydrate…200mg"
	Diary No. Date of R& I & fee	Dy.No 44566 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Third-generation cephalosporin J01DD08
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Cefixime Normon 200 mg hard capsules EFG Spain Approved.
	Me-too status	034664 Cefim 200mg Capsule Hilton Pharma (Pvt) Ltd,
	GMP status	08-02-2019, Fair Compliance:cGMP for export The firm was recommended in last inspection for purchase of FTIR ,HPLC Gradient system which are not fulfilled yet.The management has requested three months time.After thorough inspection by the team members ,keeping in view the requirement of the urgent need of GMP certificate for Cambodia as their applications for registration are on agenda of the registration committee scheduled to be held on 17-02-2019.The team recommended CGMP for export.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2072.	Name and address of manufacturer / Applicant	"M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan & M/s Mediate Pharmaceutical Pvt., ltd
	Brand Name +Dosage Form + Strength	Heliphen/Helixone Injection 500mg IV
	Composition	"Each Vial Contains: Ceftriaxone Sodium eq to Ceftriaxone…500mg"
	Diary No. Date of R& I & fee	Dy.No 43199 dated 18-12-2018 Rs.20,000/- Dated 17-12-2018 Rs.30,000/- Dated 15-03-2019
	Pharmacological Group	Third generation cephalosporin
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	1x1's,
	Approval status of product in Reference Regulatory Authorities.	065125, Company: LUPIN USFDA Approved.
	Me-too status	008435 Rocephin Roche IV Inj M/s Roche
	GMP status	04-03-2020 Conclusion: Keeping in view the areas inspected, people met, documents reviewed and the considering findings of the inspection M/s Mediate Karachi was considered to be operating at an acceptable level of good compliance with GMP guidelines.(M/s Mediate GMP Status)
	Remarks of the Evaluator (V)	• Details about total number of sections & total number of products already approved on contract manufacturing of applicant. Firms Response Total Number of products:9 Total Number of sections:8 • Submission of agreement between applicant and manufacturer. Firms Response Date of agreement:03-12-2019 Validity: 3 years.
	Decision:Approved.	
2073.	Name and address of manufacturer / Applicant	"M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan by M/s Daneen Pharma Pvt Ltd. 27, Sundar Industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Kezidime Dry Powder for Injection
	Composition	"Each Vial Contains: Ceftazidime as pentahydrate……1g
	Diary No. Date of R& I & fee	Dy.No 42751 dated 14-12-2018 Rs.50,000/- Dated 14-12-2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's,5's,10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	030048 Injex- 1gm Injection Indus Pharma,
	GMP status	08-03-2019 Recommendations: The firm Daneen Pharma was evaluated for facilities, like building, flow, HVAC, Water treatment, personnel, quality control/quality assurance and production operations and facilities. Only Dry powder injectable section (ceph) was operational at the time of inspection. Keeping in view the observations made on the day of inspection and after going through the documentation and overall operations, the panel of inspectors was of the opinion that the firm Daneen Pharma Lahore has maintained conformance to GMP Compliance in the manufacturing and quality control operations.

	Remarks of the Evaluator (V)	• Details about total number of sections & total number of products already approved on contract manufacturing of applicant. No of approved products:20 No of sections: 10 • Agreement between applicant and manufacturer has been provided.
	Decision:Approved.	
2074.	Name and address of manufacturer / Applicant	"M/s Demont Research Laboratories,20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan By M/s Welmark Pharmaceuticals.Plot #122 Phase 5, Block B, Industrial Hattar"
	Brand Name +Dosage Form + Strength	Nexa 40mg Injection
	Composition	"Each Vial Contains: Esomeprazole as sodium 40mg
	Diary No. Date of R& I & fee	Dy.No 40962 dated 06-12-2018 Rs.50,000/- Dated 04-12-2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1's, As Per SRO.
	Approval status of product in Reference Regulatory Authorities.	Nexium IV 40mg powder for solution for injection MHRA Approved.
	Me-too status	Somezol Injection of Bosch, Karachi
	GMP status	04-09-2018 & 26-09-2018. Conclusion: As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator (V)	• Details about total number of sections & total number of products already approved on contract manufacturing of applicant. No of approved products:12 No of sections:4 • Agreement between applicant and manufacturer has been provided.
	Decision:Approved.	
2075.	Name and address of manufacturer / Applicant	"M/s Demont Research Laboratories.20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan By M/s Welmark Pharmaceuticals.Plot #122 Phase 5, Block B, Industrial Hattar"
	Brand Name +Dosage Form + Strength	Omnic 40mg Injection
	Composition	"Each Vial Contains: Omeprazole as sodium 40mg
	Diary No. Date of R& I & fee	Dy.No 40963 dated 06-12-2018 Rs.50,000/- Dated 04-12-2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1's, As Per SRO.

	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for injection of MHRA Approved.
	Me-too status	Zegrid-40 Injection of Shaigan Pharma
	GMP status	04-09-2018 & 26-09-2018. Conclusion: As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator (V)	• Details about total number of sections & total number of products already approved on contract manufacturing of applicant. No of approved products:12 No of sections:4 • Agreement between applicant and manufacturer has been provided.
	Decision:Approved.	
2076.	Name and address of manufacturer / Applicant	"M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan BY M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachii"
	Brand Name +Dosage Form + Strength	Astezol Injection 40mg
	Composition	"Each vial contains: Omeprazole Sodium eq to Omeprazole …40mg"
	Diary No. Date of R& I & fee	Dy.No 42014 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	045617 Risek 40mg Injection Importer Name Julphar Pakistan (Pvt) Ltd.,
	GMP status	04-03-2019 Conclusion: All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good.
	Remarks of the Evaluator (V)	• Approval of dry powder injection section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide manufacturing outline of applied formulation. • Submission of agreement between applicant and manufacturer.
	Decision: Deferred for the following :	

	• **Approval of dry powder injection section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility of manufacturer.** • **Submit manufacturing outline of applied formulation.** • **Submit contract manufacturing agreement between applicant & manufacturer.** • **Capcacity assessment report of M/s Safe Karachi**	
2077.	Name and address of manufacturer / Applicant	"M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan BY M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachii"
	Brand Name +Dosage Form + Strength	Aste-Eso Injection 40mg
	Composition	"Each vial contains: Esomeprazole Sodium eq to Esomeprazole …40mg"
	Diary No. Date of R& I & fee	Dy.No 42015 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	As Per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	045386 Somezol Injection Bosch
	GMP status	04-03-2019 Conclusion: All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good.
	Remarks of the Evaluator (V)	• Approval of dry powder injection section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide manufacturing outline of applied formulation. • Submission of USP monograph of omeprazole injection. • Submission of agreement between applicant and manufacturer.
	Decision: Deferred for the following : • **Approval of dry powder injection section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility of manufacturer.** • **Submit manufacturing outline of applied formulation.** • **Submit contract manufacturing agreement between applicant & manufacturer.** • **Capcacity assessment report of M/s Safe Karachi**	
2078.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Abifin Tablet 5mg
	Composition	"Each tablet contains:

		Aripiprazole…5mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40638 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antipsychotics N05AX12
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ABILIFY® (aripiprazole) Tablets USFDA Approved with box warning.
	Me-too status	Registration Number: 055134 Brand Name: Ariza 5mg Tablet Manufacturer Name: HiltonPharma(Pvt.)Limited
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2079.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Abifin Tablet 10mg
	Composition	"Each tablet contains: Aripiprazole…10mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40639 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antipsychotics N05AX12
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ABILIFY® (aripiprazole) Tablets USFDA Approved with box warning.
	Me-too status	Registration Number:037686 Brand Name: Ariza 10mg Tablet Manufacturer Name: HiltonPharma(Pvt.)Limited
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2080.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Abifin Tablet 15mg

	Composition	"Each tablet contains: Aripiprazole…15mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40640 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antipsychotics N05AX12
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ABILIFY® (aripiprazole) Tablets USFDA Approved with box warning.
	Me-too status	Registration Number:037687 Brand Name: Ariza 15mg Tablet Manufacturer Name: HiltonPharma(Pvt.)Limited
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2081.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Abifin Tablet 20mg
	Composition	"Each tablet contains: Aripiprazole…20mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40641 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antipsychotics N05AX12
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ABILIFY® (aripiprazole) Tablets USFDA Approved with box warning.
	Me-too status	Registration Number:037688 Brand Name: Ariza 20mg Tablet Manufacturer Name: HiltonPharma(Pvt.)Limited
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2082.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Abifin Tablet 30mg
	Composition	"Each film tablet contains:

		Aripiprazole…30mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40642 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other antipsychotics N05AX12
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ABILIFY® (aripiprazole) Tablets USFDA Approved with box warning.
	Me-too status	Registration Number:037689 Brand Name: Ariza 30mg Tablet Manufacturer Name: HiltonPharma(Pvt.)Limited
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2083.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Resp Tablet 1mg
	Composition	"Each Film Coated Tablet Contains: Risperidone…1mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40643 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antipsychotic ATC Code: N05AX08
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,50's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL® (risperidone) tablets, USFDA Approved with Box warning. WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
	Me-too status	Registration Number: 048831 Brand Name :Risperidone-Sandoz 1mg Tablet Manufacturer Name : Novartis Pharma, Karachi
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	

2084.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Resp Tablet 2mg
	Composition	"Each Film Coated Tablet Contains: Risperidone…2mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40644 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antipsychotic ATC Code: N05AX08
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,50's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL® (risperidone) tablets, USFDA Approved with Box warning. WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
	Me-too status	Registration Number: 048832 Brand Name :Risperidone-Sandoz 2mg Tablet Manufacturer Name : Novartis Pharma, Karachi
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2085.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Resp Tablet 3mg
	Composition	"Each Film Coated Tablet Contains: Risperidone…3mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40645 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antipsychotic ATC Code: N05AX08
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL® (risperidone) tablets, USFDA Approved with Box warning. WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
	Me-too status	Registration Number: 048833 Brand Name :Risperidone-Sandoz 3mg Tablet Manufacturer Name : Novartis Pharma, Karachi
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of

		GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2086.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Resp Tablet 4mg
	Composition	"Each Film Coated Tablet Contains: Risperidone…4mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40646 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Antipsychotic ATC Code: N05AX08
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL® (risperidone) tablets, USFDA Approved with Box warning. WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
	Me-too status	Registration Number: 048834 Brand Name :Risperidone-Sandoz 4mg Tablet Manufacturer Name : Novartis Pharma, Karachi
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2087.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Canazin 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Canagliflozin as Hemihydrate…100mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40653 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK02
	Type of Form	Form 5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	7's,14's,28's, As per sro.
	Approval status of product in Reference Regulatory Authorities.	INVOKANA (canagliflozin) tablets USFDA Approved with box warning.
	Me-too status	NA
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm

		M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data of applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2088.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Canazin 300mg Tablet
	Composition	"Each Film Coated Tablet Contains: Canagliflozin as Hemihydrate…300mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40654 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK02
	Type of Form	Form 5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	7's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	INVOKANA (canagliflozin) tablets USFDA Approved with box warning.
	Me-too status	NA
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data of applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2089.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Selride Tablet 50mg
	Composition	"Each Tablet Contains: Amisulpride…50mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40647 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Benzamides N05AL05
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	063101 Brand Name:Amiride Tablet. Manufacturer Name:M/s Shrooq Pharmaceuticals (Pvt) Ltd,

	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Firms Response Firm has revised their formulation from film coated to uncoated tablets with submission of Rs. 5000/-.
	Decision: Approved.	
2090.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Selride Tablet 200mg
	Composition	"Each Tablet Contains: Amisulpride…200mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40648 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Benzamides N05AL05
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	063102 Brand Name:Amiride Tablet. Manufacturer Name:M/s Shrooq Pharmaceuticals (Pvt) Ltd,
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Firms Response Firm has revised their formulation from film coated to uncoated tablets with submission of Rs. 5000/-.
	Decision: Approved.	
2091.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Nicocard 5mg Tablet
	Composition	"Each tablet contains:

		Nicorandil…5mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40564 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Vasodilators used in cardiac diseases C01DX16
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,20's,30's,40's,50's,60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PMDA Approved. (Confirmed from M-283rd)
	Me-too status	045367 Brand Name :Nicoget 5mg Tablets Manufacturer Name: Getz Pharma,
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2092.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Nicocard 10mg Tablet
	Composition	"Each tablet contains: Nicorandil…10 mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40565 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Vasodilators used in cardiac diseases C01DX16
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,20's,30's,40's,50's,60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Nicorandil 10 mg Tablets MHRA Approved.
	Me-too status	045368 Brand Name :Nicoget 10mg Tablets Manufacturer Name: Getz Pharma,
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2093.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Nicocard 20mg Tablet
	Composition	"Each tablet contains:

		Nicorandil…20 mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 40566 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Vasodilators used in cardiac diseases C01DX16
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,20's,30's,40's,50's,60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Nicorandil 20 mg Tablets MHRA Approved.
	Me-too status	045369 Brand Name :Nicoget 20mg Tablets Manufacturer Name: Getz Pharma,
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2094.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Telcard Tablet 20mg
	Composition	"Each Tablet Contains: Telmisartan…20mg"
	Diary No. Date of R& I & fee	Dy.No 40667 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain C09CA07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MICARDIS® (telmisartan) tablets, USFDA Approved with box warning.
	Me-too status	048333 Brand Name: Telmas Tablets. Manufacturer Name: Global Pharmaceuticals
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2095.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Telcard Tablet 40mg

	Composition	"Each Tablet Contains: Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy.No 40668 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain C09CA07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MICARDIS® (telmisartan) tablets, USFDA Approved with box warning.
	Me-too status	048332 Brand Name: Telmas Tablets. Manufacturer Name: Global Pharmaceuticals
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2096.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Telcard Tablet 80mg
	Composition	"Each Tablet Contains: Telmisartan…80mg"
	Diary No. Date of R& I & fee	Dy.No 40669 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain C09CA07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MICARDIS® (telmisartan) tablets, USFDA Approved with box warning.
	Me-too status	048331 Brand Name: Telmas Tablets. Manufacturer Name: Global Pharmaceuticals
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2097.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Telmicard-H 40/12.5 mg Tablet
	Composition	"Each Tablet Contains:

		Telmisartan…40mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 40670 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics C09DA07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Micardis HCT. (USFDA Approved)
	Me-too status	081160 Brand Name: Velmon-H 40/12.5mg Tablet Manufacturer Name: Martin Dow Ltd, Karachi.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet. • Evidence of availability of bilayer machine.
	Decision: Deferred for the following: • **submission of either evidence of approval of reference product as coated single layer tablet or otherwise revision of applied formulation in line with reference product i.e. multilayer uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.** • **Evidence of availability of tablet bilayer machine.**	
2098.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Telmicard-H 80/12.5 mg Tablet
	Composition	"Each Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 40671 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics C09DA07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Micardis HCT. (USFDA Approved)
	Me-too status	047125 Brand Name: Co-Telsan 80/12.5 Tablets Manufacturer Name: Hilton Pharma (Pvt) Ltd,
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of

		inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet. • Evidence of availability of bilayer machine.
	Decision: Deferred for the following: • **submission of either evidence of approval of reference product as coated single layer tablet or otherwise revision of applied formulation in line with reference product i.e. multilayer uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.** • **Evidence of availability of tablet bilayer machine.**	
2099.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	AM Telcard Tablet 40mg/5mg
	Composition	"Each Bilayered Tablet Contains: Telmisartan…40mg Amlodipine as Besylate…5mg"
	Diary No. Date of R& I & fee	Dy.No 40649 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers C09DB04
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets USFDA Approved with box warning.
	Me-too status	066943 Brand Name: Amtas 5mg + 40mg Tablet Manufacturer Name: Getz Pharma (Pvt) Ltd.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet. • Evidence of availability of bilayer machine.
	Decision: Deferred for the following: • **submission of either evidence of approval of reference product as coated single layer tablet or otherwise revision of applied formulation in line with reference product i.e. multilayer uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.** • **Evidence of availability of tablet bilayer machine.**	
2100.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	AM Telcard Tablet 40mg/10mg

	Composition	"Each Bilayered Tablet Contains: Telmisartan…40mg Amlodipine as Besylate…10mg"
	Diary No. Date of R& I & fee	Dy.No 40650 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers C09DB04
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets USFDA Approved with box warning.
	Me-too status	066945 Brand Name: Amtas 10mg + 40mg Tablet Manufacturer Name: Getz Pharma (Pvt) Ltd.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet. • Evidence of availability of bilayer machine.
	Decision: Deferred for the following: • **submission of either evidence of approval of reference product as coated single layer tablet or otherwise revision of applied formulation in line with reference product i.e. multilayer uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.** • **Evidence of availability of tablet bilayer machine.**	
2101.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	AM Telcard Tablet 80mg/5mg
	Composition	"Each Bilayered Tablet Contains: Telmisartan…80mg Amlodipine as Besylate…5mg"
	Diary No. Date of R& I & fee	Dy.No 40651 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers C09DB04
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets USFDA Approved with box warning.
	Me-too status	066944 Brand Name: Amtas 5mg + 80mg Tablet Manufacturer Name: Getz Pharma (Pvt) Ltd.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities

		like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet. • Evidence of availability of bilayer machine.
	Decision: Deferred for the following: • **submission of either evidence of approval of reference product as coated single layer tablet or otherwise revision of applied formulation in line with reference product i.e. multilayer uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.** • **Evidence of availability of tablet bilayer machine.**	
2102.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	AM Telcard Tablet 80mg/10mg
	Composition	"Each Bilayered Tablet Contains: Telmisartan…80mg Amlodipine as Besylate…10mg"
	Diary No. Date of R& I & fee	Dy.No 40652 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers C09DB04
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets USFDA Approved with box warning.
	Me-too status	067472 Brand Name: Amtas 10mg + 80mg Tablet Manufacturer Name: Getz Pharma (Pvt) Ltd.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet. • Evidence of availability of bilayer machine.
	Decision: Deferred for the following: • **Submission of either evidence of approval of reference product as coated single layer tablet or otherwise revision of applied formulation in line with reference product i.e. multilayer uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.** • **Evidence of availability of tablet bilayer machine.**	

2103.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dapoglin Tablet 5mg
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin…5mg"
	Diary No. Date of R& I & fee	Dy.No 40656 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK01
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	FARXIGA (dapagliflozin) tablets USFDA Approved
	Me-too status	
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2104.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dapoglin Tablet 10mg
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin…10mg"
	Diary No. Date of R& I & fee	Dy.No 40657 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK01
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	FARXIGA (dapagliflozin) tablets USFDA Approved
	Me-too status	
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic, hence stability

		study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2105.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dapoglin-M 5mg/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin propanediol monohydrate equivalent to dapagliflozin…5mg Metformin HCl…850mg"
	Diary No. Date of R& I & fee	Dy.No 40658 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, 28's, 56's, 60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Xigduo 5 mg/850 mg film-coated tablets
	Me-too status	NA
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2106.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dapoglin-M 5mg/1000mg Tablet
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin propanediol monohydrate equivalent to dapagliflozin…5mg Metformin HCl…1000mg"
	Diary No. Date of R& I & fee	Dy.No 40659 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, 28's, 56's, 60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Xigduo 5 mg/1,000 mg film-coated tablets
	Me-too status	NA
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and

		Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2107.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Vildamet 50mg/1000mg Tablets
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…1000mg"
	Diary No. Date of R& I & fee	Dy.No 40672 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Eucreas 50 mg/1000 mg film-coated tablets MHRA Approved. Each film-coated tablet contains 50 mg of vildagliptin and 1000 mg of metformin hydrochloride (corresponding to 780 mg of metformin).
	Me-too status	066107 Brand Name :Galvus Met 50mg/1000mg Importer Name: Novartis Pharma (Pakistan) Limited
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision:Approved with innovator's specifications and shelf life of 18 months.	
2108.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Empazin 10mg Tablet
	Composition	"Each film coated tablet contains: Empagliflozin…10mg"
	Diary No. Date of R& I & fee	Dy.No 40560 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK03
	Type of Form	Form-5
	Finished product Specification	Inhouse

	Pack size & Demanded Price	7's.10's,14's,20's,28's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	JARDIANCE® (empagliflozin) tablets, USFDA Approved.
	Me-too status	NA
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2109.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Empazin 25mg Tablet
	Composition	"Each film coated tablet contains: Empagliflozin…25mg"
	Diary No. Date of R& I & fee	Dy.No 40561 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK03
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	7's.10's,14's,20's,28's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	JARDIANCE® (empagliflozin) tablets, USFDA Approved.
	Me-too status	NA
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2110.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Glyfozin-M 12.5mg/500mg Tablet
	Composition	"Each film coated tablet contains: Empagliflozin…12.5mg Metformin HCl…500mg"
	Diary No. Date of R& I & fee	Dy.No 40562 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018

	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD20
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,28's,56's,60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SYNJARDY® (empagliflozin and metformin hydrochloride) USFDA Approved with box warning.
	Me-too status	NA
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2111.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Glyfozin-M 12.5mg/1000mg Tablet
	Composition	"Each film coated tablet contains: Empagliflozin…12.5mg Metformin HCl…1000mg"
	Diary No. Date of R& I & fee	Dy.No 40563 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD20
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,28's,56's,60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SYNJARDY® (empagliflozin and metformin hydrochloride) USFDA Approved with box warning.
	Me-too status	
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• It is a new molecule/subsequent generic, hence stability study data as per the guidelines provided in 278th meeting of Registration Board is required.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	

2112.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Cebrol Syrup 100mg/ml
	Composition	"Each ml contains: Citicoline as sodium…100mg"
	Diary No. Date of R& I & fee	Dy.No 40655 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Other psychostimulants and nootropics N06BX06
	Type of Form	Form-5
	Finished product Specification	Inhouse.
	Pack size & Demanded Price	30ml,60ml.
	Approval status of product in Reference Regulatory Authorities.	Somazine 100 mg / ml oral solution Spain Approved.
	Me-too status	048985 "Cercolin Syrup. "M/s Schazoo Laboratories,46 Grand Trunk Road, Lahore"
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	Syrup section is approved.
	Decision: Approved as per innovator's specification.	
2113.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ertuzin 5mg Tablet Ertu
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin…5mg"
	Diary No. Date of R& I & fee	Dy.No 44246 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK04
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	STEGLATRO™ (ertugliflozin) tablets, USFDA Approved.
	Me-too status	Not Provided
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Methylene chloride is discontinued/banned

		excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2114.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ertuzin 15mg Tablet Ertu
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin…15mg"
	Diary No. Date of R& I & fee	Dy.No 44247 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK04
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	STEGLATRO™ (ertugliflozin) tablets, USFDA Approved.
	Me-too status	Not Provided
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2115.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ertuglimet 2.5mg/500mg Tablet Ertumet
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin…2.5mg Metformin HCL…500mg"
	Diary No. Date of R& I & fee	Dy.No 44243 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK04
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.

	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SEGLUROMET™ (ertugliflozin and metformin hydrochloride) USFDA Approved with box warning.
	Me-too status	Not Provided
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2116.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ertuglimet 7.5mg/500mg Tablet Ertumet
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin…7.5mg Metformin HCL…500mg"
	Diary No. Date of R& I & fee	Dy.No 44245 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK04
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SEGLUROMET™ (ertugliflozin and metformin hydrochloride) USFDA Approved with box warning.
	Me-too status	Not Provided
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.

	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2117.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ertuglimet 7.5mg/1000mg Tablet Ertumet
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin…7.5mg Metformin HCL…1000mg"
	Diary No. Date of R& I & fee	Dy.No 44244 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK04
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SEGLUROMET™ (ertugliflozin and metformin hydrochloride) USFDA Approved with box warning.
	Me-too status	Not Provided
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2118.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ertuglimet 2.5mg/1000mg Tablet Ertumet
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin…2.5mg Metformin HCL…1000mg"
	Diary No. Date of R& I & fee	Dy.No 44242 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK04
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.

	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SEGLUROMET™ (ertugliflozin and metformin hydrochloride) USFDA Approved with box warning.
	Me-too status	Not Provided
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2119.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Sitaglujan 5/100mg Tablet Sitaglu
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin…5mg Sitagliptin…100mg"
	Diary No. Date of R& I & fee	Dy.No 44256 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors : Combinations of oral blood glucose lowering drugs A10BD24
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	STEGLUJAN™ (ertugliflozin and sitagliptin) USFDA Approved with box warning.
	Me-too status	Not Provided
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.

	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2120.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Sitaglujan 15/100mg Tablet Sitaglu
	Composition	"Each Film Coated Tablet Contains: Ertugliflozin…15mg Sitagliptin…100mg"
	Diary No. Date of R& I & fee	Dy.No 44255 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors : Combinations of oral blood glucose lowering drugs A10BD24
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	STEGLUJAN™ (ertugliflozin and sitagliptin) USFDA Approved with box warning.
	Me-too status	Not Provided
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2121.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dapimet XR 10mg/500mg Tablet
	Composition	"Each extended release tablet contains: Dapagliflozin…10mg Metformin HCL…500mg"
	Diary No. Date of R& I & fee	Dy.No 44253 dated 28-12-2018 Rs.20,000/- 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.

	Approval status of product in Reference Regulatory Authorities.	XIGDUO XR (dapagliflozin and metformin HCl extended-release) USFDA Approved with box warning.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2122.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dapimet XR 5mg/500mg Tablet
	Composition	"Each extended release tablet contains: Dapagliflozin…5mg Metformin HCL…500mg"
	Diary No. Date of R& I & fee	Dy.No 44251 dated 28-12-2018 Rs.20,000/- 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XIGDUO XR (dapagliflozin and metformin HCl extended-release) USFDA Approved with box warning.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	

2123.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dapimet XR 5mg/1000mg Tablet
	Composition	"Each extended release tablet contains: Dapagliflozin…5mg Metformin HCL…1000mg"
	Diary No. Date of R& I & fee	Dy.No 44252 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XIGDUO XR (dapagliflozin and metformin HCl extended-release) USFDA Approved with box warning.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2124.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dapimet XR 10mg/1000mg Tablet
	Composition	"Each extended release tablet contains: Dapagliflozin…10mg Metformin HCL…1000mg"
	Diary No. Date of R& I & fee	Dy.No 44254 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XIGDUO XR (dapagliflozin and metformin HCl extended-release) USFDA Approved with box warning.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the

		manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2125.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Dapimet XR 2.5mg/1000mg Tablet
	Composition	"Each extended release tablet contains: Dapagliflozin…2.5mg Metformin HCL…1000mg"
	Diary No. Date of R& I & fee	Dy.No 44250, dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XIGDUO XR (dapagliflozin and metformin HCl extended-release) USFDA Approved with box warning.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2126.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Xigmet 5mg/1000mg Tablet
	Composition	"Each Film Coated Tablet Contains:

		Dapagliflozin…5mg Metformin HCL…1000mg"
	Diary No. Date of R& I & fee	Dy.No 44249, dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XIGDUO MHRA Approved.
	Me-too status	
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2127.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Xigmet 5mg/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin…5mg Metformin HCL…850mg"
	Diary No. Date of R& I & fee	Dy.No 44281, dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD15
	Type of Form	Form-5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	10's, 14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XIGDUO MHRA Approved.
	Me-too status	
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along

		with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or otherwise submission of submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.** • **Submission of justification for use of methylene chloride in applied formulation.**	
2128.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Empatin 25mg/5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…25mg Linagliptin…5mg"
	Diary No. Date of R& I & fee	Dy.No 44261, dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD19
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,28's,30's, As per PRC
	Approval status of product in Reference Regulatory Authorities.	GLYXAMBI® (empagliflozin and linagliptin) tablets USFDA Approved.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **For legal opinion as the case has been forwarded to Legal Affairs Division for its patent rights.** • **For submission of justification for use of methylene chloride in applied formulation.**	
2129.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Empatin 10mg/5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…10mg Linagliptin…5mg"
	Diary No. Date of R& I & fee	Dy.No 44260, dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD19
	Type of Form	Form 5

	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,28's,30's, As per PRC
	Approval status of product in Reference Regulatory Authorities.	GLYXAMBI® (empagliflozin and linagliptin) tablets USFDA Approved.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **For legal opinion as the case has been forwarded to Legal Affairs Division for its patent rights.** • **For submission of justification for use of methylene chloride in applied formulation.**	
2130.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Agomin 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Agomelatine…25mg"
	Diary No. Date of R& I & fee	Dy.No 44280, dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Other antidepressants N06AX22
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, 28's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Valdoxan 25 mg film-coated tablets MHRA Approved.
	Me-too status	Valdoxan 25mg of Servier
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for submission of justification for use of methylene chloride in applied formulation.	
2131.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Jampit 12.5/500mg Tablet

	Composition	"Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCL…500mg"
	Diary No. Date of R& I & fee	Dy.No 44248, dated 28-12-2018 Rs.20,000/- 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD20
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,28's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	SYNJARDY® (empagliflozin and metformin hydrochloride) tablets USFDA Approved with box warning.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection." GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.** • **For submission of justification for use of methylene chloride in applied formulation.**	
2132.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd.Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Linomet 2.5mg/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCL…850mg"
	Diary No. Date of R& I & fee	Dy.No 44262, dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD11
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,28's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	JENTADUETO® (linagliptin and metformin hydrochloride) tablets, for oral use USFDA Approved with box warning.
	Me-too status	-
	GMP status	03/11/17 Conclusion: "The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection."

		GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Methylene chloride is discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or otherwise for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.** • **For submission of justification for use of methylene chloride in applied formulation.**	
2133.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Glycon 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg"
	Diary No. Date of R& I & fee	Dy.No 449 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,30's,As per PRC.
	Approval status of product in Reference Regulatory Authorities.	JANUVIA® (sitagliptin) Tablets USFDA Approved.
	Me-too status	064196 Sitagen Tablets. Manufacturer Name Ferozsons Laboratories
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overall assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision:Approved.	
2134.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Glycon 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…100mg"
	Diary No. Date of R& I & fee	Dy.No 435 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,30's,As per PRC
	Approval status of product in Reference Regulatory Authorities.	JANUVIA® (sitagliptin) Tablets USFDA Approved.

	Me-too status	064197 Sitagen Tablets. Manufacturer Name Ferozsons Laboratories
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision:Approved.	
2135.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Glycon 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…25mg"
	Diary No. Date of R& I & fee	Dy.No 436 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10’s,14’s,30’s,As per PRC.
	Approval status of product in Reference Regulatory Authorities.	JANUVIA® (sitagliptin) Tablets USFDA Approved.
	Me-too status	064195 Sitagen Tablets 25mg. Manufacturer Name Ferozsons Laboratories
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision:Approved.	
2136.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Aspiloc 75/75 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Aspirin…75mg Clopidogrel as Bisulphate…75mg"
	Diary No. Date of R& I & fee	Dy.No 448 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Antiplatelet Agent
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	10’s,20’s,30’s, As per PRC.
	Approval status of product in	EMA Approved

	Reference Regulatory Authorities.	DuoCover is presented as film-coated tablets containing two active substances. Tablets are bilayer: clopidogrel and acetylsalicylic acid (ASA). Marketing-authorisation holder :Sanofi-Aventis Groupe
	Me-too status	075978 CoPlavix Tablets 75/75mg By M/s Sanofi Karachi . .
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Internationally it is available as bilayer tablet. Whereas, firm has applied for monolayer tablet. Revision of formulation with submission of requisite fee. Evaluation: EMA Approved DuoCover is presented as film-coated tablets containing two active substances. Tablets are bilayer clopidogrel and acetylsalicylic acid (ASA). Pharmaceutical Development The objective of the formulation development was to obtain fixed-dose combination tablets, which would be equivalent to therapy consisting of Iscover 75 mg tablets combined with commercially available acetylsalicylic acid tablets. The product has been developed as film-coated bilayer tablets containing two active substances. The aim of a preliminary development was to define the technology to be used for manufacturing tablets containing two active substances. Film-coated tablets were finally selected. The 75 mg clopidogrel granulate corresponds to the already marketed Iscover 75 mg core formula and is granulated according to the existing processing for this product. No modifications have been introduced to the formula, batch size and granulation process of the clopidogrel granulation. Further formulation development was performed on the blend containing acetylsalicylic acid. Various grades of acetylsalicylic acid granulated with maize starch with varying particle size distribution were mixed with additional excipients in order to achieve a homogenized blend. The weight of the acetylsalicylic acid blend varies proportionally in order to achieve the various strengths of the combination. The acetylsalicylic acid granulation blend was optimised for consistent release of acetylsalicylic acid and to produce granulation with good flow and compressibility properties.
	Decision: Deferred for confirmation of composition as per innovator's product.	
2137.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Resnol 0.25mg Tablet
	Composition	"Each Film Coated Tablet Contains:

		Ropinirole as HCl …0.25mg"
	Diary No. Date of R& I & fee	Dy.No 3365 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019
	Pharmacological Group	Anti-Parkinson Drugs Dopamine Agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,21's, Alu-Alu Blister,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	REQUIP USFDA Approved
	Me-too status	047376 Ronirol 0.25mg Tablets Manufacturer Name Hilton Pharma (Pvt) Ltd,
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overall assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2138.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Resnol 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ropinirole as HCl …1mg"
	Diary No. Date of R& I & fee	Dy.No 3367 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019
	Pharmacological Group	Anti-Parkinson Drugs Dopamine Agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,21's, Alu-Alu Blister, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	REQUIP USFDA Approved
	Me-too status	047378 Ronirol 1mg Tablets Manufacturer Name Hilton Pharma (Pvt) Ltd,
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overall assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2139.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Resnol 2mg Tablet

	Composition	"Each Film Coated Tablet Contains: Ropinirole as HCl …2mg"
	Diary No. Date of R& I & fee	Dy.No 3368 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019
	Pharmacological Group	Anti-Parkinson Drugs Dopamine Agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,21's, Alu-Alu Blister, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	REQUIP USFDA Approved
	Me-too status	047379 Ronirol 2mg Tablets Manufacturer Name Hilton Pharma (Pvt) Ltd,
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2140.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Resnol 3mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ropinirole as HCl …3mg"
	Diary No. Date of R& I & fee	Dy.No 3364 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019
	Pharmacological Group	Anti-Parkinson Drugs Dopamine Agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,21's, Alu-Alu Blister, ,As per SRO
	Approval status of product in Reference Regulatory Authorities.	REQUIP USFDA Approved
	Me-too status	047380 Ronirol 3mg Tablets Manufacturer Name Hilton Pharma (Pvt) Ltd,
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	

2141.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Resnol 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ropinirole as HCl …4mg"
	Diary No. Date of R& I & fee	Dy.No 3363 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019
	Pharmacological Group	Anti-Parkinson Drugs Dopamine Agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,21's, Alu-Alu Blister, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	REQUIP USFDA Approved
	Me-too status	047381 Ronirol 4mg Tablets Composition / Generic Manufacturer Name Hilton Pharma (Pvt) Ltd,
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2142.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Dopark 25mg/100mg Tablets
	Composition	"Each Tablet Contains: Carbidopa …25mg Levodopa…100mg"
	Diary No. Date of R& I & fee	Dy.No 3166 dated 23-01-2019 Rs.20,000/- Dated 22-01-2019
	Pharmacological Group	Anti-parkinson's
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30's,100's,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SINEMET® (carbidopa levodopa) Tablets USFDA Approved
	Me-too status	009116 Seinemet Plus Tablets By M/s Muller And Phipps Karachi
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	

2143.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Dopark 25mg/250mg Tablets
	Composition	"Each Tablet Contains: Carbidopa …25mg Levodopa…250mg"
	Diary No. Date of R& I & fee	Dy.No 3167 dated 23-01-2019 Rs.20,000/- 22-01-2019
	Pharmacological Group	Anti-parkinson's
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30's,100's,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SINEMET® (carbidopa levodopa) Tablets USFDA Approved
	Me-too status	003627 Sinemet Tablet By M/s Muller & Phipps
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2144.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Lesetyl 75mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Aspirin…75mg"
	Diary No. Date of R& I & fee	Dy.No 437 dated 03-01-2019 Rs.20,000/- 03-01-2019
	Pharmacological Group	Antithrombotic Agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's,30's,100's,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Micropirin® 75mg Gastro-Resistant Tablets MHRA Approved.
	Me-too status	014900; Loprin 75mg Tablet By M/s Highnoon Laboratories Ltd
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2145.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Movion 2mg Tablet
	Composition	"Each Tablet Contains: Tizanidine as HCL…2mg"

	Diary No. Date of R& I & fee	Dy.No 925 dated 08-01-2019 Rs.20,000/- 07-01-2019
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZANAFLEX® (tizanidine hydrochloride) tablets, USFDA Discon. Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	076023 Tizax 2mg Tablet Manufacturer Name:Searle Kar.
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2146.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Movion 4mg Tablet
	Composition	"Each Tablet Contains: Tizanidine as HCL…4mg"
	Diary No. Date of R& I & fee	Dy.No 926 dated 08-01-2019 Rs.20,000/- Dated 07-01-2019
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZANAFLEX® (tizanidine hydrochloride) tablets, USFDA Approved
	Me-too status	076022 Tizax 4mg Tablet Manufacturer Name Searle Kar.
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2147.	Name and address of manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form + Strength	Modigen 30mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nimodipine…30mg"
	Diary No. Date of R& I & fee	Dy.No 3369 dated 24-01-2019 Rs.20,000/- 24-01-2019

	Pharmacological Group	Calcium Channel Blocker
	Type of Form	Form-5
	Finished product Specification	Present in BP.
	Pack size & Demanded Price	10's,20's,30's,As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nimotop 30mg Tablets MHRA Approved.
	Me-too status	044185 Nimoden 30 mg Tablet Manufacturer Name High-Q Pharmaceutical,
	GMP status	29-03-2019 Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnel, Quality control/QA and production operations. Keeping in view the observations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2148.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK,"
	Brand Name +Dosage Form + Strength	Quetical 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Quetiapine as Fumarate…25mg"
	Diary No. Date of R& I & fee	Dy.No 3199 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Anti-Psychotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL® tablets, USFDA Approved with box warning.
	Me-too status	068244; "Quit 25mg Tablets M/s Navegal Laboratories, 41/1-A-2, phase-1, Industrial Estate,Hattar."
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses

		The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2149.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Quetical 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Quetiapine as Fumarate…100mg"
	Diary No. Date of R& I & fee	Dy.No 3198 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Anti-Psychotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL® tablets, USFDA Approved with box warning.
	Me-too status	056759 Pine Tablets 100mg M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2150.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Quetical 200mg Tablet
	Composition	"Each Film Coated Tablet Contains: Quetiapine as Fumarate…200mg"
	Diary No. Date of R& I & fee	Dy.No 3197 dated 23-01-2019 Rs.20,000/- 23-01-2019

	Pharmacological Group	Anti-Psychotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL® tablets, USFDA Approved with box warning.
	Me-too status	068241 "Quit 200mg Tablets. " Navegal Laboratories, 41/1-A-2, phase-1, Industrial Estate, Hattar."
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2151.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Selmer 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sevelamer HCl…400mg"
	Diary No. Date of R& I & fee	Dy.No 3195 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Drugs for treatment of hyperkalemia and hyperphosphatemia
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Renagel (sevelamer hydrochloride) tablet USFDA Approved.
	Me-too status	058394 Sevela 400mg Tablet By Hilton Pharma (Pvt.) Limited, Karachi
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which

		were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2152.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Selmer 800mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sevelamer HCl…800mg"
	Diary No. Date of R& I & fee	Dy.No 3193 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Drugs for treatment of hyperkalemia and hyperphosphatemia
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Renagel (sevelamer hydrochloride) tablet USFDA Approved.
	Me-too status	058395 Sevela 800mg Tablet By Hilton Pharma (Pvt.) Limited, Karachi
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic)

		4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2153.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Sertacal 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sertraline as Hydrochloride…50mg"
	Diary No. Date of R& I & fee	Dy.No 3194 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Antidepressant,SSRI
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZOLOFT (sertraline hydrochloride) tablets, USFDA Approved
	Me-too status	076844 "Ertalin 50 mg Tablets Genome Pharmaceuticals (Pvt,) Ltd, 16/1-Phase IV Industrial Estate,Hattar."
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2154.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Sertacal 100mg Tablet

	Composition	"Each Film Coated Tablet Contains: Sertraline as Hydrochloride…100mg"
	Diary No. Date of R& I & fee	Dy.No 3203 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Antidepressant,SSRI
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZOLOFT (sertraline hydrochloride) tablets, USFDA Approved
	Me-too status	076845 "Ertalin 100 mg Tablets Genome Pharmaceuticals (Pvt,) Ltd, 16/1-Phase IV Industrial Estate,Hattar."
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2155.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Itocal 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Itopride HCl…50mg"
	Diary No. Date of R& I & fee	Dy.No 3201 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Propulsives
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PMDA Approved. M-293
	Me-too status	075852 ITP 150mg Tablet By M/s Sami Karachi .

	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2156.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Rafaxical 550mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rifaximin…550mg"
	Diary No. Date of R& I & fee	Dy.No 3196 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Intestinal Anti-infectives
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XIFAXAN® (rifaximin) Tablets USFDA Approved.
	Me-too status	070733 Nimixa 550mg Tablet By M/s Getz Karachi .
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic)

		2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2157.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Mexical 15mg Tablet
	Composition	"Each tablet contains: Meloxicam…15mg"
	Diary No. Date of R& I & fee	Dy.No 3200 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, Non-steroids
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MOBIC® (meloxicam) tablets, for oral use USFDA Approved with box warning.
	Me-too status	070293 Meloxadvan Tablet 15mg By M/s Advanced Pharmaceuticals, RCCI, Rawat
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved.	

2158.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Etrocal 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Etoricoxib…60mg"
	Diary No. Date of R& I & fee	Dy.No 3202 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, Non-steroids
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Etoricoxib 60 mg Film-coated Tablets MHRA Approved.
	Me-too status	047529 "Arcoxia 60mg Tablets. By M/s Muller & Phipps Pakistan (Private) Limited, Uzma Court, 1st Floor, Main Clifton Road,Karachi."
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2159.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd.Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Betacal 0.1% w/w Lotion
	Composition	"Each ml Contains: Betamethasone as valerate…0.1% w/w"
	Diary No. Date of R& I & fee	Dy.No 4369 dated 31-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.Plastic bottle
	Approval status of product in	Betnovate Lotion

	Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	051176 Betamethasone Lotion By M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2160.	Name and address of manufacturer / Applicant	"M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Betacal 0.05% w/w Lotion
	Composition	"Each ml Contains: Betamethasone as Dipropionate…0.05% w/w"
	Diary No. Date of R& I & fee	Dy.No 4368 dated 31-01-2019 Rs.20,000/- Dated 30-01-2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.Plastic bottle
	Approval status of product in Reference Regulatory Authorities.	Diprosone 0.05 % w/w Lotion MHRA Approved.
	Me-too status	055223 Procort Lotion. Each Tube Contains:- Betamethasone as Dipropionate……0.05% "M/s Shrooq Pharmaceuticals (Pvt) Ltd,21-KM, Ferozepur Road, Lahore."
	GMP status	06-11-2018. Recommendations: During inspection, a few suggestions for further improvements were given to the firm's management, which were graciously accepted and agreed to be comply with by the firm. Based upon the manufacturing, quality control and

		environmental facilities provided by the firm, the technical staff employed, the documentation reviewed, the SOP's available and observations made during inspection, the pan el unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: 1- Tablet section(General) (Antibiotic, Non-Antibiotic) 2- Dry Powder suspension section, General (Antibiotic, Non-Antibiotic) 3- Capsule section General (Antibiotic, Non-Antibiotic) 4- Liquid syrup section General (Antibiotic, Non-Antibiotic) 5- QC 6- Warehouses The panel also unanimously recommends the grant of following sections as well: 1- Cream/Ointment/Lotion section General (Antibiotic, Non-Antibiotic) 2- Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2161.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	K-Tan 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Losartan Potassium…25mg"
	Diary No. Date of R& I & fee	Dy.No 2060 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	COZAAR® (losartan potassium) tablets Approved in USFDA with box warning.
	Me-too status	076112 Losaan 25mg Tablet M/s Maple Karachi . .
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• Application is not as per prescribed form only checklist is provided with annexures.
	Decision: Deferred for submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976.	
2162.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	K-Tan 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Losartan Potassium…50mg"
	Diary No. Date of R& I & fee	Dy.No 2061 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,As per SRO.

	Approval status of product in Reference Regulatory Authorities.	COZAAR® (losartan potassium) tablets Approved in USFDA with box warning.
	Me-too status	057848 Losanta 50mg Tablet M/s Asian Continental (Pvt.) Ltd Karachi
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• Application is not as per prescribed form only checklist is provided with annexures.
	Decision: Deferred for submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976.	
2163.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	K-Tan 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Losartan Potassium…100mg"
	Diary No. Date of R& I & fee	Dy.No 2062 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10’s,20’s,30’s,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	COZAAR® (losartan potassium) tablets Approved in USFDA with box warning.
	Me-too status	079743 "Xavor Tablet M/s Ferozesons Labs,P.O Ferozesons Amangarh,Nowshera."
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• Application is not as per prescribed form only checklist is provided with annexures.
	Decision: Deferred for submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976.	
2164.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Meslid 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nimesulide…100mg"
	Diary No. Date of R& I & fee	Dy.No 2059 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs.
	Pack size & Demanded Price	10’s,20’s,30’s, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	EMA Approved.
	Me-too status	044756 "Frendcogen Tablets 100mg. M/s Friends Pharma (Pvt.) Ltd.,d31 KM Ferozepur Road,Lahore."

	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance

	Remarks of the Evaluator (V)	• Internationally it is available as uncoated tablet.
		• Keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board in its 269th approved the formulation of Nimesulide Tablets 100mg with a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice.
		  • Treatment of acute pain
		  • Primary dysmenorrhea

	Decision: Deferred for revision of coating and fee as per reference regulatory authoriries	
2165.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Esmide 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Leflunomide…10mg"
	Diary No. Date of R& I & fee	Dy.No 3176 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Immunosuppressants
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10’s,20’s,30’s, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ARAVA (leflunomide), tablets, Approved in USFDA with box warning.
	Me-too status	070350 "Lefonate Tablets 10mg M/s Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar"
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	Belongs to L04 class.
	Decision: Approved.	
2166.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Vasium 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin Calcium eq to Rosuvastatin …5mg"
	Diary No. Date of R& I & fee	Dy.No 2065 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10’s,20’s,30’s, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.
	Me-too status	056102 Pasage Tablets Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.

	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2167.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Vasium 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin Calcium eq to Rosuvastatin …10mg"
	Diary No. Date of R& I & fee	Dy.No 2066 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.
	Me-too status	054788 Pasage Tablets 10mg Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2168.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Vasium 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin Calcium eq to Rosuvastatin …20mg"
	Diary No. Date of R& I & fee	Dy.No 2067 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.
	Me-too status	054789 Pasage Tablets 20mg M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2169.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Xofen 60mg Tablet

	Composition	"Each Film Coated Tablet Contains: Fexofenadine HCl…60mg"
	Diary No. Date of R& I & fee	Dy.No 2063 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Antihistamine for systemic use. R06AX26
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30'sAs per SRO.
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA® USFDA Approved.
	Me-too status	052779 Fanoxin Tablets 60mg "M/s Jawa Pharmaceutical (Pvt) Ltd, Industrial Area Kot Lakhpat,Lahore
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2170.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Xofen 120mg Tablet
	Composition	"Each Film Coated Tablet Contains: Fexofenadine HCl…120mg"
	Diary No. Date of R& I & fee	Dy.No 2064 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Antihistamine for systemic use. R06AX26
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30'sAs per SRO.
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA® USFDA Approved.
	Me-too status	052778 Fanoxin Tablets 120mg "M/s Jawa Pharmaceutical (Pvt) Ltd, Industrial Area Kot Lakhpat,Lahore
	GMP status	
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2171.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Esfen 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Flurbiprofen…100mg"
	Diary No. Date of R& I & fee	Dy.No 765 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,20's,30's,As per SRO.
	Approval status of product in	Couldnot be confirmed as film coated tablets.

	Reference Regulatory Authorities.	
	Me-too status	058160; Fenbiflor 100mg Tablet M/s Lisko Pakistan Ltd, Karachi
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	Evidence international availability as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for submission of either evidence of approval of reference product as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite fee, master formulation & manufacturing method.	
2172.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Padrin 450mg/35mg Tablet
	Composition	"Each Tablet Contains: Paracetamol…450mg Orphenadrine Citrate…35mg"
	Diary No. Date of R& I & fee	Dy.No 3178 dated 23-01-2019 Rs.20,000/- Dated 18-01-2019
	Pharmacological Group	Skeletal muscle relaxant
	Type of Form	Form 5
	Finished product Specification	Manufacture Specs
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Norgesic USFDA Approved.
	Me-too status	078572 "Barfim Tablets M/s Wisdom Pharmaceuticals Industry, 78-A Industrial Estate, Hayatabad Peshawar
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2173.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Padrin 650mg/50mg Tablet
	Composition	"Each Tablet Contains: Paracetamol…650mg Orphenadrine Citrate…50mg"
	Diary No. Date of R& I & fee	Dy.No 3179 dated 23-01-2019 Rs.20,000/- Dated 18-01-2019
	Pharmacological Group	Skeletal muscle relaxant
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs.
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	075984 Orthoflex-D 50mg Tablet By M/s Noa Hemis Karachi . .
	GMP status	Last inspection conducted on 28-09-2017 and report

		concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for status in reference regulatory authorities	
2174.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Glipt M 50/500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…500mg"
	Diary No. Date of R& I & fee	Dy.No 773 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Drugs Used In Diabetes A10BD08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	GALVUMET TGA Approved
	Me-too status	081905 Galmet 50mg/500mg Tablet M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2175.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Glipt M 50/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…850mg"
	Diary No. Date of R& I & fee	Dy.No 774 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Drugs Used In Diabetes A10BD08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	GALVUMET TGA Approved
	Me-too status	081906 Galmet 50mg/850mg Tablet M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	

2176.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Hyperil 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Atenolol…50mg"
	Diary No. Date of R& I & fee	Dy.No 769 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Beta Blocking Agents
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TENORMIN® (atenolol), Uncoated Tablets USFDA Approved.
	Me-too status	079888 M-Nol 50 mg Tablet By M/s Mafins Karachi . .
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2177.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Hyperil 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Atenolol…100mg"
	Diary No. Date of R& I & fee	Dy.No 770 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Beta Blocking Agents
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TENORMIN® (atenolol), Uncoated Tablets USFDA Approved
	Me-too status	073308 "Atenocard Tablets 100mg By "Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar"
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2178.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Bactalid 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Linezolid…400mg"
	Diary No. Date of R& I & fee	Dy.No 776 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Antibacterial for systemic use. J01XX08
	Type of Form	Form-5

	Finished product Specification	Inhouse Spec.
	Pack size & Demanded Price	6x1's,6x2's,6x3's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX Tablets 400MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons* Discontinued USFDA Approved.
	Me-too status	055434 Lyzon 400mg Tablet By M/s Getz Pharma Karachi
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2179.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Bactalid 600mg Tablet
	Composition	"Each Film Coated Tablet Contains: Linezolid…600mg"
	Diary No. Date of R& I & fee	Dy.No 776 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Antibacterial for systemic use. J01XX08
	Type of Form	Form-5
	Finished product Specification	Inhouse Spec.
	Pack size & Demanded Price	6x1's,6x2's,6x3's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX Tablets USFDA Approved.
	Me-too status	055773 Leckzolid 600mg Tablet Medimarker's Pharmaceutical, Hyderabad
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2180.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Litamet 15/500 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg Metformin HCL…500mg"
	Diary No. Date of R& I & fee	Dy.No 771 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET USFDA Approved with box warning.
	Me-too status	070493 Prefair 500/15mg M/s Merck, Balochistan
	GMP status	Last inspection conducted on 28-09-2017 and report

		concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	The applied formulation is "Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg whereas, firm has mentioned in master formulation "Each Film Coated Tablet Contains: Pioglitazone HCL…15mg.
	Decision: Deferred for submission of applied formulation in line with reference product alongwith submission of composition/label claim & master formulation accordingly.	
2181.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Litamet 15/850 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg Metformin HCL…850mg"
	Diary No. Date of R& I & fee	Dy.No 772 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET USFDA Approved with box warning.
	Me-too status	076217 Muppet 15mg/850mg Tablet M/s PPP, Karachi . .
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	The applied formulation is "Each Film Coated Tablet Contains: Pioglitazone as HCL…15mg whereas, firm has mentioned in master formulation "Each Film Coated Tablet Contains: Pioglitazone HCL…15mg.
	Decision: Deferred for submission of applied formulation in line with reference product alongwith submission of composition/label claim & master formulation accordingly.	
2182.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Bactalid Suspension 100mg/5ml
	Composition	"Each 5ml contains: Linezolid…100mg"
	Diary No. Date of R& I & fee	Dy.No 775 dated 07-01-2019 Rs.20,000/- Dated 03-01-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	60ml,90ml,120ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) injection, tablets and oral suspension USFDA approved.
	Me-too status	081983 Linzol 100mg /5ml oral dry suspension M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• Justification for the qty of linezolid i.e 1.2 g per

		bottle mentioned in master formulation. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for scientific Justification for using overage	
2183.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Laxit 3.35g/5ml Syrup
	Composition	"Each 5ml Contains: Lactulose…3.35g"
	Diary No. Date of R& I & fee	Dy.No 768 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Osmotically acting laxatives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml,90ml,120ml,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Lactusure Syrup of Medisure Laboratories Pakistan
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Lactulose solution is present in USP you have applied for syrup. • Submission of details regarding source of Lactulose, GMP certificate of manufacturer, stability studies of 03 batches conducted under the conditions of Zone IV-A and if Lactulose is imported then the fee Rs. 100,000/- should be submitted.
	Decision: Deferred for submission of COA, GMP of lactulose manufacturer and stability studies of three batches of lactulose conducted in accordance with zone IV-A conditions. & differential fee of Rupee 80,000/- in case of imported lactulose.	
2184.	Name and address of manufacturer / Applicant	**"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"**
	Brand Name +Dosage Form + Strength	Pipral 15mg/120mg Powder for Oral Suspension
	Composition	"Each sachet contains: Dihydroartemisinin…15mg Piperaquine Phosphate…120mg"
	Diary No. Date of R& I & fee	Dy.No 3175 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x8's,16's,24's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed in sachet form.
	Me-too status	078608 "Temquin Sachet "M/s Searle IV Solutions (Pvt.) Ltd,

		(Formeraly M/s Mac & Rains Pharma) 1.5 km Manga Raiwind Road, Manga Mandi, Lahore"
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • The manufacturing outline in packaging operation mentions inspection of tablet however, sachet is applied. • Evidence of approval of applied formulation in sachet form. in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submit outline of manufacturing method of applied formulation.**	
2185.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Pipral 40mg/320mg Capsule
	Composition	"Each capsule contains: Dihydroartemisinin…40mg Piperaquine Phosphate…320mg"
	Diary No. Date of R& I & fee	Dy.No 3174 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x8's,16's,24's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed in capsule form.
	Me-too status	070697 Neo Fansidar 40mg/320mg Capsule By M/s Martin Dow
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	Evidence of approval of applied formulation in capsule form. in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2186.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Spamnil 4mg Capsule
	Composition	"Each Capsule Contains: Thiocolchicoside…4mg"
	Diary No. Date of R& I & fee	Dy.No 766 dated 07-01-2019 Rs.20,000/- Dated 03-01-

		2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's,2x10's,3x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MuscoRil 4 mg capsule rigide MuscoRil 8 mg capsule rigide AIFA Approved
	Me-too status	069906 "Caelyx Capsules M/s Rotex Medica Pakistan (Pvt) Ltd., P.No. 206-207, Industrial Triangle, Kahuta Road, Islamabad
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• European Medicines Agency recommends restricting use of thiocolchicoside by mouth or injection. • Medicine only to be used at low doses for additional short-term relief of painful muscle contractures
	Decision: Approved as per innovator's specification.	
2187.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Obsonil 120mg Capsule
	Composition	"Each Capsule Contains: Orlistat…120mg"
	Diary No. Date of R& I & fee	Dy.No 3173 dated 23-01-2019 Rs.20,000/- Dated 23-01-2019
	Pharmacological Group	Peripherally acting anti-obesity products
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's,2x10's, 3x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	068689 "Orly Capsules 120 mg M/s Rotex Medica Pakistan (Pvt) Ltd., P.No. 206-207, Industrial Triangle, Kahuta Road, Islamabad
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	• The applied formulation is present in the form of pellets whereas, you have not applied for pellets. • Submission of source of pellets , GMP of manufacturer of pellets,Certificate of analysis of pellets, Real time and accelerated stability study data of 3 batches, conducted according to the requirements of zone IV-A, Differential fee (if the pellets are imported). *Deferred in previous meetings for further deliberation upon requirement of accelerated stability studies data of Orlistat IR pellets*.
	Decision: Deferred for COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	
2188.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals,PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"

	Brand Name +Dosage Form + Strength	Zibix 200mg Capsule
	Composition	"Each Capsule Contains: Celecoxib…200mg"
	Diary No. Date of R& I & fee	Dy.No 767 dated 07-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's,2x10's,3x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CELEBREX ® (celecoxib) capsules, USFDA Approved.
	Me-too status	065859 "Selxib -200mg Capsule "M/s Fynk Pharmaceuticals,19 K.M. G.T. Road, Kala Shah Kaku, Lahore"
	GMP status	Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2189.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Notramol Tablet 650mg/75mg "
	Composition	"Each Tablet Contains: Paracetamol…650mg Tramadol HCL…75mg"
	Diary No. Date of R& I & fee	Dy.No 3973 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics. N02AJ13
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, 200/- per pack.,Alu-Alu blister.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in applied strength.
	Me-too status	Could not be confirmed in applied strength.
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2190.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Notramol Tablet 325mg/37.5mg
	Composition	"Each film coated Tablet Contains: Paracetamol…325mg

		Tramadol HCL…37.5mg"
	Diary No. Date of R& I & fee	Dy.No 3972 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics. N02AJ13
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, 120/- per pack.,Alu-Alu blister.
	Approval status of product in Reference Regulatory Authorities.	Tramacet film coated Manufacturer/sponsor:Janssen Ortho Inc. Health Canada Approved
	Me-too status	081956 Radol-P Tablet 325/37.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2191.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Novaset Tablet 4mg
	Composition	"Each Film Coated Tablet Contains: Ondansetron HCl dihydrate eq. to ondansetron…4mg"
	Diary No. Date of R& I & fee	Dy.No 3974 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Antiemetics And Antinauseants A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP.
	Pack size & Demanded Price	Rs 600/pack, 1x10's
	Approval status of product in Reference Regulatory Authorities.	ZOFRAN® (ondansetron hydrochloride) tablets USFDA Approved.
	Me-too status	081545 Ondonix 4mg Tablet By M/s Genix Pharma Karachi . .
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2192.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Novaset Tablet 8mg
	Composition	"Each Film Coated Tablet Contains: Ondansetron HCl Dihydrate eq. to Ondansetron…8mg"
	Diary No. Date of R& I & fee	Dy.No 3974 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Antiemetics And Antinauseants A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP.
	Pack size & Demanded Price	Rs 4000/pack, 1x10's
	Approval status of product in Reference Regulatory Authorities.	ZOFRAN Tablets, 8 mg (ondansetron HCl dihydrate equivalent to 8 mg of ondansetron), USFDA Approved.

	Me-too status	081451 Ondonx Tablet Genix Pharma Karachi . .
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2193.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Novolox Tablet 400mg
	Composition	"Each Film Coated Tablet Contains: Moxifloxacin HCl eq toMoxifloxacin…400mg"
	Diary No. Date of R& I & fee	Dy.No 3971 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Fluoroquinolones J01MA14
	Type of Form	Form 5
	Finished product Specification	USP specs
	Pack size & Demanded Price	Rs 1000/1x10's,
	Approval status of product in Reference Regulatory Authorities.	Moxifloxacin 400mg Tablet by Bayer Health Care USFDA Approved
	Me-too status	074931 Moxpin 400 mg Tablet M/s Winthrox Karachi . .
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2194.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Noxapro 10mg Tablet
	Composition	Each film coated tablet contains: Escitalopram Oxalate eq to Escitalopram…10mg
	Diary No. Date of R& I & fee	Dy.No 3969 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Antidepressants Selective serotonin reuptake inhibitors N06AB10
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 460/pack of 14's, Rs. 570/pack of 20's.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved with boxwarning.
	Me-too status	054911 Citowel 10mg Tablets Wellborne Pharmachem and Biologicals, Plot#51/1 Phase I&II Industrial Estate,Hattar.
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2195.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Noxapro 20mg Tablet
	Composition	Each film coated tablet contains:

		Escitalopram Oxalate eq to Escitalopram…20mg
	Diary No. Date of R& I & fee	Dy.No 3970 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Antidepressants Selective serotonin reuptake inhibitors N06AB10
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 500/pack of 14's, Rs. 625/pack of 20's.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved with box warning.
	Me-too status	052510 "Neolexa-20 Tablets. "M/s Shrooq Pharmaceuticals (Pvt) Ltd,21-KM, Ferozepur Road, Lahore."
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2196.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Pirocam Tablets 20mg
	Composition	"Each Tablet Contains: Piroxicam as Betacyclodextrin…20mg"
	Diary No. Date of R& I & fee	Dy.No 3977 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,20's,30's, Rs 125/pack of 10's, Rs. 215/pack of 20's.
	Approval status of product in Reference Regulatory Authorities.	ANSM and ITALY Approved.
	Me-too status	079264 "Fedracam-BCD Tablets 20mg "Fedro Pharmaceutical, 149, Industrial Estate, Jamrud Road,Peshawar
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	The signature of applicant is missing.
	Decision: Approved as per innovator's specification.	
2197.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Vilmet Tablets 50/500mg
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…500mg"
	Diary No. Date of R& I & fee	Dy.No 3978 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Drugs Used In Diabetes A10BD08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1400/pack of 30's tablets,14's.

	Approval status of product in Reference Regulatory Authorities.	GALVUMET\ TGA Approved
	Me-too status	081905 Galmet 50mg/500mg Tablet M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	• Form 5 not signed by applicant.
	Decision: Deferred for submission of signed application for applied formulation.	
2198.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Vilmet Tablets 50/1000mg
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…1000mg"
	Diary No. Date of R& I & fee	Dy.No 3979 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Drugs Used In Diabetes A10BD08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1900/pack of 30's tablets,14's.
	Approval status of product in Reference Regulatory Authorities.	TGA Approved.
	Me-too status	081907 Galmet 50mg/1000mg Tablet M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	• Form 5 not signed by applicant.
	Decision: Deferred for submission of signed application for applied formulation.	
2199.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Novofen Suspension 100mg/5ml
	Composition	"Each 5ml contains: Ibuprofen…100mg"
	Diary No. Date of R& I & fee	Dy.No 3985 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs 30.00/pack of 60ml, Rs 55.00/pack of 120ml,
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	062324 "Pironec Suspension "Atlantic Pharmaceutical (Pvt) Ltd,89-D, Industrial Eastate, Hayatabad,Peshawar.(contract manufacturing from M/s Polyfine Chempharma, Peshawar)"
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	• The manufacturing outline of applied formulation has not been provided.

		• Firm has liquid syrup, Capsule and Tablet section.
	Decision: Deferred for submission of manufacturing outline for applied formulation.	
2200.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Dominov Suspension 5mg/5ml
	Composition	"Each 5ml contains: Domperidone …5mg"
	Diary No. Date of R& I & fee	Dy.No 3984 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs 45/pack of 60ml, Rs. 79.50/Pack of 120ml.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	062318 "Epodom Suspension M/s "Atlantic Pharmaceutical (Pvt) Ltd,89-D, Industrial Eastate, Hayatabad,Peshawar.(contract manufacturing from M/s Polyfine Chempharma, Peshawar)"
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Firm has liquid syrup section.
	Decision: Approved as per innovator's specification.	
2201.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Noracetam Oral liquid 100mg/ml
	Composition	"Each 5ml contains: Levetiracetam…500mg"
	Diary No. Date of R& I & fee	Dy.No 3981 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Anti-epileptics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 325/pack of 60ml, Rs. 720/pack of 120ml.
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam Rosemont 100mg/ml Oral Solution MHRA Approved.
	Me-too status	081613 Tamlev 100mg/ml oral Solution By M/s Medisure Lab. Karachi . .
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Firm has liquid syrup section.
	Decision: Approved.	
2202.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Thiosid Capsules 4mg
	Composition	"Each Capsule Contains: Thiocolchicoside…4mg"
	Diary No. Date of R& I & fee	Dy.No 3965 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs. 345/pack 2x10's Capsule.
	Approval status of product in	MuscoRil 4 mg capsule rigide

	Reference Regulatory Authorities.	MuscoRil 8 mg capsule rigide AIFA Approved
	Me-too status	069906 "Caelyx Capsules M/s Rotex Medica Pakistan (Pvt) Ltd., P.No. 206-207, Industrial Triangle, Kahuta Road, Islamabad
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	• The manufacturing outline of applied formulation has not been provided. • European Medicines Agency recommends restricting use of thiocolchicoside by mouth or injection. • Medicine only to be used at low doses for additional short-term relief of painful muscle contractures
	Decision: Deferred for submission of manufacturing outline for applied formulation.	
2203.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Thiosid Capsules 8mg
	Composition	"Each Capsule Contains: Thiocolchicoside…8mg"
	Diary No. Date of R& I & fee	Dy.No 3966 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs. 525/pack 2x10's Capsule.
	Approval status of product in Reference Regulatory Authorities.	MuscoRil 4 mg capsule rigide MuscoRil 8 mg capsule rigide AIFA Approved
	Me-too status	069906 "Caelyx Capsules M/s Rotex Medica Pakistan (Pvt) Ltd., P.No. 206-207, Industrial Triangle, Kahuta Road, Islamabad
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	• The manufacturing outline of applied formulation has not been provided. • European Medicines Agency recommends restricting use of thiocolchicoside by mouth or injection. • Medicine only to be used at low doses for additional short-term relief of painful muscle contractures
	Decision: Deferred for submission of manufacturing outline for applied formulation.	
2204.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Diclonov Capsules 75mg
	Composition	"Each Capsule Contains: Diclofenac sodium…75mg"
	Diary No. Date of R& I & fee	Dy.No 3963 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs. 255/2x10's ,
	Approval status of product in	Couldnot be confirmed.

	Reference Regulatory Authorities.	
	Me-too status	068239 "Naveflam Capsules 75mg. " Navegal Laboratories, 41/1-A-2, phase-1, Industrial Estate,Hattar."
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • The Form 5 doesnot mention enteric coated pellets.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Correction in Form 5**	
2205.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Diclonov Capsules 100mg
	Composition	"Each Capsule Contains: Diclofenac sodium enteric coated pellets…100mg"
	Diary No. Date of R& I & fee	Dy.No 3964 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs. 120/2x10's ,
	Approval status of product in Reference Regulatory Authorities.	Couldnot beconfirmed.
	Me-too status	042985; "Movom –P Capsules 100mg M/s "Nenza Pharmaceuticals (Pvt) Ltd., 33-A, Hayatabad Industrial Estate, Peshawar."
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • The Form 5 doesnot mention enteric coated pellets.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
2206.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Lungzorex DM 6.25mg/5mg
	Composition	"Each 5ml contains: Diphenhydramine HBr…6.25mg Dextromethorphan HCl…5mg"
	Diary No. Date of R& I & fee	Dy.No 3983 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Expectorant
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs 50/60ml, Rs 85/120ml
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in applied strength.

	Me-too status	074514 "Kufmed DM Syrup. " Fozan Pharmaceuticals (Pvt) Ltd,36-A, industrial Estate, Hayatabad,Peshawar"
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Firm has liquid syrup section.
	Decision: Deferred for submission of reference regulatory authority status	
2207.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Lungzorex Syrup
	Composition	"Each 5ml contains: Ammonium chloride…30mg Menthol…0.98mg Aminophylline…32mg Diphenhydramine HCl…8mg"
	Diary No. Date of R& I & fee	Dy.No 3982 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Antitussive
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs 40/60ml, Rs 68/120ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed.
	Me-too status	073704 Adalin Syrup Sugar Free M/s Macter, F-216, Karachi . .
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Firm has liquid syrup section.
	Decision: Deferred for submission of reference regulatory authority status	
2208.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Nozic Syrup 10mg/5ml
	Composition	"Each 5ml contains: Zinc sulphate eq. to elemental zinc…10mg"
	Diary No. Date of R& I & fee	Dy.No 3986 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Anti-Diarrheal
	Type of Form	Form 5
	Finished product Specification	IP
	Pack size & Demanded Price	Rs 60/60ml, Rs 115/120ml,
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed.
	Me-too status	Zevro Syrup 10mg. Reg. No. 77058
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Firm has liquid syrup section.
	Decision: Approved as per innovator's specification.	
2209.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Nozic Syrup 20mg/5ml
	Composition	"Each 5ml contains: Zinc sulphate eq. to elemental zinc…20mg"
	Diary No. Date of R& I & fee	Dy.No 3987 dated 29-01-2019 Rs.20,000/- Dated 28-01-2019

	Pharmacological Group	Anti-Diarrheal
	Type of Form	Form 5
	Finished product Specification	IP
	Pack size & Demanded Price	Rs 70/60ml, Rs 135/120ml,
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed.
	Me-too status	075129 "Hi-Z 20mg/5ml syrup "M/s Gulf Pharmaceuticals, P45,S-5, Industrial zone ,Rawat ,Islamabad"
	GMP status	CLB in its 267th meeting held on 31st December 2018.Has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Firm has liquid syrup section.
	Decision: Approved as per innovator's specification.	
2210.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore"
	Brand Name +Dosage Form + Strength	Vemteno 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Tenofovir Alafenamide Fumarate eq to Tenofovir…25mg"
	Diary No. Date of R& I & fee	Dy.No 8888 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Nucleoside and nucleotide reverse transcriptase inhibitors
	Type of Form	Form 5
	Finished product Specification	Present in IP.
	Pack size & Demanded Price	As per Brand leader, 10's,14's,20's,28's,30's
	Approval status of product in Reference Regulatory Authorities.	Vemlidy USFDA Approved with box warning.
	Me-too status	NA
	GMP status	08-03-2017 & 31-03-2017. Recommendations: The firm M/s CCL Pharmaceuticals Lahore was evaluated with respect to production operation, personnel, documentation, Quality assurance and Quality control etc. Based on the observations, the firm was found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Internationally it is approved as "Tenofovir Alafenamide Fumarate eq to Tenofovir Alafenamide …25mg whereas,firm has applied for Each Film Coated Tablet Contains:Tenofovir Alafenamide Fumarate eq to Tenofovir…25mg". • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/.
	Decision: Deferred for the following: • **For submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.** • **For correction of composition /label claim of applied formulation keeping it in line with reference product i.e. "Tenofovir Alafenamide Fumarate eq to Tenofovir Alafenamide …25mg film coated tablet.**	
2211.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK"
	Brand Name +Dosage Form + Strength	Profen Tablets 50mg/200µg
	Composition	"Each delayed release tablet contains: Diclofenac Sodium…50mg Misoprostol 1 %HPMC dispersion…200µg

	Diary No. Date of R& I & fee	Dy.No 8805 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	NSAID with mucoprotective
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Arthrotec(diclofenac sodium and misoprostol tablets), USFDA Approved with box warning.
	Me-too status	053327 Rotec-50 Tablet M/s Searle Pakistan Limited Karachi
	GMP status	12-05-2018 Overall the firm was operating under good level of cGMP.
	Remarks of the Evaluator (V)	FID confirmed availability of bilayer tablet compression machine in report dated 03.05.2019
	Decision: Approved	
2212.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK"
	Brand Name +Dosage Form + Strength	Ipod 50mg/5ml Suspension
	Composition	"Each 5ml suspension contains: Cefpodoxime Proxetil as Cefpodoxime…50mg"
	Diary No. Date of R& I & fee	Dy.No 7313 dated 20-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	NTIN Cefpodoxime Proxetil Eq 50mg Base/5ml **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	060519; "Qink Dry Suspension "M/s. Wilshire Laboratories (Pvt) Ltd;124/1 Industrial Estate, Kot Lakhpat,Lahore."
	GMP status	12-05-2018 Overall the firm was operating under good level of cGMP.
	Remarks of the Evaluator (V)	Dry Powder Suspension (Cephalosporin) section confirmed vide letter No.F.3-7/95-Lic(Vol-I) dated 19.02.2016
	Decision: Approved	
2213.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK"
	Brand Name +Dosage Form + Strength	Ipod 100mg/5ml Suspension
	Composition	"Each 5ml suspension contains: Cefpodoxime Proxetil as Cefpodoxime…100mg"
	Diary No. Date of R& I & fee	Dy.No 7314 dated 20-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	NTIN Cefpodoxime Proxetil Eq 100mg Base/5ml **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	053636 "Qink Dry Suspension "M/s. Wilshire Laboratories (Pvt) Ltd;124/1 Industrial Estate, Kot Lakhpat,Lahore."

	GMP status	12-05-2018 Overall the firm was operating under good level of cGMP.
	Remarks of the Evaluator (V)	Dry Powder Suspension (Cephalosporin) section confirmed vide letter No.F.3-7/95-Lic(Vol-I) dated 19.02.2016
	Decision: Approved	
2214.	Name and address of manufacturer / Applicant	"M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu"
	Brand Name +Dosage Form + Strength	T Caine Injection 1% w/v
	Composition	Each ml of solution contains: Lidocaine HCl…10mg"
	Diary No. Date of R& I & fee	Dy.No 7056 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Anesthetics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2ml glass ampoule, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed.
	Me-too status	076468 Lidocaine HCl 1% Injection 2ml M/s Healthtek Karachi . .
	GMP status	06-11-2018 Conclusion: The firm may be considered to be operating at satisfactory level of cGMP Compliance.
	Remarks of the Evaluator (V)	• Panel in inspection dated 05.1.2017 confirmed ampoule section. • Signature of applicant is missing on Form 5. • Evidence of approval of "lidocaine without preservative" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for the following: • **Submission of signed application of applied formulation on Form 5.** • **Confirmation whether formulation will be preservative free or otherwise with scientific rational.**	
2215.	Name and address of manufacturer / Applicant	"M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu"
	Brand Name +Dosage Form + Strength	Olania 10mg Tablet
	Composition	"Each Tablet Contains: Olanzapine…10mg"
	Diary No. Date of R& I & fee	Dy.No 7055 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zyprexa film coated tablet USFDA Approved.
	Me-too status	080870 "Olazap 10mg Tablet " Wellborne Pharmachem and Biologicals, Plot#51/1 Phase I&II Industrial Estate,Hattar."
	GMP status	06-11-2018 Conclusion: The firm may be considered to be operating at satisfactory

		level of Cgmp Compliance.
	Remarks of the Evaluator (V)	• Signature of applicant is missing on Form 5. • Evidence of approval of olanzapine as uncoated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for the following: • **Submission of either evidence of approval of reference product as uncoated tablet or otherwise revision of applied formulation in line with reference product i.e. film coated tablet along with submission of requisite fee, master formulation & manufacturing method.** • **Submission of signed application of applied formulation on Form 5.**	
2216.	Name and address of manufacturer / Applicant	"M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu"
	Brand Name +Dosage Form + Strength	Temzol Plus 20mg/1100mg
	Composition	"Each Capsule Contains: Omeprazole…20mg Sodium Bicarbonate…1100mg
	Diary No. Date of R& I & fee	Dy.No 7057 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	2x7's, 1x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zegerid USFDA Approved.
	Me-too status	072153 "Omsod 20 mg Capsules "Reliance Pharma, P No 8,Street S-8, RCCI, Industrial State, Rawat"
	GMP status	06-11-2018 Conclusion: The firm may be considered to be operating at satisfactory level of Cgmp Compliance.
	Remarks of the Evaluator (V)	• Source of pellets: Vision Pharma. • Signature of applicant is missing on Form 5. • The form 5 doesnot mention enteric coated pellets. Clarification of composition is required.
	Decision: Deferred for submission of signed application of applied formulation on Form 5 alongwith composition/label claim in line with reference product.	
2217.	Name and address of manufacturer / Applicant	"M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu"
	Brand Name +Dosage Form + Strength	Temzol Plus 40mg/1100mg
	Composition	"Each Capsule Contains: Omeprazole…40mg Sodium Bicarbonate…1100mg
	Diary No. Date of R& I & fee	Dy.No 7058 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	2x7's, 1x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zegerid USFDA Approved.

	Me-too status	072154 "Omsod 40 mg Capsules "Reliance Pharma, P No 8,Street S-8, RCCI, Industrial State, Rawat"
	GMP status	06-11-2018 Conclusion: The firm may be considered to be operating at satisfactory level of Cgmp Compliance.
	Remarks of the Evaluator (V)	• Source of pellets: Vision Pharma. • Signature of applicant is missing on Form 5. • The form 5 doesnot mention enteric coated pellets. Clarification of composition is required.
	Decision: Deferred for submission of signed application of applied formulation on Form 5 alongwith composition/label claim in line with reference product	
2218.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot no 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Fabulas 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Febuxostat…40mg"
	Diary No. Date of R& I & fee	Dy.No 5813 dated 11-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Preparations inhibiting uric acid production
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ULORIC (febuxostat) tablets, USFDA Approved with boxwarning.
	Me-too status	081104 Febuxin 40mg Tablet By M/s AGP Pvt. Ltd. Karachi . .
	GMP status	17-01-2019 Recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2219.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot no 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Fabulas 80mg Tablet
	Composition	"Each Film Coated Tablet Contains: Febuxostat…80mg"
	Diary No. Date of R& I & fee	Dy.No 5815 dated 11-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Preparations inhibiting uric acid production
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ULORIC (febuxostat) tablets, USFDA Approved with boxwarning.
	Me-too status	081105 Febuxin 80mg Tablet

		By M/s AGP Pvt. Ltd. Karachi . .
	GMP status	17-01-2019 Recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2220.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot no 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Valtril 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Valsartan…25.7mg Sacubitril…24.3mg"
	Diary No. Date of R& I & fee	Dy.No 5820 dated 11-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ENTRESTO® (sacubitril and valsartan) tablets USFDA Approved.
	Me-too status	NA
	GMP status	17-01-2019 Recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- • The internationally approved product "ENTRESTO" label claim is "Each film-coated tablet contains Sacubitril…24 mg and Valsartan….26 mg". Whereas, firm has applied for "Each Film Coated Tablet Contains: Sacubitril…24.3mg Valsartan…25.7mg". EPAR of Innovator. • The isolated active substance is a co-crystal complex of the sodium salts of two individual active

		components, sacubitril and valsartan, in hydrated form. • The sacubitril-valsartan complex is a white to almost white crystalline powder and is hygroscopic above 60% RH so needs to be protected from water. • Entresto is a fixed-dose combination product presented as film-coated tablets containing sacubitril and valsartan as active substances as a trisodium hemipentahydrate co-crystal. Conclusion Hence, sacubitril-valsartan is available in the form of co crystal complex instead of two individual active components.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version	
2221.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot no 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Valtril 200mg Tablet
	Composition	"Each Film Coated Tablet Contains: Valsartan…102.8mg Sacubitril…97.2mg"
	Diary No. Date of R& I & fee	Dy.No 5816 dated 11-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ENTRESTO® (sacubitril and valsartan) tablets USFDA Approved.
	Me-too status	NA
	GMP status	17-01-2019 Recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- • The internationally approved product "ENTRESTO" label claim is "Each film-coated tablet contains Sacubitril…97 mg and Valsartan….103 mg". Whereas, firm has applied for "Each Film Coated Tablet Contains: Sacubitril…97.2mg Valsartan…102.8 mg". EPAR of Innovator. • The isolated active substance is a co-crystal

		complex of the sodium salts of two individual active components, sacubitril and valsartan, in hydrated form. • The sacubitril-valsartan complex is a white to almost white crystalline powder and is hygroscopic above 60% RH so needs to be protected from water. • Entresto is a fixed-dose combination product presented as film-coated tablets containing sacubitril and valsartan as active substances as a trisodium hemipentahydrate co-crystal. Conclusion • Hence, sacubitril-valsartan is available in the form of co crystal complex instead of two individual active components.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version	
2222.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot no 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Valtril 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…51.4mg Sacubitril…48.6mg"
	Diary No. Date of R& I & fee	Dy.No 5819 dated 11-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ENTRESTO® (sacubitril and valsartan) tablets USFDA Approved.
	Me-too status	NA
	GMP status	17-01-2019 Recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- • The internationally approved product "ENTRESTO" label claim is "Each film-coated tablet contains Sacubitril…49 mg and Valsartan….51 mg". Whereas, firm has applied for "Each Film Coated Tablet Contains: Sacubitril…48.6mg Valsartan…51.4 mg".

		EPAR of Innovator. • The isolated active substance is a co-crystal complex of the sodium salts of two individual active components, sacubitril and valsartan, in hydrated form. • The sacubitril-valsartan complex is a white to almost white crystalline powder and is hygroscopic above 60% RH so needs to be protected from water. • Entresto is a fixed-dose combination product presented as film-coated tablets containing sacubitril and valsartan as active substances as a trisodium hemipentahydrate co-crystal. Conclusion • Hence, sacubitril-valsartan is available in the form of co crystal complex instead of two individual active components.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2223.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot no 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Empazin XR 5mg/1000mg Tablet
	Composition	"Each extended release tablet contains: Empagliflozin…5mg Metformin HCl…1000mg"
	Diary No. Date of R& I & fee	Dy.No 5818 dated 11-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SYNJARDY® XR (empagliflozin and metformin hydrochloride extended-release) tablets, for oral use USFDA Approved with box warning.
	Me-too status	NA
	GMP status	17-01-2019 Recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/-.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	

2224.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot no 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Empazin XR 12.5mg/1000mg Tablet
	Composition	"Each extended release tablet contains: Empagliflozin…12.5mg Metformin Hcl…1000mg"
	Diary No. Date of R& I & fee	Dy.No 5817 dated 11-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SYNJARDY® XR (empagliflozin and metformin hydrochloride extended-release) tablets, for oral use USFDA Approved with box warning.
	Me-too status	NA
	GMP status	17-01-2019 Recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/-.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version	
2225.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot no 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Vortine 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine as HCl…20mg"
	Diary No. Date of R& I & fee	Dy.No 5814 dated 11-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TRINTELLIX (vortioxetine) tablets, is an immediate-release tablet for oral administration that contains the beta (β) polymorph of vortioxetine hydrobromide (HBr). USFDA Approved with box warning.
	Me-too status	NA
	GMP status	17-01-2019 Recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide

		letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation as "Vortioxetine as HCl" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version & also correction of salt form of applied formulation in line with reference product i.e. Vortioxetine as HBr alongwith submission of requisite fee.	
2226.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	V Tetrol 20mg Tablet
	Composition	"Each Tablet Contains: Bambuterol HCl…20mg"
	Diary No. Date of R& I & fee	Dy.No 8271 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Groupc	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10x10's,1x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Bambec Tablets 10mg MHRA Approved.
	Me-too status	068406 "Tarobax Tablets " Cirin Pharmaceuticals,32/2A Industrial Estate,Hattar "
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2227.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	V Tetrol 10mg Tablet
	Composition	"Each Tablet Contains: Bambuterol HCl…10mg"
	Diary No. Date of R& I & fee	Dy.No 8270 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished product Specification	Inhouse

	Pack size & Demanded Price	3x10's,10x10's,1x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Bambec Tablets 10mg MHRA Approved.
	Me-too status	073789 Pulmiterol 10mg Tablet By M/s Kaizen Karachi .
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2228.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Cloprin-300 Tablet
	Composition	"Each Film Coated Tablet Contains: Clopidogrel as bisulfate…300mg"
	Diary No. Date of R& I & fee	Dy.No 4900 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Anti-thrombotic Agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, 1x30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Plavix USFDA Approved with box warning.
	Me-too status	075977 ; Plavix Tablets By M/s Sanofi Karachi
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2229.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Cloprin-V Tablet
	Composition	"Each Film Coated Tablet Contains: Clopidogrel as Bisulphate…75mg Aspirin…75mg"
	Diary No. Date of R& I & fee	Dy.No 4899 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antithrombotic Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Approved.
	Me-too status	081533 Lopiril-AP 75/75mg Tablet

		By M/s Medisure Lab. Karachi . .
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	The applied formulation is monolayer tablet whereas, it is internationally approved as bilayer tablet.
	Decision: Approved as per innovator's specification.	
2230.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Cloprin-AP Tablet
	Composition	"Each Film Coated Tablet Contains: Clopidogrel as Bisulphate…75mg Aspirin…150mg"
	Diary No. Date of R& I & fee	Dy.No 4899 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Antithrombotic Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in applied strength.
	Me-too status	044022 Ogrel Plus-162 Tablets By M/s Bosch Pharmaceutical, Karachi
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Approved as per innovator's specification.	
2231.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Maridone Tablet 10mg
	Composition	"Each film coated tablet Contains: Domperidone …10mg"
	Diary No. Date of R& I & fee	Dy.No 8273 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished product Specification	BP.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Motilium domperidone 10mg tablet by Janssen Cilag (TGA approved)
	Me-too status	081026 Plidome 10mg Tablet By M/s Pliva Baluchistan

	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Approved.	
2232.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Maridone V Tablet 10mg
	Composition	"Each film coated tablet Contains: Domperidone as Maleate …10mg"
	Diary No. Date of R& I & fee	Dy.No 8272 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished product Specification	BP.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Domperidone10mgFilm-CoatedTablets MHRA Approved.
	Me-too status	067955 "Residone-10 Tablet "M/s Rasco Pharma,5.5 KM Raiwind Road, Ali Razabad, Lahore"
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2233.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	V-Cox 30mg Tablet
	Composition	"Each film coated tablet contains: Etoricoxib…30mg"
	Diary No. Date of R& I & fee	Dy.No 4903 dated 04-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	Couldnot be confirmed in applied strength.
	GMP status	09-07-2018. Recommendations:

		In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- • Signature of applicant is missing on Form 5. • Evidence of availability of applied formulation in BP.
	Decision: Deferred for the following: • **Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.** • **Submission of signed application of applied formulation.**	
2234.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	V-Cox 60mg Tablet
	Composition	"Each film coated tablet contains: Etoricoxib…60mg"
	Diary No. Date of R& I & fee	Dy.No 4904 dated 04-02-2019 Rs.20,000/- 04-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	081647 Etroxin tablet 60mg By M/s Akson Pharmaceuticals Pvt Ltd, Islamabad
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	• Signature of applicant is missing on Form 5. • Evidence of availability of applied formulation in BP.
	Decision: Deferred for submission of signed application of applied formulation on Form 5.	
2235.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	V-Cox 90mg Tablet
	Composition	"Each Tablet Contains: Etoricoxib…90mg"
	Diary No. Date of R& I & fee	Dy.No 4905 dated 04-02-2019 Rs.20,000/- 04-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP

	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	Could not be confirmed.
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- • Signature of applicant is missing on Form 5. • Evidence of availability of applied formulation in BP.
	Decision: Deferred for the following: • **Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.** • **Submission of signed application of applied formulation.**	
2236.	Name and address of manufacturer / Applicant	"M/s Venus Pharma. 23 km, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Conazole-V 150mg Capsule
	Composition	"Each Capsule Contains: Fluconazole…150mg"
	Diary No. Date of R& I & fee	Dy.No 4902 dated 04-02-2019 Rs.20,000/- 04-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO.1x1;s, 1x4's
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	069263 "Alfumet 150mg Capsule "M/s. Wilshire Laboratories (Pvt) Ltd;124/1 Industrial Estate, Kot Lakhpat,Lahore."
	GMP status	09-07-2018. Recommendations: In the light of the inspection conducted by the panel and based on the people met, documents reviewed and finding during inspection, M/s Venus Pharma Lahore considered to be operating at satisfactory level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends the firm for grant of cGMP certificate for export purpose
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2237.	Name and address of manufacturer / Applicant	"M/s Martin Dow Limited.Plot No. 37, Sector 19, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Sacuval Tablet 24mg/26mg
	Composition	"Each Film Coated Tablet Contains: Sacubitril…24mg Valsartan as sodium salt complex…26mg"

	Diary No. Date of R& I & fee	Dy.No 5085 dated 06-02-2019 Rs.20,000/- 04-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ENTRESTO® (sacubitril and valsartan) tablets USFDA Approved.
	Me-too status	NA
	GMP status	4-12-2018 Approval of Amendments in Approval Facility: Research and Development Laboratory.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- EPAR of innovator The isolated active substance is a co-crystal complex of the sodium salts of two individual active components, sacubitril and valsartan, in hydrated form. The sacubitril-valsartan complex is a white to almost white crystalline powder and is hygroscopic above 60% RH so needs to be protected from water. Entresto is a fixed-dose combination product presented as film-coated tablets containing sacubitril and valsartan as active substances as a trisodium hemipentahydrate co-crystal.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2238.	Name and address of manufacturer / Applicant	"M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Sacuval Tablet 49mg/51mg
	Composition	"Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan as sodium salt complex…51mg"
	Diary No. Date of R& I & fee	Dy.No 5086 dated 06-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ENTRESTO® (sacubitril and valsartan) tablets USFDA Approved.
	Me-too status	NA
	GMP status	4-12-2018 Approval of Amendments in Approval Facility: Research and Development Laboratory.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- EPAR of innovator

		The isolated active substance is a co-crystal complex of the sodium salts of two individual active components, sacubitril and valsartan, in hydrated form. The sacubitril-valsartan complex is a white to almost white crystalline powder and is hygroscopic above 60% RH so needs to be protected from water. Entresto is a fixed-dose combination product presented as film-coated tablets containing sacubitril and valsartan as active substances as a trisodium hemipentahydrate co-crystal.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2239.	Name and address of manufacturer / Applicant	"M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Sacuval Tablet 97mg/103mg
	Composition	"Each Film Coated Tablet Contains: Sacubitril…97mg Valsartan as sodium salt complex…103mg"
	Diary No. Date of R& I & fee	Dy.No 5087 dated 06-02-2019 Rs.20,000/- 04-02-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ENTRESTO® (sacubitril and valsartan) tablets USFDA Approved.
	Me-too status	
	GMP status	4-12-2018 Approval of Amendments in Approval Facility: Research and Development Laboratory.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- EPAR of innovator The isolated active substance is a co-crystal complex of the sodium salts of two individual active components, sacubitril and valsartan, in hydrated form. The sacubitril-valsartan complex is a white to almost white crystalline powder and is hygroscopic above 60% RH so needs to be protected from water. Entresto is a fixed-dose combination product presented as film-coated tablets containing sacubitril and valsartan as active substances as a trisodium hemipentahydrate co-crystal.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2240.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited.7, Jail Road, Quetta, Pakistan"
	Brand Name +Dosage Form + Strength	Apixa 2.5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Apixaban…2.5mg"
	Diary No. Date of R& I & fee	Dy.No 6548 dated 13-02-2019 Rs.20,000/- Dated 14-02-

		2019
	Pharmacological Group	Antithrombotic Agents Direct factor Xa Inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's/Rs. 350, Rs. 35/Tablet.
	Approval status of product in Reference Regulatory Authorities.	ELIQUIS (apixaban) tablets Approved in USFDA with box warning.
	Me-too status	NA
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/-
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2241.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited.7, Jail Road, Quetta, Pakistan"
	Brand Name +Dosage Form + Strength	Apixa 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Apixaban…5mg"
	Diary No. Date of R& I & fee	Dy.No 654 dated 13-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antithrombotic Agents Direct factor Xa Inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's/Rs. 550, Rs. 550/Tablet.
	Approval status of product in Reference Regulatory Authorities.	ELIQUIS (apixaban) tablets Approved in USFDA with box warning.
	Me-too status	NA
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator (V)	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/-
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2242.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited.7, Jail Road, Quetta, Pakistan"
	Brand Name +Dosage Form + Strength	Loxacin 400mg Tablets
	Composition	"Each Film Coated Tablet Contains: Moxifloxacin HCL eq to Moxifloxacin…400mg"
	Diary No. Date of R& I & fee	Dy.No 6341 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Fluoroquinolones

		J01MA14
	Type of Form	Form 5
	Finished product Specification	USP specs
	Pack size & Demanded Price	5's/Rs 400. Rs. 80/Tab.
	Approval status of product in Reference Regulatory Authorities.	Moxifloxacin 400mg Tablet by Bayer Health Care USFDA Approved
	Me-too status	074931 Moxpin 400 mg Table0t M/s Winthrox Karachi . .
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2243.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited.7, Jail Road, Quetta, Pakistan"
	Brand Name +Dosage Form + Strength	Acidex 30mg Capsule
	Composition	"Each Capsule Contains: Enteric Coated Granules of Dexlansoprazole Eq. to Dexlansoprazole…30mg"
	Diary No. Date of R& I & fee	Dy.No 6338 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Proton Pump Inhibitor.
	Type of Form	Form 5.
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs.415/30's, Rs. 13.83/Capsule
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	NA
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- • Provide source of pellets, GMP report of source, stability data and submission of Rs. 100000/- in case of imported pellets.
	Decision: Deferred for the following: • **Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.** • **COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions & differential fee of Rupee 80,000/- in case of imported pellets.**	
2244.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited.7, Jail Road, Quetta, Pakistan"
	Brand Name +Dosage Form + Strength	Acidex 60mg Capsule
	Composition	"Each Capsule Contains: Enteric Coated Granules of Dexlansoprazole Eq. to Dexlansoprazole…60mg"

	Diary No. Date of R& I & fee	Dy.No 6339 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Proton Pump Inhibitor.
	Type of Form	Form 5.
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs.680/30's, Rs. 22.66/Capsule
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	NA
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/- • Provide source of pellets, GMP report of source, stability data and submission of Rs. 100000/- in case of imported pellets.
	Decision: Deferred for the following: • **Submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.** • **COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions & differential fee of Rupee 80,000/- in case of imported pellets.**	
2245.	Name and address of manufacturer / Applicant	"M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi"
	Brand Name +Dosage Form + Strength	Ivadine 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ivabradine…5mg"
	Diary No. Date of R& I & fee	Dy.No 5385 dated 07-02-2019 Rs.20,000/- 28-01-2019
	Pharmacological Group	Cardiac Preparations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CORLANOR® (ivabradine) tablets USFDA Approved.
	Me-too status	078161 "Coralan 5mg Tablet. "M/s. Servier Research And Pharmaceuticals (Pakistan) (Pvt.) Limited,9th Km Sheikhupura Road, Lahore."
	GMP status	
	Remarks of the Evaluator (V)	• Signature of applicant is missing on form 5. • Internationally,the applied formulation is approved as 5 mg of ivabradine, equivalent to 5.39 mg of ivabradine hydrochloride whereas, you have applied for only only Ivabradine without HCl. • Latest GMP inspection report (which should have been conducted within the period of last three years).
	Decision: Deferred for the following: • **Submission of signed application of applied formulation on Form 5.** • **Submission of application in line with reference product including salt form of API alongwith submission of requisite fee, master formulation & manufacturing method.**	

2246.	Name and address of manufacturer / Applicant	"M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi"
	Brand Name +Dosage Form + Strength	Ivadine 7.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ivabradine…7.5mg"
	Diary No. Date of R& I & fee	Dy.No 5386 dated 07-02-2019 Rs.20,000/- Dated 28-01-2019
	Pharmacological Group	Cardiac Preparations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CORLANOR® (ivabradine) tablets USFDA Approved.
	Me-too status	078162 "Coralan 10mg Tablet. "M/s. Servier Research And Pharmaceuticals (Pakistan) (Pvt.) Limited,9th Km Sheikhupura Road, Lahore."
	GMP status	
	Remarks of the Evaluator (V)	• Signature of applicant is missing on form 5. • Internationally,the applied formulation is approved as 7.5 mg of ivabradine, equivalent to 8.09 mg of ivabradine hydrochloride whereas, you have applied for only Ivabradine without HCl. • Latest GMP inspection report (which should have been conducted within the period of last three years).
	Decision: Deferred for the following: • **Submission of signed application of applied formulation on Form 5.** • **Submission of application in line with reference product including salt form of API alongwith submission of requisite fee, master formulation & manufacturing method.**	
2247.	Name and address of manufacturer / Applicant	"M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi"
	Brand Name +Dosage Form + Strength	Ropin 1 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ropinirole as HCl…1 mg"
	Diary No. Date of R& I & fee	Dy.No 7835 dated 22-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Anti-Parkinson Drugs Dopamine Agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's,30's,50's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	REQUIP USFDA Approved
	Me-too status	047378 Ronirol 1mg Tablets Manufacturer Name Hilton Pharma (Pvt) Ltd,
	GMP status	
	Remarks of the Evaluator (V)	• The master formulation mentions quantity of Ropinirole as 1.140mg whereas, the label claim is 1mg. • Latest GMP inspection report (which should have been conducted within the period of last three years).

	Decision: Deferred for submission of master formulation of applied drug product in line with composition/label claim.	
2248.	Name and address of manufacturer / Applicant	"M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi"
	Brand Name +Dosage Form + Strength	Ropin 0.25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ropinirole as HCL…0.25mg"
	Diary No. Date of R& I & fee	Dy.No 7834 dated 22-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Anti-Parkinson Drugs Dopamine Agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's,30's,50's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	REQUIP USFDA Approved
	Me-too status	047376 Ronirol 0.25mg Tablets Manufacturer Name Hilton Pharma (Pvt) Ltd,
	GMP status	
	Remarks of the Evaluator (V)	Latest GMP inspection report (which should have been conducted within the period of last three years).
	Decision: Approved.	
2249.	Name and address of manufacturer / Applicant	"M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi"
	Brand Name +Dosage Form + Strength	Ropin 2mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ropinirole as HCL…2mg"
	Diary No. Date of R& I & fee	Dy.No 7836 dated 22-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Anti-Parkinson Drugs Dopamine Agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's,30's,50's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	REQUIP USFDA Approved
	Me-too status	047379 Ronirol 2mg Tablets Manufacturer Name Hilton Pharma (Pvt) Ltd,
	GMP status	
	Remarks of the Evaluator (V)	• The master formulation mentions quantity of Ropinirole as 2.280mg whereas, the label claim is 2mg. • Latest GMP inspection report (which should have been conducted within the period of last three years).
	Decision: Deferred for submission of master formulation of applied drug product in line with composition/label claim.	
2250.	Name and address of manufacturer / Applicant	"M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi"
	Brand Name +Dosage Form + Strength	Bislol 2.5mg Tablet

	Composition	"Each Film Coated Tablet Contains: Bisoprolol as fumarate…2.5mg
	Diary No. Date of R& I & fee	Dy.No 8133 dated 25-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta Blocking Agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,50's,100's, As per sro.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	077054 "Bisfat Tablets 2.5mg "M/s. Dyson Research Laboratories (Pvt) Ltd,28Km, Ferozepur Road, Lahore."
	GMP status	
	Remarks of the Evaluator (V)	Latest GMP inspection report (which should have been conducted within the period of last three years).
	Decision: Approved.	
2251.	Name and address of manufacturer / Applicant	"M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi"
	Brand Name +Dosage Form + Strength	Bislol 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Bisoprolol as fumarate….5mg
	Diary No. Date of R& I & fee	Dy.No 8134 dated 25-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta Blocking Agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,50's,100's, As per sro.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	077052 "Bisfat Tablets 5mg "M/s. Dyson Research Laboratories (Pvt) Ltd,28Km, Ferozepur Road, Lahore."
	GMP status	
	Remarks of the Evaluator (V)	Latest GMP inspection report (which should have been conducted within the period of last three years).
	Decision: Approved.	
2252.	Name and address of manufacturer / Applicant	"M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi"
	Brand Name +Dosage Form + Strength	Bislol 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Bisoprolol as fumarate….10mg
	Diary No. Date of R& I & fee	Dy.No 8135 dated 25-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Beta Blocking Agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's,30's,50's,100's, As per sro.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	077051 "Bisfat Tablets 10mg "M/s. Dyson Research Laboratories (Pvt) Ltd,28Km, Ferozepur Road, Lahore."

	GMP status	
	Remarks of the Evaluator (V)	Latest GMP inspection report (which should have been conducted within the period of last three years).
	Decision: Approved.	
2253.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Rivoxa Tablet 2.5mg
	Composition	"Each Film Coated Tablet Contains: Rivaroxaban…2.5mg"
	Diary No. Date of R& I & fee	Dy.No 8882 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti-thrombotic Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's,2x7=14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XARELTO (rivaroxaban) tablets USFDA Approved
	Me-too status	074794 Xarelto 2.5mg Tablets "M/s. Bayer Pakistan (Private) Limited, C/21, S.I.T.E.,Karachi."
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator (V)	
	Decision: Approved with innovator's specification.	
2254.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Rivoxa Tablet 10mg
	Composition	"Each Film Coated Tablet Contains: Rivaroxaban…10mg"
	Diary No. Date of R& I & fee	Dy.No 8883 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti-thrombotic Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's,2x7=14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XARELTO (rivaroxaban) tablets USFDA Approved
	Me-too status	080611 Revoban 10mg Tablet M/s Atco Lab. Karachi . .
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator (V)	
	Decision: Approved with innovator's specification.	
2255.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Rivoxa Tablet 15mg
	Composition	"Each Film Coated Tablet Contains: Rivaroxaban…15mg"
	Diary No. Date of R& I & fee	Dy.No 8884 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti-thrombotic Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse

	Pack size & Demanded Price	1x10's,2x7=14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XARELTO (rivaroxaban) tablets USFDA Approved
	Me-too status	072549 "Xarelto 15mg Tablets "M/s. Bayer Pakistan (Private) Limited,C/21, S.I.T.E.,Karachi."
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator (V)	
	Decision: Approved with innovator's specification.	
2256.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Rivoxa Tablet 20mg
	Composition	"Each Film Coated Tablet Contains: Rivaroxaban…20mg"
	Diary No. Date of R& I & fee	Dy.No 8885 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti-thrombotic Agents
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's,2x7=14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XARELTO (rivaroxaban) tablets USFDA Approved
	Me-too status	081158 Mabinat 20mg Tablet By M/s Martin Dow Ltd. Karachi . .
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator (V)	
	Decision: Approved with innovator's specification.	
2257.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Exaban 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Apixaban...5mg"
	Diary No. Date of R& I & fee	Dy.No 6968 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antithrombotic Agents Direct factor Xa Inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's/Rs. 550, Rs. 550/Tablet.
	Approval status of product in Reference Regulatory Authorities.	ELIQUIS (apixaban) tablets Approved in USFDA with box warning.
	Me-too status	NA
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/-
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	

2258.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Exaban 2.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Apixaban...2.5mg"
	Diary No. Date of R& I & fee	Dy.No 6969 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antithrombotic Agents Direct factor Xa Inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's/Rs. 350, Rs. 35/Tablet.
	Approval status of product in Reference Regulatory Authorities.	ELIQUIS (apixaban) tablets Approved in USFDA with box warning.
	Me-too status	NA
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required OR submission of application on requisite form ,stability data and fee of Rs. 50,000/-
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board, as the applied formulation is subsequent drug generic version.	
2259.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Titrazole Insta 20/1100 mg Capsule
	Composition	"Each Capsule Contains: Omeprazole…20mg Sodium Bicarbonate…1100mg"
	Diary No. Date of R& I & fee	Dy.No 5384 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Proton pump inhibitors,Antacid
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zegerid USFDA Approved.
	Me-too status	072153 "Omsod 20 mg Capsules "Reliance Pharma, P No 8,Street S-8, RCCI, Industrial State, Rawat"
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2260.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Titrazole Insta 40/1100 mg Capsule
	Composition	"Each Capsule Contains: Omeprazole…40mg Sodium Bicarbonate…1100mg"

	Diary No. Date of R& I & fee	Dy.No 5383 dated 07-02-2019 Rs.20,000/- Dated 07-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's, 28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zegerid USFDA Approved.
	Me-too status	072154 "Omsod 40 mg Capsules "Reliance Pharma, P No 8,Street S-8, RCCI, Industrial State, Rawat"
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2261.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Depin Tablet 12.5mg
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…12.5mg"
	Diary No. Date of R& I & fee	Dy.No 8758 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP extended release monograph.
	Pack size & Demanded Price	10's,14's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	081953 Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix. • The master formulation mentions quantity of API as 13.87mg.Justify the qty. of API.
	Decision: Deferred for revision of formulation as per the innovator / reference product along with submission of requisite fee.	
2262.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Depin Tablet 25mg

	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…25mg"
	Diary No. Date of R& I & fee	Dy.No 8759 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	081954 Panox CR Tablet 25 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix. • The master formulation mentions quantity of API as 27.75mg.Justify the qty. of API.
	Decision: Deferred for revision of formulation as per the innovator / reference product along with submission of requisite fee.	
2263.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Depin Tablet 37.5mg
	Composition	"Each enteric coated tablet contains: Paroxetine as HCL…37.5mg"
	Diary No. Date of R& I & fee	Dy.No 8760 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PAXIL CR (paroxetine) extended-release tablets USFDA Approved with box warning.
	Me-too status	069948 Deroxat CR 37.5mg Tablets M/s Global Pharmaceuticals, Plot No 204-205, Kahuta Triangle, Industrial Area, Islamabad.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations.

		Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• The applied formulation is internationally approved as enteric coated controlled release tablet whereas, firm has applied for only enteric coated. • The innovator product consists of two layers. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix. • The master formulation mentions quantity of API as 41.62 mg.Justify the qty. of API.
	Decision: Deferred for revision of formulation as per the innovator / reference product along with submission of requisite fee.	
2264.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Nebest Tablet 2.5mg
	Composition	"Each Tablet Contains: Nebivolol HCl eq to Nebivolol…2.5mg"
	Diary No. Date of R& I & fee	Dy.No 8761 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,28's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol) tablets USFDA Approved.
	Me-too status	062776 "Nebix Tablets By M/s. Highnoon Laboratories,17.5 Km Multan Road,Lahore."
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2265.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Nebest Tablet 5mg
	Composition	"Each Tablet Contains: Nebivolol HCl eq to Nebivolol…..5mg"
	Diary No. Date of R& I & fee	Dy.No 8762 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Beta Blocking Agents
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,30's, As per SRO.

	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol) tablets USFDA Approved.
	Me-too status	078842 "Nibovo Tablets 5mg "M/s. Dyson Research Laboratories (Pvt) Ltd,28Km, Ferozepur Road, Lahore."
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification	
2266.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Nebest Tablet 10mg
	Composition	"Each Tablet Contains: Nebivolol HCl eq to Nebivolol…..10mg"
	Diary No. Date of R& I & fee	Dy.No 8763 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Beta Blocking Agents
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	14's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol) tablets USFDA Approved.
	Me-too status	078850 "Nibovo Tablets 10mg By M/s. Dyson Research Laboratories (Pvt) Ltd,28Km,Ferozepur Road, Lahore."
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification	
2267.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Palipesol Tablet 3mg
	Composition	"Each extended release tablet contains: Paliperidone…3mg
	Diary No. Date of R& I & fee	Dy.No 8764 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-psychotics
	Type of Form	Form-5
	Finished product Specification	Inhouse

	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	INVEGA® (paliperidone) Extended-Release Tablets USFDA Approved with box warning.
	Me-too status	"Invega Extended Release Tablets 3mg M/s. Johnson & Johnson Pakistan (Pvt.) Ltd., Plot Nos. 10 & 25, Sector 20, Korangi Industrial Area, Karachi."
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology. Description of Innovator Product Delivery System Components and Performance INVEGA® uses osmotic pressure to deliver paliperidone at a controlled rate. The delivery system, which resembles a capsule-shaped tablet in appearance, consists of an osmotically active trilayer core surrounded by a subcoat and semipermeable membrane. The trilayer core is composed of two drug layers containing the drug and excipients, and a push layer containing osmotically active components. There are two precision laser-drilled orifices on the drug-layer dome of the tablet. Each tablet strength has a different colored water-dispersible overcoat and print markings. In an aqueous environment, such as the gastrointestinal tract, the water-dispersible color overcoat erodes quickly. Water then enters the tablet through the semipermeable membrane that controls the rate at which water enters the tablet core, which, in turn, determines the rate of drug delivery. The hydrophilic polymers of the core hydrate and swell, creating a gel containing paliperidone that is then pushed out through the tablet orifices. The biologically inert components of the tablet remain intact during gastrointestinal transit and are eliminated in the stool as a tablet shell, along with insoluble core components.
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2268.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Palipesol Tablet 6mg
	Composition	"Each extended release tablet contains: Paliperidone…6mg
	Diary No. Date of R& I & fee	Dy.No 8765 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-psychotics
	Type of Form	Form-5
	Finished product Specification	Inhouse

	Pack size & Demanded Price	10's,14's,20's,30's As per SRO.
	Approval status of product in Reference Regulatory Authorities.	INVEGA® (paliperidone) Extended-Release Tablets USFDA Approved with box warning.
	Me-too status	"Invega Extended Release Tablets 6mg M/s. Johnson & Johnson Pakistan (Pvt.) Ltd., Plot Nos. 10 & 25, Sector 20, Korangi Industrial Area, Karachi."
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology. Description of Innovator Product Delivery System Components and Performance INVEGA® uses osmotic pressure to deliver paliperidone at a controlled rate. The delivery system, which resembles a capsule-shaped tablet in appearance, consists of an osmotically active trilayer core surrounded by a subcoat and semipermeable membrane. The trilayer core is composed of two drug layers containing the drug and excipients, and a push layer containing osmotically active components. There are two precision laser-drilled orifices on the drug-layer dome of the tablet. Each tablet strength has a different colored water-dispersible overcoat and print markings. In an aqueous environment, such as the gastrointestinal tract, the water-dispersible color overcoat erodes quickly. Water then enters the tablet through the semipermeable membrane that controls the rate at which water enters the tablet core, which, in turn, determines the rate of drug delivery. The hydrophilic polymers of the core hydrate and swell, creating a gel containing paliperidone that is then pushed out through the tablet orifices. The biologically inert components of the tablet remain intact during gastrointestinal transit and are eliminated in the stool as a tablet shell, along with insoluble core components.
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2269.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Palipesol Tablet 9mg
	Composition	"Each extended release tablet contains: Paliperidone…9mg
	Diary No. Date of R& I & fee	Dy.No 8766 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-psychotics
	Type of Form	Form-5
	Finished product Specification	Inhouse

	Pack size & Demanded Price	14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	INVEGA® (paliperidone) Extended-Release Tablets USFDA Approved with box warning.
	Me-too status	"Invega Extended Release Tablets 6mg M/s. Johnson & Johnson Pakistan (Pvt.) Ltd., Plot Nos. 10 & 25, Sector 20, Korangi Industrial Area, Karachi."
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology. Description of Innovator Product Delivery System Components and Performance INVEGA® uses osmotic pressure to deliver paliperidone at a controlled rate. The delivery system, which resembles a capsule-shaped tablet in appearance, consists of an osmotically active trilayer core surrounded by a subcoat and semipermeable membrane. The trilayer core is composed of two drug layers containing the drug and excipients, and a push layer containing osmotically active components. There are two precision laser-drilled orifices on the drug-layer dome of the tablet. Each tablet strength has a different colored water-dispersible overcoat and print markings. In an aqueous environment, such as the gastrointestinal tract, the water-dispersible color overcoat erodes quickly. Water then enters the tablet through the semipermeable membrane that controls the rate at which water enters the tablet core, which, in turn, determines the rate of drug delivery. The hydrophilic polymers of the core hydrate and swell, creating a gel containing paliperidone that is then pushed out through the tablet orifices. The biologically inert components of the tablet remain intact during gastrointestinal transit and are eliminated in the stool as a tablet shell, along with insoluble core components.
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull technology.	
2270.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Pidone Tablet 200mg
	Composition	"Each Film Coated Tablet Contains: Pirfenidone…200mg"
	Diary No. Date of R& I & fee	Dy.No 8767 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Immunosuppressants
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,20's,30's, As per SRO.

	Approval status of product in Reference Regulatory Authorities.	PMDA Couldnot be confirmed.
	Me-too status	Couldnot be confirmed.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.	
2271.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Pidone Tablet 267mg
	Composition	"Each Film Coated Tablet Contains: Pirfenidone…267mg"
	Diary No. Date of R& I & fee	Dy.No 8768 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Immunosuppressants
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ESBRIET® (pirfenidone) capsules and film-coated tablets, USFDA Approved.
	Me-too status	Could not be confirmed.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.	
2272.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Pidone Tablet 801mg
	Composition	"Each Film Coated Tablet Contains:

		Pirfenidone…801mg"
	Diary No. Date of R& I & fee	Dy.No 8769 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Immunosuppressants
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ESBRIET® (pirfenidone) capsules and film-coated tablets, USFDA Approved.
	Me-too status	Couldnot be confirmed.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of stability study data for applied formulation as per guidelines approved in 251st& later amended in 278th meeting of Registration Board.	
2273.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Soliten Tablet 5mg
	Composition	"Each Film Coated Tablet Contains: Solifenacin succinate…5mg"
	Diary No. Date of R& I & fee	Dy.No 8777 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	VESIcare (solifenacin succinate) tablet USFDA Approved.
	Me-too status	081958 Solfin Tablet 5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	

	Decision: Approved as per innovator's specification.	
2274.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Soliten Tablet 10mg
	Composition	"Each Film Coated Tablet Contains: Solifenacin succinate…10mg"
	Diary No. Date of R& I & fee	Dy.No 8778 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,20's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	VESIcare (solifenacin succinate) tablet USFDA Approved.
	Me-too status	081958 Solfin Tablet 5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2275.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Selpram Tablet 20mg
	Composition	"Each Film Coated Tablet Contains: Escitalopram as Oxalate …20mg"
	Diary No. Date of R& I & fee	Dy.No 8770 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-depressant, SSRI
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lexapro® (escitalopram) Tablets USFDA Approved with boxwarning.
	Me-too status	081963 Repram Tablet 20 mg By M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Tartrazine yellow lake is discontinued excipients. For this reason, therefore revision of formulation is

		required.
	Decision: Registration Board deliberated that tartrazine yellow lake also known as FD&C Yellow No. 5 is available in FDA inactive ingredients database, therefore the Board decided to approve the case.	
2276.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Zafler 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Zafirlukast…20mg"
	Diary No. Date of R& I & fee	Dy.No 8779 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Accolate®(zafirlukast) tablets USFDA Approved.
	Me-too status	069791 "Z-Kast Tablets By M/s Lowitt Pharmaceutical (Pvt) Ltd,Plot.No.24 Industrial Estate,Peshawar."
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2277.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Velna D XR Tablet 50mg
	Composition	"Each extended release tablet contains: Desvenlafaxine as Succinate…50mg
	Diary No. Date of R& I & fee	Dy.No 8772 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-depressants
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,14's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Pristiq™ (desvenlafaxine) Extended-Release Tablets USFDA Approved with boxwarning.
	Me-too status	070761 Desvel XR 50mg Tablet By M/s Hilton Karachi .
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator (V)	
	Decision: Approved with innovator's specifications.	
2278.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Velna D XR Tablet 100mg
	Composition	"Each extended release tablet contains: Desvenlafaxine as Succinate…100mg
	Diary No. Date of R& I & fee	Dy.No 8773 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-depressants
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's,14's,20's,28's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Pristiq™ (desvenlafaxine) Extended-Release Tablets USFDA Approved with boxwarning.
	Me-too status	070760 Desvel XR 100mg Tablet By M/s Hilton Karachi .
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved with innovator's specifications.	
2279.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Ostenate Injection 3mg/3ml
	Composition	"Each 3ml ampoule contains: Ibandronate Sodium Monohydrate is eq. to Ibandronic Acid…3mg"
	Diary No. Date of R& I & fee	Dy.No 8776 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Drugs Affecting Bone Structure and Mineralization
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	3ml glass ampoule,1's
	Approval status of product in Reference Regulatory Authorities.	Ibandronate Sodium Injection, 3 mg (base)/3mL (Vial) by M/s Sun Pharmaceutical Industries Ltd. (USFDA Approved)
	Me-too status	081544 Ibnate 3mg/3ml Injection By M/s Genix Pharma Karachi . .
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	Firm has liquid ampoule general section.
	Decision: Approved	

2280.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dopicard Injection 40mg/5ml
	Composition	"Each 5ml ampoule contains: Dopamine HCl…40mg"
	Diary No. Date of R& I & fee	Dy.No 8775 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Monoamine oxidase B inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's,10's,50's,100's, 5ml glass ampoules
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Could not be confirmed.
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2281.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Solap Syrup 10mg/ml
	Composition	"Each ml contains: Lacosamide…10mg"
	Diary No. Date of R& I & fee	Dy.No 8771 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	60ml,120ml,200ml, glass bottle, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lacosamide G.L. Pharma GmbH MHRA Approved.
	Me-too status	Lalap syrup 10mg/ml by Genix Pharma (Reg #089376)
	GMP status	08-07-2019 & 25-07-2019 Recommendations: The firm M/s Pharmasol Pvt Ltd was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, and Quality Control/QA and production operations. Keeping in view the observations made on the day of inspection and after going through the documentation and overall assessment, the panel is of the opinion that the firm M/s Pharmasol Lahore was operating at satisfactory level of

		GMP compliance.
	Remarks of the Evaluator (V)	•
	Decision: Approved	
2282.	Name and address of manufacturer / Applicant	"M/s Fahmir Pharma Pvt Ltd.26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura"
	Brand Name +Dosage Form + Strength	Gemimir 320mg Tablet,Gemifah,Gemifox
	Composition	"Each Film Coated Tablet Contains: Gemifloxacin mesylate eq. to Gemifloxacin…320mg"
	Diary No. Date of R& I & fee	Dy.No 7035 dated 19-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs. 150/Tab, Rs. 1050 per 7 Tab.
	Approval status of product in Reference Regulatory Authorities.	FACTIVE® (gemifloxacin mesylate) tablets, USFDA Approved with box warning.
	Me-too status	073730 Ifactiv 320mg Tablet By M/s Hilton Karachi .
	GMP status	Central Licensing Board in its 259th meeting held on 29-30th March 2018 has considered and approved the grant of drug manufacturing license by way of formulation with Tablet (General) Section.
	Remarks of the Evaluator (V)	
	Decision: Approved	
2283.	Name and address of manufacturer / Applicant	"M/s Fahmir Pharma Pvt Ltd.26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura"
	Brand Name +Dosage Form + Strength	Naxin 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Naproxen sodium 550mg eq. to Naproxen…500mg"
	Diary No. Date of R& I & fee	Dy.No 7030 dated 19-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 9.15/Tab, Rs. 183.00 per 20 Tab.
	Approval status of product in Reference Regulatory Authorities.	Anaprox Ds (naproxen sodium tablets), USFDA Approved with box warning.
	Me-too status	080439 Freshnap Tablet 550mg M/s Fresh Pharmaceuticals, Islamabad
	GMP status	Central Licensing Board in its 259th meeting held on 29-30th March 2018 has considered and approved the grant of drug manufacturing license by way of formulation with Tablet (General) Section.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2284.	Name and address of manufacturer / Applicant	"M/s Fahmir Pharma Pvt Ltd.26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura"
	Brand Name +Dosage Form + Strength	Dona 50mg Capsule
	Composition	"Each Capsule Contains: Diclofenac potassium pellets…50mg"
	Diary No. Date of R& I & fee	Dy.No 7033 dated 19-02-2019 Rs.20,000/- Dated 15-02-

		2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	2x10's,Rs.3.5/Capsule, Rs.70/20 capsule
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed.
	Me-too status	068238 "Naveflam Capsules 50mg. Navegal Laboratories, 41/1-A-2, phase-1, Industrial Estate,Hattar."
	GMP status	Central Licensing Board in its 259th meeting held on 29-30th March 2018 has considered and approved the grant of drug manufacturing license by way of formulation with Tablet (General) Section.
	Remarks of the Evaluator (V)	Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.
	Decision: Deferred for COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	
2285.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	M-Quin Plus Tablet 20mg
	Composition	"Each Tablet Contains: Piroxicam B Cyclodextrin 191.2mg eq to Piroxicam…20mg"
	Diary No. Date of R& I & fee	Dy.No 8638 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs 850/20 Tablet.
	Approval status of product in Reference Regulatory Authorities.	ANSM and ITALY Approved.
	Me-too status	079264 "Fedracam-BCD Tablets 20mg "Fedro Pharmaceutical, 149, Industrial Estate, Jamrud Road,Peshawar
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved as per innovator's specification.	
2286.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Antimal Plus Tablet 80/480mg
	Composition	"Each Tablet Contains: Artemether…80mg Lumefantrine…480mg"
	Diary No. Date of R& I & fee	Dy.No 8639 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs 600/6 Tablet
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified drug

	Me-too status	081928 Marlin DS Tablet M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	• Manufacturing outline of the applied formulation not provided. • Clarification of dosage form whether film coated or uncoated tablet. The form 5 and composition mentions uncoated and whereas specifications of Finished product mentions film coated tablets.
	Decision: Deferred for the following: • **Submission of manufacturing outline of applied formulation.** • **Clarification of applied formulation regarding coated or uncoated tablet is required as submitted Form 5 & composition depicts uncoated tablet but FPP Specifications depicts film coated tablets**.	
2287.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Euro XR Tablet 1000mg
	Composition	"Each extended release tablet contains: Ciprofloxacin as HCL…1000mg"
	Diary No. Date of R& I & fee	Dy.No 8640 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs 900/10 Tab.
	Approval status of product in Reference Regulatory Authorities.	CIPRO XR Ciprofloxacin;Ciprofloxacin Hydrochloride 425.2mg; Eq 574.9mg Base USFDA Approved.
	Me-too status	076579 Novidat XR 1000mg Tablet By M/s Sami Pharmaceuticals, Karachi . .
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	• Provide manufacturing outline. • The qty. of API in master formulation is 117.2 kg whereas, the label claim is 1000mg per tablet. • Revision of formulation as per innovator is required. <u>Innovator Formulation</u> CIPRO XR Tablets are coated, bilayer tablets consisting of an immediate-release layer and an erosion-matrix type controlled-release layer. The tablets contain a combination of two types of ciprofloxacin drug substance, ciprofloxacin hydrochloride and ciprofloxacin betaine (base). Each CIPRO XR 1000 mg tablet contains 1000 mg of ciprofloxacin as ciprofloxacin HCl (574.9 mg, calculated as ciprofloxacin on the dried basis) and ciprofloxacin† (425.2 mg, calculated on the dried basis).
	Decision: Deferred for the following: • **Submission of master formulation and manufacturing outline of applied formulation in line with reference product i.e. coated, bilayer tablet consisting of an immediate-release layer and an erosion-matrix type controlled-release layer.** •	

2288.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Mafox Tablet 250mg
	Composition	"Each Film Coated Tablet Contains: Levofloxacin…250mg
	Diary No. Date of R& I & fee	Dy.No 8642 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Quinolone Antibacterials
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 900.00/10 tab
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	065254 "Levoquin Tablets 250mg M/s Advanced Pharmaceuticals
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	• The composition of the applied formulation doesnot mention coating material. • Manufacturing outline has not been provided. • The applied formulation is Levofloxacin …250 mg whereas, it is internationally approved as levofloxacin as hemihydrate..250mg.
	Decision: Deferred for the following: • **Submit clarification regarding hydrate form of API.** • **Submit composition of applied formulation after correction by keeping it in line with reference product & manufacturing outline of applied formulation levofloxacin as hemihydrates 250mg film coated tablets.**	
2289.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Mafox Tablet 500mg
	Composition	"Each Film Coated Tablet Contains: Levofloxacin…500mg
	Diary No. Date of R& I & fee	Dy.No 8643 dated 26-02-2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Quinolone Antibacterials
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 1400.00/10 tab
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	065255 "Levoquin Tablets 500mg M/s Advanced Pharmaceuticals
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	• The composition of the applied formulation doesnot mention coating material. • Manufacturing outline has not been provided. • The applied formulation is Levofloxacin …500 mg whereas, it is internationally approved as levofloxacin as hemihydrate..500mg.
	Decision: Deferred for the following: • **Submit clarification regarding hydrate form of API.** • **Submit composition of applied formulation after correction by keeping it in line with reference product & manufacturing outline of applied formulation levofloxacin as hemihydrates 500mg film coated tablets.**	

2290.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Eznil Tablet 400mg
	Composition	"Each film coated tablet Contains: Linezolid…400mg"
	Diary No. Date of R& I & fee	Dy.No 8645 dated 26-02-2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Antibacterial for systemic use. J01XX08
	Type of Form	Form-5
	Finished product Specification	Inhouse Spec.
	Pack size & Demanded Price	Rs 1800/12 Tab
	Approval status of product in Reference Regulatory Authorities.	ZYVOX Tablets 400MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons* Discontinued USFDA Approved.
	Me-too status	055434; Lyzon 400mg Tablet Getz Pharma Karachi
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	• The Film coating ingredients have not been mentioned in composition of the applied formulation. • The Manufacturing outline of the applied formulation has not been provided.
	Decision: Deferred for the following: **Submit composition of applied formulation after correction by keeping it in line with reference product & also submit manufacturing outline of applied formulation.**	
2291.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Eznil Tablet 600mg
	Composition	"Each film coated Tablet Contains: Linezolid…600mg"
	Diary No. Date of R& I & fee	Dy.No 8646 dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antibacterial for systemic use. J01XX08
	Type of Form	Form-5
	Finished product Specification	Inhouse Spec.
	Pack size & Demanded Price	Rs 3650/12 Tab.
	Approval status of product in Reference Regulatory Authorities.	ZYVOX Tablets USFDA Approved.
	Me-too status	055773 Leckzolid 600mg Tablet Medimarker's Pharmaceutical, Hyderabad
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	• The Film coating ingredients have not been mentioned in composition of the applied formulation. • The Manufacturing outline of the applied formulation has not been provided.
	Decision: Deferred for the following: **Submit composition of applied formulation after correction by keeping it in line with reference product & also submit manufacturing outline of applied formulation.**	

2292.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Eznil Syrup 100mg/5ml
	Composition	"Each 5ml contains: Linezolid…100mg"
	Diary No. Date of R& I & fee	Dy.No 8644 dated 26-02-2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs 550/60ml.
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed.
	Me-too status	Couldnot be confirmed.
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	• The Manufacturing outline of the applied formulation has not been provided. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.** • **Submit outline of manufacturing method the applied formulation.**	
2293.	Name and address of manufacturer / Applicant	"M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Ferol D3 Injection IM.Oral
	Composition	"Each 1ml Ampoule contains: Cholecalciferol vit-D3…5mg(200,000 IU)"
	Diary No. Date of R& I & fee	Dy.No 8637-a dated 26-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Solution is present in USP.
	Pack size & Demanded Price	Rs 500/ml ampoule,
	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200,000 IU / 1 ml, IM solution for injection in ampoule ANSM Approved.
	Me-too status	082005 Drol-D injection By M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad

	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator (V)	• The Manufacturing outline of the applied formulation has not been provided. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for the following: **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.** **Submit outline of manufacturing method the applied formulation.**	
2294.	Name and address of manufacturer / Applicant	"M/s Hizat Pharmaceutical Industries. Plot No. 170 Industrial Estate,Hayatabad Peshawar, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Roxedex 20mg Tablet
	Composition	"Each Tablet Contains: Piroxicam Betacyclodextrin Eq. to Piroxicam…20mg"
	Diary No. Date of R& I & fee	Dy.No 5392 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ANSM and ITALY Approved.
	Me-too status	079264 "Fedracam-BCD Tablets 20mg "Fedro Pharmaceutical, 149, Industrial Estate, Jamrud Road,Peshawar
	GMP status	26-12-2018, Restoration of production activities.
	Remarks of the Evaluator (V)	
	Decision: Referred to QA Division for updated GMP status.	
2295.	Name and address of manufacturer / Applicant	"M/s Hizat Pharmaceutical Industries. Plot No. 170 Industrial Estate,Hayatabad Peshawar, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Moflazin 400mg Tablet
	Composition	"Each film coated tablet Contains: Moxifloxacin Hcl Eq. to Moxifloxacin…400mg"
	Diary No. Date of R& I & fee	Dy.No 5391 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Fluoroquinolones J01MA14
	Type of Form	Form 5
	Finished product Specification	USP specs
	Pack size & Demanded Price	20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Moxifloxacin 400mg Tablet by Bayer Health Care USFDA Approved with box warning.
	Me-too status	074931 Moxpin 400 mg Tablet M/s Winthrox Karachi . .
	GMP status	26-12-2018, Restoration of production activities.
	Remarks of the Evaluator (V)	
	Decision: Referred to QA Division for updated GMP status.	

2296.	Name and address of manufacturer / Applicant	"M/s Hizat Pharmaceutical Industries. Plot No. 170 Industrial Estate,Hayatabad Peshawar, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Irozat 50mg/5ml Oral Syrup
	Composition	"Each 5ml Contains: Iron III Hydroxide Polymaltose complex eq. to elemental iron …50mg"
	Diary No. Date of R& I & fee	Dy.No 5390 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Anti-anemic Preparations
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	120ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	---
	Me-too status	074894 Irofin 50mg/5ml Syrup M/s AlinaCombine Karachi
	GMP status	26-12-2018, Restoration of production activities.
	Remarks of the Evaluator (V)	CLB in its 265th meeting has decided to constitute panel and stopped production until the panel perform GMP inspection as per Schedule B-II and until CLB approves resumption.
	Decision: Referred to QA Division for updated GMP status	
2297.	Name and address of manufacturer / Applicant	"M/s Hizat Pharmaceutical Industries. Plot No. 170 Industrial Estate,Hayatabad Peshawar, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Fusizat 2% Cream
	Composition	"Each g contains: Fusidic Acid…20mg"
	Diary No. Date of R& I & fee	Dy.No 5389 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antibiotics For Topical Use
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	25g, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Fucidin 20 mg/g Cream MHRA Approved.
	Me-too status	078563 Mrozan Cream By M/s Wisdom Pharmaceuticals Industry, 78-A Industrial Estate, Hayatabad Peshawar
	GMP status	26-12-2018, Restoration of production activities.
	Remarks of the Evaluator (V)	• CLB in its 265th meeting has decided to constitute panel and stopped production until the panel perform GMP inspection as per Schedule B-II and until CLB approves resumption.
	Decision: Referred to QA Division for updated GMP status	
2298.	Name and address of manufacturer / Applicant	"M/s Hizat Pharmaceutical Industries.Plot No. 170 Industrial Estate,Hayatabad Peshawar, KPK, Pakistan"
	Brand Name +Dosage Form + Strength	Rupirox 0.5% Gel
	Composition	"Each g contains: Piroxicam…5mg"
	Diary No. Date of R& I & fee	Dy.No 5393 dated 07-02-2019 Rs.20,000/- Dated 06-02-2019

	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	25 g, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Feldene 0.5% w/w Gel. MHRA Approved.
	Me-too status	079900 M-Piro 0.5% Gel M/s Mafins Karachi . .
	GMP status	26-12-2018, Restoration of production activities.
	Remarks of the Evaluator (V)	CLB in its 265th meeting has decided to constitute panel and stopped production until the panel perform GMP inspection as per Schedule B-II and until CLB approves resumption.
	Decision: Referred to QA Division for updated GMP status	
2299.	Name and address of manufacturer / Applicant	"M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore, By M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi,
	Brand Name +Dosage Form + Strength	Hooxim Capsule 400mg Winxim Fixim
	Composition	"Each capsule contains: Cefixime as Cefixime Trihydrate…400mg"
	Diary No. Date of R& I & fee	Dy.No 6205 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	055093 Vasix 400mg Capsule M/s Alfalah Pharma (Pvt.) Ltd.,
	GMP status	09-10-2018 Conclusion: All the observations noted during the inspections were discussed with their CEO and technical persons for earlier compliance. Based on above observations, documentations reviwed and personnel met their overall GMP compliance level is rated as good.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.**	
2300.	Name and address of manufacturer / Applicant	"M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore By M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Hooxim Dry Suspension 100mg/5ml
	Composition	"Each 5ml contains: Cefixime as Cefixime Trihydrate…100mg"

	Diary No. Date of R& I & fee	Dy.No 6206 dated 13-02-2019 Rs.50,000/- Dated 12-02-2019
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	055092 M/s Vasix 100mg/5ml Dry Suspension M/s Alfalah Pharma (Pvt.) Ltd.,
	GMP status	09-10-2018 Conclusion: All the observations noted during the inspections were discussed with their CEO and technical persons for earlier compliance. Based on above observations, documentations reviwed and personnel met their overall GMP compliance level is rated as good.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.**	
2301.	Name and address of manufacturer / Applicant	"M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore By M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Hooxim Dry Suspension 200mg/5ml Winxim Fixim
	Composition	"Each 5ml contains: Cefixime as Cefixime Trihydrate…200mg"
	Diary No. Date of R& I & fee	Dy.No 6207 dated 13-02-2019 Rs.50,000/- 12-02-2019
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	073248 Stlicef Dry Suspension 200mg Treat Pharma A-37, Industrial Estate Kohat Road,Bnnu (contract manufacturing will be conducted by M/s. Shawan Pharmaceuticals, Rawat)"
	GMP status	09-10-2018 Conclusion: All the observations noted during the inspections were discussed with their CEO and technical persons for earlier compliance. Based on above observations, documentations reviwed and personnel met their overall GMP compliance level is rated as good.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.**	

2302.	Name and address of manufacturer / Applicant	"M/s Surge Laboratories Pvt Ltd. 10 km, Faisalabad Road, Bikhi, District Sheikhupura"
	Brand Name +Dosage Form + Strength	Magtense Injection 50% w/v ,Magreif, Admag
	Composition	"Each ml contains: Magnesium sulfate as heptahydrate…500mg"
	Diary No. Date of R& I & fee	Dy.No 6550 dated 14-02-2019 Rs.20,000/- 14-02-2019
	Pharmacological Group	Mineral Supplements
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10ml ampoule,1's.
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed.
	Me-too status	Couldnot be confirmed.
	GMP status	05-05-2019 Conclusion: Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Surge Lab, it was concluded that M/s Surge Lab is operating at a good level of cGMP compliance on the day of inspection as per Drugs Act, 1976 and rules framed there under.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2303.	Name and address of manufacturer / Applicant	"M/s Surge Laboratories Pvt Ltd. 10 km, Faisalabad Road, Bikhi, District Sheikhupura"
	Brand Name +Dosage Form + Strength	Magtense Injection 50% w/v, Magreif, Admag
	Composition	"Each ml contains: Magnesium sulfate…500mg"
	Diary No. Date of R& I & fee	Dy.No 6549 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Mineral Supplements
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2ml ampoule, 5's,10's
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Couldnot be confirmed.
	GMP status	05-05-2019 Conclusion: Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Surge Lab, it was concluded that M/s Surge Lab is operating at a good level of Cgmp compliance on the day of inspection as per Drugs Act, 1976 and rules framed there under.
	Remarks of the Evaluator (V)	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
2304.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals.146 S.I.Z. Risalpur, KPK, Pakistan by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awatan 2.25g Injection
	Composition	"Each Vial Contains: Piperacillin sodium eq to Piperacillin…2.0g Tazobactam sodium eq to Tazobactam…0.25g"
	Diary No. Date of R& I & fee	Dy.No 7048 dated 19-02-2019 Rs.50,000/- Dated 19-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.1's Vial.
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for Injection USFDA Approved.
	Me-too status	044142; Tazobact 2.25g Injection M/s Jinnah Pharmaceuticals, Multan manufactured by Lowitt Pharma, Peshawar .
	GMP status	11 & 24-10-2018. Conclusion: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.**	
2305.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals.146 S.I.Z. Risalpur, KPK, by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Awatan 4.5g Injection
	Composition	"Each Vial Contains: Piperacillin sodium eq to Piperacillin…4.0g Tazobactam sodium eq to Tazobactam…0.5g"
	Diary No. Date of R& I & fee	Dy.No 7049 dated 19-02-2019 Rs.50,000/- 19-02-2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.1's Vial.
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for Injection USFDA Approved.
	Me-too status	044143 Tazobact 4.5g Injection M/s Jinnah Pharmaceuticals, Multan manufactured by Lowitt Pharma, Peshawar .
	GMP status	11 & 24-10-2018. Conclusion: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.**	

2306.	Name and address of manufacturer / Applicant	"M/s Unisa Pharmaceuticals Industries Ltd Maint G.T Road, Adam Zai, Akora Khattak, Distt Nowshehra"
	Brand Name +Dosage Form + Strength	Unidol IV Infusion
	Composition	"Each 100ml contains: Paracetamol…1000mg"
	Diary No. Date of R& I & fee	Dy.No 6770 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Analgesics And Antipyretics
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	As per SRO.Polyethylene bottle.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved with box warning.
	Me-too status	082000 Paedal Infusion M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	15-05-2019 Non Compliance of Sub Rule (14) of Rule 19 of the Drugs (Licensing, Registration and Advertising) Rule, 1976.
	Remarks of the Evaluator (V)	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for evidence of approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	
2307.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt) Ltd.Sheikhupura Road,Lahore"
	Brand Name +Dosage Form + Strength	Vancin 500mg Powder for concentrate for solution
	Composition	"Each vial contains: Vancomycin HCl eq to Vancomycin Lyophilized…500mg"
	Diary No. Date of R& I & fee	Dy.No 5111 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA approved.
	Me-too status	081901 Vanzy 500mg M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	GMP status	18-07-2017 Recommendations: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm Neutro pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator (V)	• General lyophilized section is present. • The method of manufacturing of vancomycin injection is required. • Type of container not provided.

	Decision: Deferred for the following: • **Submit outline of manufacturing method of applied formulation.** • **Mention type of primary packaging material whether it is type I, II, or III glass container.**	
2308.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt) Ltd.Sheikhupura Road,Lahore"
	Brand Name +Dosage Form + Strength	Tyginen 50mg/5ml Injection
	Composition	"Each vial contains: Tigecycline…50mg
	Diary No. Date of R& I & fee	Dy.No 5112 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Tygacil®(Tigecycline) For Injection, Approved in USFDA with Boxwarning.
	Me-too status	081904 Tigelin 50mg Injection M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	GMP status	18-07-2017 Recommendations: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm Neutro pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator (V)	•
	Decision: Approved.	
2309.	Name and address of manufacturer / Applicant	"M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	New Dol Injection 100mg/2ml
	Composition	"Each ampoule of 2ml contains: Tramadol HCl…100mg"
	Diary No. Date of R& I & fee	Dy.No 7578 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Opoid Analgesic
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs 350/Pack,5x2ml, Glass ampoules,Type I.
	Approval status of product in Reference Regulatory Authorities.	MHRA approved.
	Me-too status	024430 "Tramed Injection "Cirin Pharmaceuticals, 32/2A, Phase III, Industrial Estate, Hattar (Manufactured By M/s. Standpharma, Lahore)"
	GMP status	26-4-2018. GMP certificate is provided.
	Remarks of the Evaluator (V)	• Ampoule section vide Licensing Division letter No. F.1-14/2006-Lic dated 18.02.2013. • The manufacturing outline specific to the applied formulation is required.
	Decision: Deferred for the following: • **Submit outline of manufacturing method specific to the applied formulation**.	

2310.	Name and address of manufacturer / Applicant	"M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Adrenalin Injection 0.1%w/v
	Composition	"Each ml contains Adrenaline(Epinephrine)…1mg
	Diary No. Date of R& I & fee	Dy.No 7577 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	Rs 450/- per Pack.USP type 1 glass.,100x1ml ampoules.
	Approval status of product in Reference Regulatory Authorities.	Adrenalin (Epinephrine Injection) 1 Mg/Ml, For Intramuscular, Subcutaneous, And Intravenous Use USFDA Approved.
	Me-too status	080303 Adrenaline 1mg/ml Injection M/s Safe Pharmaceuticals, Karachi . .
	GMP status	26-4-2018. GMP certificate is provided.
	Remarks of the Evaluator (V)	• Ampoule section vide Licensing Division letter No. F.1-14/2006-Lic dated 18.02.2013. • The manufacturing outline specific to the applied formulation is required.
	Decision: Deferred for the following: • **Submit outline of manufacturing method specific to the applied formulation**.	
2311.	Name and address of manufacturer / Applicant	"M/s News Pharma. 42-Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	New Zone Injection 1gm IM
	Composition	"Each Vial Contains: Ceftriaxone as sodium eq to Ceftriaxone…1gm"
	Diary No. Date of R& I & fee	Dy.No 7579 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's,Along with diluent, Rs 450/pack.,Type I glass vials.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	079446 Accucef Injection 1 gm IM Injection M/s Wel Wink Pharmaceuticals, G.T Road, Industrial Estate Gujranwala Cantt.
	GMP status	26-4-2018. GMP certificate is provided.
	Remarks of the Evaluator (V)	• Dry Powder (Cphalosporin) Injection section vide Licensing Division letter No. F.1-14/2006-Lic dated 06.06.2016.
	Decision: Approved.	
2312.	Name and address of manufacturer / Applicant	"M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pantas Capsule 40mg
	Composition	"Each Capsule Contains: Pantoprazole as sodium (enteric coated pellets)…40mg
	Diary No. Date of R& I & fee	Dy.No 8240 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5

	Finished product Specification	Inhouse
	Pack size & Demanded Price	Brand leader,1x10's;2x10's,3x10's
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed for capsules.
	Me-too status	076139 Aprant 40mg Capsule M.s Adamjee Karachi . .
	GMP status	07-01-2020 Personal Hearing Before 271st Meeting of CLB.
	Remarks of the Evaluator (V)	• Capsule section confirmed vide Licensing Division letter No.F.1-4-/84-Lic(Pt) dated 06.09.2018 • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Provide source of pellets. • Evidence of USP monograph of pantoprazole capsules.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.**	
2313.	Name and address of manufacturer / Applicant	"M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Temrid 1g/100ml IV Infusion
	Composition	"Each 100ml vial contains: Paracetamol…1g"
	Diary No. Date of R& I & fee	Dy.No 8166 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Analgesic and Antipyretic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	Rs 140/glass vial,
	Approval status of product in Reference Regulatory Authorities.	MHRA approved.
	Me-too status	082000 Paedal Infusion M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	-
	Remarks of the Evaluator (V)	• Justification of 3% overage on the basis of scientific data. • Latest GMP inspection report is required.
	Decision: Deferred for the following: • **Deferred for justification on scientific grounds for addition of 3% overage in master formulation** • **Submit latest GMP inspection report.**	
2314.	Name and address of manufacturer / Applicant	"M/s Le Mendoza Pharmaceuticals Pvt Ltd. Plot No.7, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Ciprocam 200mg/100ml IV Infusion
	Composition	"Each 100ml contains: Ciprofloxacin as HCL…200mg"
	Diary No. Date of R& I & fee	Dy.No 8165 dated 25-02-2019 Rs.20,000/- 25-02-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	Rs 250/vial
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed as HCl salt.
	Me-too status	Could not be confirmed as HCl salt.
	GMP status	Latest GMP inspection report is required.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation as Ciprofloxacin as HCL in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation as Ciprofloxacin as HCL already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • The qty. of API in master formulation is 244.544mg/100ml. Clarify.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation as Ciprofloxacin as HCL infusion in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation as Ciprofloxacin as HCL infusion already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **The qty. of API in master formulation is 244.544mg/100ml. Clarify.**	
2315.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Mox 400mg Tablet
	Composition	"Each Film Coated oral Tablet Contains: Moxifloxacin as HCL…400MG"
	Diary No. Date of R& I & fee	Dy.No 8286 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Fluoroquinolones J01MA14
	Type of Form	Form 5
	Finished product Specification	USP specs
	Pack size & Demanded Price	5's, 10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Moxifloxacin 400mg Tablet by Bayer Health Care USFDA Approved
	Me-too status	074931 Moxpin 400 mg Tablet M/s Winthrox Karachi . .
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	•
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Justification for contract manufacturing as G T Pharma has own tablet section** • **Capacity assessment of M/s Medisave Pharma**	
2316.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave harmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Cip 250mg Tablet

	Composition	"Each Film Coated Tablet Contains: Ciprofloxacin HCL eq to Ciprofloxacin…250mg"
	Diary No. Date of R& I & fee	Dy.No 8284 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipro® (Ciprofloxacin Hydrochloride) Tablet Approved In USFDA with Box Warning.
	Me-too status	056372 "Ciprowrd 250mg Tablets " Welwrd Pharmaceuticals, Plot No.3, Block No.A, Phase I-II, Industrial Estate,Hattar"
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2317.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Cip 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ciprofloxacin HCL eq to Ciprofloxacin…500mg"
	Diary No. Date of R& I & fee	Dy.No 8285 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipro® (Ciprofloxacin Hydrochloride) Tablet Approved In USFDA with Box Warning.
	Me-too status	056373 "Ciprowrd 500mg Tablets " Welwrd Pharmaceuticals, Plot No.3, Block No.A, Phase I-II, Industrial Estate,Hattar"
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2318.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	G-Mont chewable 5mg Tablet
	Composition	"Each chewable Tablet Contains: Montelukast Sodium eq to Montelukast…5mg"

	Diary No. Date of R& I & fee	Dy.No 8274 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	079342 "NenKast 5 mg Tablets Each Chewable Tablet contains:- " Nenza Pharmaceuticals, 33-A, Hayatabad, Peshawar
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2319.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	G-Mont 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Montelukast Sodium eq to Montelukast…10mg"
	Diary No. Date of R& I & fee	Dy.No 8275 dated 25-02-2019 Rs.50,000/- 25-02-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	076530 Umcast 10mg Tablet By M/s Umema Pharma Baluchistan.
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2320.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Nestor 8mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ondansetron HCl dihydrate eq to Ondansetron…8mg"
	Diary No. Date of R& I & fee	Dy.No 8288 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Antiemetics And Antinauseants A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form 5

	Finished product Specification	USP.
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZOFRAN Tablets, 8 mg (ondansetron HCl dihydrate equivalent to 8 mg of ondansetron),USFDA Approved.
	Me-too status	081451 Ondonx Tablet ,Genix Pharma Karachi . .
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2321.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Line 600mg Tablet
	Composition	"Each Film Coated Tablet Contains: Linezolid…600mg"
	Diary No. Date of R& I & fee	Dy.No 8278 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Antibacterial for systemic use. J01XX08
	Type of Form	Form-5
	Finished product Specification	Inhouse Spec.
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZYVOX Tablets USFDA Approved.
	Me-too status	055773 Leckzolid 600mg Tablet Medimarker's Pharmaceutical, Hyderabad
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2322.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Mycin 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clarithromycin HCl eq to Clarithromycin…250mg"
	Diary No. Date of R& I & fee	Dy.No 8276 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in	Biaxin 250mg (Available as only Clarithromycin without

	Reference Regulatory Authorities.	HCl) **Federal Register Determination That Product Was Not Discontinued Or Withdrawn For Safety Or Efficacy Reasons** USFDA Approved.
	Me-too status	082036 Claramet -250 Tablets M/s Metro Pharmaceuticals,Plot No.14, Street No.SS-2,National Industrial Zone RCCI,Rawat, Islamabad
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	• Details about total number of sections & total number of products already approved on contract manufacturing of applicant. • Submission of agreement between applicant and manufacturer. • Evidence of approval of applied formulation as "Clarithromycin HCl eq to Clarithromycin…250mg" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Submit composition of applied formulation in line with label cliam of reference product i.e. "Clarithromycin as HCl 250mg film coated tablet.** • **Capacity assessment of M/s Medisave Pharma**	
2323.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Mycin 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clarithromycin HCl eq to Clarithromycin…500mg"
	Diary No. Date of R& I & fee	Dy.No 8277 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Biaxin 500mg **Federal Register Determination That Product Was Not Discontinued Or Withdrawn For Safety Or Efficacy Reasons** USFDA Approved.
	Me-too status	082037 Claramet -500 Tablets M/s Metro Pharmaceuticals,Plot No.14, Street No.SS-2,National Industrial Zone RCCI,Rawat, Islamabad
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.**	

	• **Submit contract manufacturing agreement between applicant and manufacturer.** • **Submit composition of applied formulation in line with label cliam of reference product i.e. "Clarithromycin as HCl 250mg film coated tablet.** • **Capacity assessment of M/s Medisave Pharma**	
2324.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Xime 400mg Capsule
	Composition	"Each Capsule Contains: Cefixime Trihydrate eq to Cefixime…400mg"
	Diary No. Date of R& I & fee	Dy.No 8287 dated 25-02-2019 Rs.50,000/- 25-02-2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	1x5's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) capsules USFDA Approved.
	Me-too status	055093; Vasix 400mg ' By M/s Alfalah Pharma (Pvt.) Ltd.,
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2325.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Xime 100mg Dry powder suspension
	Composition	"Each 5ml of reconstituted suspension contains: Cefixime Trihydrate eq to Cefixime…100mg"
	Diary No. Date of R& I & fee	Dy.No 8279 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml bottle, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	073247 Stlicef Dry Suspension 200mg Treat Pharma A-37, Industrial Estate Kohat Road,Bnnu (contract manufacturing will be conducted by M/s. Shawan Pharmaceuticals, Rawat)"
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.**	

	• **Capacity assessment of M/s Medisave Pharma**	
2326.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Xime 200mg Dry powder suspension
	Composition	"Each 5ml of reconstituted suspension contains: Cefixime Trihydrate eq to Cefixime…200mg"
	Diary No. Date of R& I & fee	Dy.No 8280 dated 25-02-2019 Rs.50,000/- 25-02-2019
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml bottle, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	073248; Stlicef Dry Suspension 200mg Treat Pharma A-37, Industrial Estate Kohat Road,Bnnu (contract manufacturing will be conducted by M/s. Shawan Pharmaceuticals, Rawat)"
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2327.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Zone 250mg Injection IV
	Composition	"Each Vial Contains: Ceftriaxone sodium eq to Ceftriaxone…250mg"
	Diary No. Date of R& I & fee	Dy.No 8281 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Third-generation cephalosporins J01DD04
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's Type II Vial, as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Rocephin 250 mg Powder for solution for injection. MHRA Approved.
	Me-too status	075935 Breezon Injection 250mg M/s Pliva Balochistan
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Clarification regarding brand name is required whether it is as GT CIP or GT Zone**. • **Capacity assessment of M/s Medisave Pharma**	

2328.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Zone 500mg Injection
	Composition	"Each Vial Contains: Ceftriaxone sodium eq to Ceftriaxone…500mg"
	Diary No. Date of R& I & fee	Dy.No 8282 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, Glass III vials, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocephin powder for solution for Injection vials by Roche (MHRA Approved)
	Me-too status	062328 "Cefaben 500 mg IV Injection " Imco Pharmaceuticals Laboratories, 73/A.S Industrial Estate, Jamrud Road, Peshawar. (contract manufacturing conducted by M/s. Caraway Pharmaceuticals, Rawat, Islamabad)"
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2329.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gt Zone 1g Injection
	Composition	"Each Vial Contains: Ceftriaxone as sodium eq to Ceftriaxone…1g"
	Diary No. Date of R& I & fee	Dy.No 8283 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Glass II vials, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocephin powder for solution for Injection vials by Roche (MHRA Approved)
	Me-too status	070663 Martixon 1gm I.V Dry powder Injection by Alkemy Hyderabad
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	

2330.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	C Pime Injection 500mg
	Composition	"Each Vial Contains: Cefepime HCL…500 mg Arginine…326.5 mg
	Diary No. Date of R& I & fee	Dy.No 8290 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Fourth-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Type II, 1's Vial, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Maxipime (cefepime hydrochloride) for injection, for intravenous or intramuscular use USFDA Approved
	Me-too status	055465 KC-Pime 500mg Injection M/s Karachi Chemical Industrial
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	•
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2331.	Name and address of manufacturer / Applicant	M/s GT Pharma Pvt Ltd,23km, Raiwind Road, Lahore contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	C Pime Injection 1000mg
	Composition	"Each Vial Contains: Cefepime as HCL…1000 mg Arginine…725 mg
	Diary No. Date of R& I & fee	Dy.No 8291 dated 25-02-2019 Rs.50,000/- Dated 25-02-2019
	Pharmacological Group	Fourth-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Type II, 1's Vial, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Maxipime (cefepime hydrochloride) for injection, for intravenous or intramuscular use USFDA Approved
	Me-too status	055466 KC-Pime 1000mg Injection M/s Karachi Chemical Industrial
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator (V)	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for the following: • **Submit detail about total number of sections & total number of products already approved on contract manufacturing of applicant.**	

	• **Submit contract manufacturing agreement between applicant and manufacturer.** • **Capacity assessment of M/s Medisave Pharma**	
2332.	Name and address of manufacturer / Applicant	"M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Kaytrigine 25mg Tablet
	Composition	"Each film coated tablet Contains: Lamotrigine…25mg"
	Diary No. Date of R& I & fee	Dy.No 6571 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Available As Uncoated Tablet.
	Me-too status	070344 "Sportin 25mg Tablets "Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar"
	GMP status	Last GMP inspection was conducted on 17-04-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for Evidence of approval of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2333.	Name and address of manufacturer / Applicant	"M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Kaytrigine 50mg Tablet
	Composition	"Each film coated tablet Contains: Lamotrigine…50mg"
	Diary No. Date of R& I & fee	Dy.No 6572 dated 14-02-2019 Rs.20,000/- 14-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Couldnot be confirmed as film coated tablet.
	Me-too status	070345 "Sportin 50mg Tablets "Fassgen Pharmaceuticals, Plot No. 67/1-A, Phase-III, Industrial Estate, Hattar"
	GMP status	Last GMP inspection was conducted on 17-04-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for Evidence of approval of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2334.	Name and address of manufacturer / Applicant	"M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Kedronate 70mg Tablet
	Composition	"Each film coated Tablet Contains:

		Alendronate sodium trihydrate eq. to Alendronate…70mg"
	Diary No. Date of R& I & fee	Dy.No 6569 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	FOSAMAX® (alendronate sodium) tablets
	Me-too status	068396 "Deonate Tablets 70mg " Cirin Pharmaceuticals,32/2A Industrial Estate,Hattar "
	GMP status	Last GMP inspection was conducted on 17-04-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for Evidence of approval of applied formulation as film coated tablets in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
2335.	Name and address of manufacturer / Applicant	"M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	DEE 3 Dry powder Injection
	Composition	"Each ml contains: Vitamin D3…5mg"
	Diary No. Date of R& I & fee	Dy.No 6567 dated 14-02-2019 Rs.20,000/- 14-02-2019
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Solution is present in USP.
	Pack size & Demanded Price	1x1's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200,000 IU / 1 ml, IM solution for injection in ampoule ANSM Approved.
	Me-too status	082005 Drol-D injection By M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	Last GMP inspection was conducted on 17-04-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Deferred for confirmation about composition of product as Dry powder Injection and manufacrturing facility.	
2336.	Name and address of manufacturer / Applicant	"M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi"
	Brand Name +Dosage Form + Strength	Koxib 60mg Tablet
	Composition	"Each Tablet Contains: Etoricoxib…60mg"
	Diary No. Date of R& I & fee	Dy.No 6568 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.

	Me-too status	081647 Etroxin tablet 60mg By M/s Akson Pharmaceuticals Pvt Ltd, Islamabad
	GMP status	Last GMP inspection was conducted on 17-04-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2337.	Name and address of manufacturer / Applicant	"M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore. By M/s MTI Medical Pvt Ltd.586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Esotek 40mg Injection
	Composition	"Each Vial Contains: Esomeprazole Sodium…40mg"
	Diary No. Date of R& I & fee	Dy.No 6985 dated 19-02-2019 Rs.50,000/- Dated 19-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	Glass vial, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Esomeprazole 40 mg Powder for Solution for Injection/Infusion MHRA Approved.
	Me-too status	080975 "SAF-ESO 40mg powder for Injection M/s Saaaf Pharmaceuticals,Industrial Estate, (SIZ) Risaipur, Nowshera"
	GMP status	The firm is granted GMP certificate based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator (V)	• Contract has been provided by the firm.
	Decision: Approved.	
2338.	Name and address of manufacturer / Applicant	"M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore. By M/s MTI Medical Pvt Ltd.586-587, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ometek 40mg Lyophilized Injection
	Composition	"Each Vial Contains: Omeprazole as Sodium Lyophilized …40mg"
	Diary No. Date of R& I & fee	Dy.No 6984 dated 19-02-2019 Rs.50,000/- Dated 19-02-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Inhouse Specs.
	Pack size & Demanded Price	Glass vial, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg Powder for Solution for Infusion MHRA Approved.
	Me-too status	070680 Loprot I.V. 40mg Injection M/s Nabiqasim Karachi . .
	GMP status	The firm is granted GMP certificate based on inspection conducted on 25-09-2019.
	Remarks of the Evaluator (V)	• Contract has been provided by the firm. • Latest GMP inspection report of manufacturer is required.

	Decision: Approved.	
2339.	Name and address of manufacturer / Applicant	"M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small Industries Estate, Sargodha"
	Brand Name +Dosage Form + Strength	Tamson 0.4mg Capsule
	Composition	"Each Capsule Contains: Tamsulosin HCl…0.4mg"
	Diary No. Date of R& I & fee	Dy.No 5179 dated 06-02-2019 Rs.20,000/- Dated 04-02-2019
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's,
	Approval status of product in Reference Regulatory Authorities.	FLOMAX® (tamsulosin hydrochloride, USP) Capsules USFDA Approved.
	Me-too status	077087 "Urimax 0.4 mg Capsule "M/s English Pharm, Link Katarband Road, Thokar Niaz Beg, Lahore."
	GMP status	Panel inspection conducted on 22-08-2017 & 12-10-2017 recommended grant of renewal of DML by the way of formulation for following sections: General tablet section. General capsule section General dry Powder suspension section.
	Remarks of the Evaluator (V)	• Clarification of dosage form immediate release or sustain release formulation. • Incase of pellets provide source,GMP, stability data and differential fee in case of imported.
	Decision: Deferred for the following: **COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.** **Submit clarification of dosage form whether immediate release or sustain release formulation**	
2340.	Name and address of manufacturer / Applicant	"M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Napsum Tablet
	Composition	"Each film coated tablet contains: Sumatriptan Succinate eq to Sumatriptan…85mg Naproxen sodium…500mg"
	Diary No. Date of R& I & fee	Dy.No 6982 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Migraine Management
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	2's,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TREXIMET (sumatriptan and naproxen sodium) tablets USFDA Approved with box warning.
	Me-too status	075904 Sumtan Plus Tablet M/s Medisure Karachi . .
	GMP status	09-01-2019 The firm has rectified majority of observations noted in the previous inspection and the management is committed to improve their cGMP compliance.The firm may be considered operating in satisfactory level of cGMP compliance. Recommendations:They are advised to:

		• Purchase FTIR and column oven for HPLC • Provide a shelter on material entry gate. • Increase number of dehumidifier in general production area. • Provide a split AC in dispensing room. • Provide room for retention samples.
	Remarks of the Evaluator (V)	
	Decision: Deferred for updated GMP status from QA Division.	
2341.	Name and address of manufacturer / Applicant	"M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Delor 5mg tablets
	Composition	"Each film coated tablet Contains: Desloratadine…5mg"
	Diary No. Date of R& I & fee	Dy.No 6979 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Anti-histamine for systemic use.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CLARINEX® (desloratadine) Tablets, USFDA Approved.
	Me-too status	080821 Desdine 5mg Tablet M/s Hygeia Pharmaceuticals, Islamabad
	GMP status	09-01-2019 The firm has rectified majority of observations noted in the previous inspection and the management is committed to improve their cGMP compliance.The firm may be considered operating in satisfactory level of cGMP compliance. Recommendations:They are advised to: • Purchase FTIR and column oven for HPLC • Provide a shelter on material entry gate. • Increase number of dehumidifier in general production area. • Provide a split AC in dispensing room. • Provide room for retention samples.
	Remarks of the Evaluator (V)	
	Decision: Deferred for updated GMP status from QA Division.	
2342.	Name and address of manufacturer / Applicant	"M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Ternix forte 4mg Tablets
	Composition	"Each Tablet Contains: Tizanidine…4mg"
	Diary No. Date of R& I & fee	Dy.No 6981 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Muscle relaxants
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZANAFLEX® (tizanidine hydrochloride) tablets, USFDA Approved.
	Me-too status	080865 "Zinzan 4mg Tablet " Wellborne Pharmachem and Biologicals, Plot#51/1 Phase I&II Industrial Estate,Hattar."

	GMP status	09-01-2019 The firm has rectified majority of observations noted in the previous inspection and the management is committed to improve their cGMP compliance.The firm may be considered operating in satisfactory level of cGMP compliance. Recommendations:They are advised to: • Purchase FTIR and column oven for HPLC • Provide a shelter on material entry gate. • Increase number of dehumidifier in general production area. • Provide a split AC in dispensing room. • Provide room for retention samples.
	Remarks of the Evaluator (V)	• The firm has applied for only Tizanidine however, the product is internationally approved as Tizanidine as HCl.
	Decision: Deferred for clarification regarding salt form of API alongwith submission of requisite fee and updated GMP status of firm.	
2343.	Name and address of manufacturer / Applicant	"M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Doksal 100mg/5ml Syrup
	Composition	"Each 5ml contains: Doxofylline…100mg"
	Diary No. Date of R& I & fee	Dy.No 6983 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Systemic Drugs for Obstructive Airway Diseases
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	60ml glass bottle, plastic bottle. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Ansimar Company: Abc Farmaceutici Spa AIFA Approved.
	Me-too status	047180 Unifyline Syrup M/s Platinum Pharmaceuticals, Karachi
	GMP status	09-01-2019 The firm has rectified majority of observations noted in the previous inspection and the management is committed to improve their cGMP compliance.The firm may be considered operating in satisfactory level of cGMP compliance. Recommendations:They are advised to: • Purchase FTIR and column oven for HPLC • Provide a shelter on material entry gate. • Increase number of dehumidifier in general production area. • Provide a split AC in dispensing room. • Provide room for retention samples.
	Remarks of the Evaluator (V)	Liquid syrup section is present.
	Decision: Deferred for updated GMP status from QA Division.	
2344.	Name and address of manufacturer / Applicant	"M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Delor Syrup 2.5mg/ml
	Composition	"Each 5ml contains: Desloratadine…2.5mg"
	Diary No. Date of R& I & fee	Dy.No 6978 dated 19-02-2019 Rs.20,000/- Dated 19-02-

		2019
	Pharmacological Group	Antihistamines For Systemic Use
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	60ml amber glass,plastic bottle, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Clarinex® (Desloratadine) and Oral Solution USFDA Approved.
	Me-too status	076743 Genelor 2.5mg Syrup M/s Zanctok Karachi . .
	GMP status	09-01-2019 The firm has rectified majority of observations noted in the previous inspection and the management is committed to improve their cGMP compliance.The firm may be considered operating in satisfactory level of cGMP compliance. Recommendations:They are advised to: • Purchase FTIR and column oven for HPLC • Provide a shelter on material entry gate. • Increase number of dehumidifier in general production area. • Provide a split AC in dispensing room. • Provide room for retention samples.
	Remarks of the Evaluator (V)	Liquid syrup section is present.
	Decision: Deferred for updated GMP status from QA Division.	
2345.	Name and address of manufacturer / Applicant	"M/s Universal Pharmaceuticals Pvt Ltd. 131-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Lezene 2.5mg/5ml
	Composition	"Each 5ml contains: Levocetirizine Dihydrochloride…2.5mg"
	Diary No. Date of R& I & fee	Dy.No 6980 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Antihistamines for systemic use
	Type of Form	Form 5
	Finished product Specification	
	Pack size & Demanded Price	60ml plastic bottle,amber glass,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	XYZAL oral solution USFDA approved.
	Me-too status	076688 Atiza Syrup 2.5mg/ 5ml M/s Asian Continental Karachi .
	GMP status	09-01-2019 The firm has rectified majority of observations noted in the previous inspection and the management is committed to improve their cGMP compliance.The firm may be considered operating in satisfactory level of cGMP compliance. Recommendations:They are advised to: • Purchase FTIR and column oven for HPLC • Provide a shelter on material entry gate. • Increase number of dehumidifier in general production area. • Provide a split AC in dispensing room. • Provide room for retention samples.
	Remarks of the Evaluator (V)	Liquid syrup section is present.
	Decision: Deferred for updated GMP status from QA Division.	

2346.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name +Dosage Form + Strength	Angitril 2.6mg Tablet
	Composition	"Each Sustained Release Tablet Contains: Glyceryl Trinitrate…2.6mg"
	Diary No. Date of R& I & fee	Dy.No 6326 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Vasodilators used in Cardiac Diseases.
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Sustac Tablets 2.6mg MHRA Approved.
	Me-too status	055421 Glyrate-SR 2.6mg Tablet By M/s Getz Pharma, Karachi
	GMP status	08-10-2019 Recommendations: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Saffron Pvt Ltd was considered to be operating at Good level of compliance with GMP guidelines as per Drugs Act 1976, and rules framed there under, The panel recommends considering the firm for grant of Cgmp certificate, un respect of all approved sections.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2347.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name +Dosage Form + Strength	Angitril 6.4mg Tablet
	Composition	"Each Sustained Release Tablet Contains: Glyceryl Trinitrate…6.4mg"
	Diary No. Date of R& I & fee	Dy.No 6327 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Vasodilators used in Cardiac Diseases.
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Sustac Tablets 6.4mg MHRA Approved.
	Me-too status	055422 Glyrate-SR 6.4mg Tablet By M/s Getz Pharma, Karachi
	GMP status	08-10-2019 Recommendations: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Saffron Pvt Ltd was considered to be operating at Good level of compliance with GMP guidelines as per Drugs Act 1976, and rules framed there under, The panel recommends considering the firm for grant of Cgmp certificate, un respect of all approved sections.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2348.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name +Dosage Form + Strength	Trifort DS Tablet
	Composition	"Each Film Coated Tablet Contains:

		Tramadol HCL…75mg Paracetamol…650mg"
	Diary No. Date of R& I & fee	Dy.No 6328 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics.
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in applied strength.
	Me-too status	Could not be confirmed in applied strength.
	GMP status	08-10-2019 Recommendations: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Saffron Pvt Ltd was considered to be operating at Good level of compliance with GMP guidelines as per Drugs Act 1976, and rules framed there under, The panel recommends considering the firm for grant of Cgmp certificate, un respect of all approved sections.
	Remarks of the Evaluator (V)	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2349.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name +Dosage Form + Strength	Fortin IV/IM 50mg/ml Injection or Infusion
	Composition	"Each ml Contains: Tramadol HCl…50mg"
	Diary No. Date of R& I & fee	Dy.No 6329 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Opioids
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	5's,10's of 2ml glass ampoule, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	052629 "Welmadol injection By M/s Welwrd pharmaceuticals,Industrial estate,Hattar."
	GMP status	08-10-2019 Recommendations: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Saffron Pvt Ltd was considered to be operating at Good level of compliance with GMP guidelines as per Drugs Act 1976, and rules framed there under, The panel recommends considering the firm for grant of Cgmp certificate, un respect of all approved sections.
	Remarks of the Evaluator (V)	• Step of terminal sterilization has not been mentioned in manufacturing outline.

		• Approval of Small volume ampoule parenteral section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for the following: • **Step of terminal sterilization has not been mentioned in manufacturing outline.** • **Approval of Small volume ampoule parenteral section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.**	
2350.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Diclonov Tablet 75mg
	Composition	"Each film coated tablet Contains: Diclofenac Sodium…75mg
	Diary No. Date of R& I & fee	Dy.No 6576 dated 14-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	USP Monograph of extended release is available.
	Pack size & Demanded Price	2x10's Tablets/ Pack,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Dicloflex 75 mg SR Fenactol 75 mg SR MHRA Approved.
	Me-too status	038001 "Falonac 75mg Tablets "Farm Aid Group (Pvt) Ltd., Plot No. 3/2, Hattar Indus. Area, Hattar."
	GMP status	CLB in its 267th meeting held on 31st December 2018 has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	The applied formulation is internationally approved as Sustain release tablet of Diclofenac sodium.
	Decision: Deferred for submission of evidence of approval of applied formulation in reference agencies as film coated tablet or otherwise revision of applied formulation in line with reference product i.e. sustained release tablet alongwith submission of requisite fee master formulation & manufacturing method.	
2351.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Diclonov SR Tablet 100mg
	Composition	"Each Tablet Contains: Diclofenac Sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 6577 dated 14-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	USP Monograph of extended release is available.
	Pack size & Demanded Price	2x10's Tablets Pack, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Dicloflex Retard 100 mg Fenactol Retard 100mg MHRA Approved.
	Me-too status	036328 "Fenal-SR Tablets 100mg By M/s Alsons Pharmaceuticals 169-Hayatabad Industrial Estate, Peshawar"
	GMP status	CLB in its 267th meeting held on 31st December 2018 has considered and approved the renewal of DML.

	Remarks of the Evaluator (V)	The firm has not mentioned whether sustain release or immediate release formulation.
	Decision: Deferred for clarification of applied formulation whether it is sustained or immediate release tablet.	
2352.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Cipron 250mg Tablet
	Composition	"Each film coated tablet Contains: Ciprofloxacin as HCl…250mg
	Diary No. Date of R& I & fee	Dy.No 6575 dated 14-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipro® (Ciprofloxacin Hydrochloride) Tablet Approved In USFDA with Box Warning.
	Me-too status	056372 "Ciprowrd 250mg Tablets " Welwrd Pharmaceuticals, Plot No.3, Block No.A, Phase I-II, Industrial Estate,Hattar"
	GMP status	CLB in its 267th meeting held on 31st December 2018 has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2353.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Venlaxin 37.5mg tablet
	Composition	"Each Tablet Contains: Venlafaxine as HCl…37.5mg"
	Diary No. Date of R& I & fee	Dy.No 6573 dated 14-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Effexor® (venlafaxine hydrochloride) USFDA Approved with box warning.
	Me-too status	053551 "Venlor-37.5 Tablets "M/s Genome Pharmaceuticals (Pvt,) Ltd,16/1-Phase IV Industrial Estate,Hattar."
	GMP status	CLB in its 267th meeting held on 31st December 2018 has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Signature of applicant is missing on Form 5.
	Decision: deferred for submission of signed application of applied formulation on Form 5.	
2354.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Venlaxin XR 75mg Tablet
	Composition	"Each Extended Release Tablet Contains: Venlafaxine HCl Eq. to Venlafaxine…75mg"
	Diary No. Date of R& I & fee	Dy.No 6574 dated 14-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	079368 "Lafix Tablet 75 mg " WnsFeild Pharmaceuticals,Plot.No.122, Block-A, Phase-V,Industrial Estate,Hattar."
	GMP status	CLB in its 267th meeting held on 31st December 2018 has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Signature of applicant is missing on Form 5.
	Decision: Deferred for submission of signed application of applied formulation on Form 5.	
2355.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Prebalin 300mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…300mg"
	Diary No. Date of R& I & fee	Dy.No 6578 dated 14-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	2x7's Capsule/Pack.As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lyrica USFDA Approved
	Me-too status	050259 "Gablin Capusle 300mg. "M/s CCL Pharmaceuticals (Pvt) Ltd., 62 Industrial Estate, Kot Lakhpat, Lahore."
	GMP status	CLB in its 267th meeting held on 31st December 2018 has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved.	
2356.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Noxor XR Capsule 75mg
	Composition	"Each Capsule Contains: Venlafaxine HCl eq to Venlafaxine (extended release)…75mg"
	Diary No. Date of R& I & fee	Dy.No 6579 dated 14-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x7 Capsules/Pack, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	EFFEXOR XR USFDA Approved.
	Me-too status	053625 "Enpress XR Capsules. M/s Bryon Pharma (Pvt.) Ltd., 48 Hayatabad, Indus. Estate, Peshawar."
	GMP status	CLB in its 267th meeting held on 31st December 2018 has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.

	Decision: Deferred for COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	
2357.	Name and address of manufacturer / Applicant	"M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Clindanov Capsule 300mg
	Composition	"Each Capsule Contains: Clindamycin HCl eq to Clindamycin …300mg"
	Diary No. Date of R& I & fee	Dy.No 6580 dated 14-02-2019 Rs.20,000/- Dated 13-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2x8's Capsules/ Pack,As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Clindamycin 300mg Hard Capsules MHRA Approved.
	Me-too status	076494 Clindacure Capsule By M/sHiranis Karachi . .
	GMP status	CLB in its 267th meeting held on 31st December 2018 has considered and approved the renewal of DML.
	Remarks of the Evaluator (V)	
	Decision: Approved.	

Case no. 02 Registration applications for local manufacturing of (Veterinary) drugs

a. Deferred cases

2358.	Name and address of Manufacturer / Applicant	"M/s D-Haans Pharmaceuticals. Plot No. 9/A, Industrial Estate, Bhimber"
	Brand Name +Dosage Form + Strength	Hansydox-80% Powder
	Composition	"Each g Contains: Doxycycline HCl…800mg"
	Diary No. Date of R&I &fee	Dy.No 1884 (19-02-2020) Rs.20,000/- (17-02-2020)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10kg
	Me-too status	082504; "Doxyral 80% Water Soluble Powder For Oral Route "M/s. Orient Animal Health (Pvt.) Limited, Karachi-75100"
	GMP status	CLB in its 273rd meeting held on 15th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals.Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.
	Remarks of the Evaluator (V)	The drug already approved by DRAP (generic / me-too status) provided by you mention "Doxycycline hyclate…...923.32mg (eq. To 800mg doxycycline)" whereas, you have applied for "Doxycycline HCl…800mg".
	Decision of 294th Meeting: Deferred for revision of formulation as per the DRAP approved generic product along with submission of requisite fee. Firms Response Firm has revised their formulation with submission of requisite fee dated 06-04-2020 & revised formulation:.	
	Decision: Approved as per innovator's specification.	
2359.	Name and address of Manufacturer / Applicant	"M/s D-Haans Pharmaceuticals. Plot No. 9/A, Industrial Estate, Bhimber"
	Brand Name +Dosage Form + Strength	CRD HAANS-42 W/S Powder
	Composition	"Each 100g Contains: Doxycyline Hcl…40g Tylosin Tartrate…20g Colistin Sulphate…6g Bromhexine Hcl…2g"
	Diary No. Date of R&I &fee	Dy.No 2053 dated 20-02-2020 Rs.20,000/- (20-02-2020)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10kg
	Me-too status	062127; NOBI TDC 680 Oral Powder. "Each 1000gm Contains: - Tylosin Tartarte…200gm. Doxycycline Hcl…400gm. Colistine Sulphate…60gm. Bromhexine…20gm. "M/S Noble Pharma, Mirpur Azad Kashmir."
	GMP status	CLB in its 273rd meeting held on 15th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals.Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.

	Remarks of the Evaluator (V)	
	Decision of 294th Meeting: Deferred for revision of formulation as per the DRAP approved generic product along with submission of requisite fee. Firms Response Firm has revised their formulation with submission of requisite fee dated 06-04-2020 & revised formulation.	
	Decision: Approved as per innovator's specification.	
2360.	Name and address of Manufacturer / Applicant	"M/s D-Haans Pharmaceuticals. Plot No. 9/A, Industrial Estate, Bhimber"
	Brand Name +Dosage Form + Strength	CRD HAANS-66 W/S Powder
	Composition	"Each 100g Contains: Doxycyline Hcl…20g Tylosin Tartrate…10g Colistin Sulphate…3g Bromhexine Hcl…10g"
	Diary No. Date of R&I &fee	Dy.No 2056 dated 20-02-2020 Rs.20,000/- (20-02-2020)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10kg
	Me-too status	044951; Biosin Td Powder. "Each 100gm Contains:- Tylosin Tartrate…… 10gm. Doxycycline……. 20gm. Bromhexine…….. 10gm. Colistin Sulphate ……. 3gm. M/s Leads Pharma (Pvt) Ltd., Islamabad.
	GMP status	CLB in its 273rd meeting held on 15th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals.Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.
	Remarks of the Evaluator (V)	The drug already approved by DRAP (generic / me-too status) provided by you mentions: "Doxycycline……20g ,Bromhexine…10g" whereas, you have applied for "Doxycyline HCl…20g,Bromhexine HCl…10g"
	Decision of 294th Meeting: Deferred for revision of formulation as per the DRAP approved generic product along with submission of requisite fee. Firms Response Firm has revised their formulation with submission of requisite fee dated 06-04-2020 & revised formulation.	
	Decision: Approved as per innovator's specification.	
2361.	Name and address of Manufacturer / Applicant	"M/s D-Haans Pharmaceuticals. Plot No. 9/A, Industrial Estate, Bhimber"
	Brand Name +Dosage Form + Strength	Sulpamed-60 W/S Powder
	Composition	"Each 100g Contains: Oxytetracycline Hcl…20g Colistin Sulphate…20g Neomycin Sulphate…20g"
	Diary No. Date of R&I &fee	Dy.No 2060 dated 20-02-2020 Rs.20,000/- (20-02-2020)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10kg
	Me-too status	075659; NCO-60 "Each Gm Contains:- Oxytetracycline Hcl……...20% W/V

		Colistin Sulphate……...20% W/V Neomycin…….20% W/V "M/S. Breeze Pharma (Pvt.) Ltd., Kahuta Road, Islamabad."
	GMP status	CLB in its 273rd meeting held on 15th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals.Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.
	Remarks of the Evaluator (V)	The drug already approved by DRAP (generic / me-too status) provided by you mentions "Neomycin" whereas, you have applied for "Neomycin Sulphate".
	Decision of 294th Meeting: Deferred for revision of formulation as per the DRAP approved generic product along with submission of requisite fee. Firms Reponse Firm has revised their formulation with submission of requisite fee dated 06-04-2020 & revised formulation.	
	Decision: Approved as per innovator's specification.	
2362.	Name and address of Manufacturer / Applicant	"M/s D-Haans Pharmaceuticals. Plot No. 9/A, Industrial Estate, Bhimber"
	Brand Name +Dosage Form + Strength	Beracin W/S Powder
	Composition	"Each 100g Contains: Fosfomycin Calcium…….20g Tylosin Tartrate……..10g Fructose……18g Sodium Phosphate…….15g Magnesium Phosphate…..10g"
	Diary No. Date of R&I &fee	Dy.No 2068 dated 20-02-2020 Rs.20,000/- (20-02-2020)
	Pharmacological Group	Antibacterial, Electrolyte Replenisher
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100g, 250g, 500g,1Kg,5Kg,10kg
	Me-too status	078240; Fosfotyl Powder "Each 100gm Contains:- Fosfomycin Calcium ……20gm Tylosin Tartrate……10gm Fructose…….18gm Sodium Phosphate ……...15gm Magnesium Sulphate ..…10 Gm "M/s. Leads Pharma (Pvt) Ltd., Islamabad."
	GMP status	CLB in its 273rd meeting held on 15th Jan, 2020 considered the case of M/s D-Haans Pharmaceuticals.Plot No. 9/A, Industrial Estate, Bhimber Pakistan and approved the grant of DML by way of formulation with following four sections.
	Remarks of the Evaluator (V)	The drug already approved by DRAP (generic / me-too status) provided by you mentions "Magnesium Sulphate" whereas applied formulation is Magnesium Phosphate".
	Decision of 294th Meeting Deferred for revision of formulation as per the DRAP approved generic product along with submission of requisite fee. Firms Response Firm has revised their formulation with submission of requisite fee dated 06-04-2020 & revised formulation.	
	Decision: Approved as per innovator's specification.	

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

a. New cases

2363.	Name and address of manufacturer/ Applicant	M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Ternafin 250mg Tablet
	Composition	Each Tablet Contains: Terbinafine as HCL…250mg
	Diary No. Date of R & I & fee	Dy. No. 40973; 06.12.2018 PKR. 20,000/-; 06.12.2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil® Tablets 250mg by, MHRA Approved.
	Me-too status	Logirid Tablet 250mg, Reg No. 80847
	GMP status	The firm was inspected on 07.11.2018 with the following conclusion: As per available manufacturing, quality control and environmental facilities provided, documentation reviewed, technical/qualified personnel employed and observations made during inspection, the firm Wellborne Hattar is considered to be operating under satisfactory level of cGMP compliance and hence recommend for the grant of cGMP certificate.
	Remarks of the Evaluator	•
	Decision: Approved.	
2364.	Name and address of manufacturer/ Applicant	M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Ternafin 125mg Tablet
	Composition	Each Tablet Contains: Terbinafine as HCL…125mg
	Diary No. Date of R & I & fee	Dy. No. 40972; 06.12.2018 PKR. 20,000/-; 06.12.2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil® Tablets 125mg, TGA Australia approved.
	Me-too status	Logirid Tablet 125mg, Reg No. 80846
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2365.	Name and address of manufacturer/ Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Rivoxban 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…20mg
	Diary No. Date of R & I & fee	Dy. No. 44514; 31.12.2018 PKR. 20,000/-; 31.12.2018
	Pharmacological Group	Factor Xa inhibitor

	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 20 mg film-coated tablets by Milpharm Limited. **MHRA** approved
	Me-too status	Rivaxo 20mg film-coated Tablet by Getz Pharma. Reg. No. 80791
	GMP status	The firm was inspected on 28.06.2018 with GOOD level of GMP compliance.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2366.	Name and address of manufacturer/ Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Nebisure 5mg Tablet
	Composition	Each Tablet Contains: Nebivolol as HCl…5mg
	Diary No. Date of R & I & fee	Dy. No. 44520; 31.12.2018 PKR. 20,000/-; 31.12.2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 5mg) tablets, for oral use by Allergan Sales LLC. **US-FDA** approved
	Me-too status	Bynevol 5mg Tablet by Atco Lab Karachi. Reg No. 81099
	GMP status	The firm was inspected on 28.06.2018 with GOOD level of GMP compliance.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2367.	Name and address of manufacturer/ Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Nebisure 10mg Tablet
	Composition	Each Tablet Contains: Nebivolol as HCl…10mg
	Diary No. Date of R & I & fee	Dy. No. 44521; 31.12.2018 PKR. 20,000/-; 31.12.2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 10mg) tablets, for oral use by Allergan Sales LLC. **US-FDA** approved
	Me-too status	Bynevol 10mg Tablet by Atco Lab Karachi. Reg No. 81562
	GMP status	The firm was inspected on 28.06.2018 with GOOD level of GMP compliance.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2368.	Name and address of manufacturer/ Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Mirtaziyan 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Mirtazapine…15mg
	Diary No. Date of R & I & fee	Dy. No. 44522; 31.12.2018 PKR. 20,000/-; 31.12.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Remeron film-coated 15mg tablet. **USFDA** approved
	Me-too status	Remirta 15mg Tablet. Reg. No. 82605
	GMP status	The firm was inspected on 28.06.2018 with GOOD level of GMP compliance.
	Remarks of the Evaluator	•
	Decision: Approved.	
2369.	Name and address of manufacturer/ Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Mirtaziyan 30mg Tablet
	Composition	Each Film Coated Tablet Contains: Mirtazapine…30mg
	Diary No. Date of R & I & fee	Dy. No. 44523; 31.12.2018 PKR. 20,000/-; 31.12.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Remeron film-coated 30mg tablet. **USFDA** approved
	Me-too status	Remirta 30mg Tablet. Reg. No. 82606
	GMP status	The firm was inspected on 28.06.2018 with GOOD level of GMP compliance.
	Remarks of the Evaluator	•
	Decision: Approved.	
2370.	Name and address of manufacturer/ Applicant	M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan
	Brand Name + Dosage Form + Strength	Blucinol 62.333mg/80 mg Tablet
	Composition	Each Sugar Coated Tablet Contains: Phloroglucinol hydrate eq. to anhydrous Phloroglucinol…62.233mg Trimethylphloroglucinol…80mg
	Diary No. Date of R & I & fee	Dy. No. 41698; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2x10's, 3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PHLOROGLUCINOL / TRIMETHYLPHLOROGLUCINOL ACINO 62.233 mg / 80 mg, coated tablet by ACINO France SAS. Approved by ANSM
	Me-too status	Despasm Tablet by Irza Pharmaceuticals. Reg. No. 85210
	GMP status	The firm was inspected on 07.04.2018 with the following conclusion: Overall the firm was operating under good level of CGMP.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2371.	Name and address of manufacturer/ Applicant	M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name + Dosage Form + Strength	Trifer 50mg/ml Oral Drops
	Composition	Each ml Contains: Iron (as Iron III Hydroxide Polymaltose Complex)…50mg
	Diary No. Date of R & I & fee	Dy. No. 43665; 21.12.2018

		PKR. 20,000/-; 21.12.2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	30ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ferosoft Drops (50mg/5ml). Reg. No. 30052
	GMP status	The firm was inspected on 20.02.2018 with the following conclusion: Based on the areas inspected the document reviewed and considering the finding of inspection M/s Aspin Pharma is considered to be operating at satisfactory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012
	Remarks of the Evaluator	•
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
2372.	Name and address of manufacturer/ Applicant	M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name + Dosage Form + Strength	Trifer 50mg/5ml Syrup
	Composition	Each 5ml Contains: Iron (as Iron III Hydroxide Polymaltose Complex)…50mg
	Diary No. Date of R & I & fee	Dy. No. 43664; 21.12.2018 PKR. 20,000/-; 21.12.2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Iropharm Syrup (50mg/5ml). Reg. No. 83956
	GMP status	The firm was inspected on 20.02.2018 with the following conclusion: Based on the areas inspected the document reviewed and considering the finding of inspection M/s Aspin Pharma is considered to be operating at satisfactory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012
	Remarks of the Evaluator	•
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
2373.	Name and address of manufacturer/ Applicant	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad
	Brand Name + Dosage Form + Strength	Remet Plus Tablets 50/1000mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…1000mg
	Diary No. Date of R & I & fee	Dy. No. 41744; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's, 20's, 30's; as per SRO
	Approval status of product in Reference	GALVUMET 50/1000 vildagliptin 50 mg/metformin

	Regulatory Authorities.	hydrochloride 1000 mg film coated tablet. **TGA** approved
	Me-too status	Valiant-M Tablets by Ferozsons Labs., Nowshehra. Reg No. 77485
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 09.11.2018.
	Remarks of the Evaluator	• The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
2374.	Name and address of manufacturer/ Applicant	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad
	Brand Name + Dosage Form + Strength	Remet Plus Tablets 50/850mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…850mg
	Diary No. Date of R & I & fee	Dy. No. 41743; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's, 20's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/850 vildagliptin 50 mg/metformin hydrochloride 850 mg film coated tablet. **TGA** approved
	Me-too status	GALVUS MET 50MG/850MG TABLETS. Reg. No. 66106
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 09.11.2018.
	Remarks of the Evaluator	• The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
2375.	Name and address of manufacturer/ Applicant	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad
	Brand Name + Dosage Form + Strength	Remet Plus Tablets 50/500mg
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCL…500mg
	Diary No. Date of R & I & fee	Dy. No. 41742; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's, 20's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/500 vildagliptin 50 mg/metformin hydrochloride 500 mg film coated tablet. **TGA** approved
	Me-too status	Galmet 50mg/500mg Tablet by Vision Pharma. Reg No. 81905
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 09.11.2018.
	Remarks of the Evaluator	• The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
2376.	Name and address of manufacturer/ Applicant	M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name + Dosage Form + Strength	Trifer-Fol Chewable Tablets
	Composition	Each Chewable Tablet Contains: Iron (as Iron III Hydroxide Polymaltose Complex)…100mg Folic Acid…0.350mg

	Diary No. Date of R & I & fee	Dy. No. 43664; 21.12.2018 PKR. 20,000/-; 21.12.2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ferosoft F.A Tablets by Hilton Pharma (pvt) Ltd. Reg. No. 23996
	GMP status	The firm was inspected on 20.02.2018 with the following conclusion: Based on the areas inspected the document reviewed and considering the finding of inspection M/s Aspin Pharma is considered to be operating at satisfactory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012
	Remarks of the Evaluator	•
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
2377.	Name and address of manufacturer/ Applicant	M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan
	Brand Name + Dosage Form + Strength	Blodox 100mg/5ml Syrup
	Composition	Each 5ml Contains: Doxofylline…100mg
	Diary No. Date of R & I & fee	Dy. No.37400; 12.11.2018 PKR. 20,000/-; 12.11.2018
	Pharmacological Group	Other systemic drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	DOXOFILLINA ABC "200 mg/10 ml Sciroppo" Flacone da 200 ml. **AIFA** approved
	Me-too status	Unifyline Syrup. Reg. No. 47180
	GMP status	The inspection report dated 07.04.2018 concluded that Overall the firm was operating under good level of CGMP.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2378.	Name and address of manufacturer/ Applicant	M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan
	Brand Name + Dosage Form + Strength	Blodox 400mg Tablets
	Composition	Each Tablet Contains: Doxofylline…400mg
	Diary No. Date of R & I & fee	Dy. No.37399; 12.11.2018 PKR. 20,000/-; 12.11.2018
	Pharmacological Group	Other systemic drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	DOXOFILLINA ABC 400 mg Compresse (DOXOFILLINA ABC 400 mg tablet). AIFA approved
	Me-too status	Maxfyl Tablet 400mg. Reg. No. 059838
	GMP status	The inspection report dated 07.04.2018 concluded that Overall the firm was operating under good level of CGMP.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	

2379.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Chicowel 4mg/2ml Injection
	Composition	Each 2ml Injection Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy. No. 41761: 07.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	THIOCOLCHICOSIDE PHARMY II 4 mg/2 ml, solution injectable ampule. ANSM approved
	Me-too status	Myolax Injection. Reg. No. Reg. No. 69277
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2380.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Desvenla 50mg Tablet
	Composition	Each Extended Release Tablet Contains: Desvenlafaxine as Succinate monhydrate…50mg
	Diary No. Date of R& I & fee	Dy. No. 40866: 06.12.2018 Rs. 20,000: 04.12.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pristiq extended release tablets 50mg (film-coated). USFDA approved
	Me-too status	Denla XR 50mg Tablet. Reg. No. 70433
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2381.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Desvenla 100mg Tablet
	Composition	Each Extended Release Tablet Contains: Desvenlafaxine as Succinate…100mg
	Diary No. Date of R& I & fee	Dy. No. 40865: 06.12.2018 Rs. 20,000: 04.12.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pristiq extended release tablets 100mg (film-coated). USFDA approved
	Me-too status	Denla XR 100mg Tablet. Reg. No. 70434
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2382.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Schizo 15mg Tablets
	Composition	Each Tablet Contains: Aripiprazole…15mg

	Diary No. Date of R& I & fee	Dy. No. 41750: 07.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Other antipsychotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ABILIFY® (aripiprazole) Tablets. USFDA approved
	Me-too status	Raylify 15mg tablet. Reg. No. 66721
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved.	
2383.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Schizo 30mg Tablets
	Composition	Each Tablet Contains: Aripiprazole…30mg
	Diary No. Date of R& I & fee	Dy. No. 41760: 07.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Other antipsychotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ABILIFY® (aripiprazole) Tablets. USFDA approved
	Me-too status	Ariza 30Mg Tablet. Reg. No. 37689
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved.	
2384.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Simvas 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Simvastatin…20mg
	Diary No. Date of R& I & fee	Dy. No. 41860: 06.12.2018 Rs. 20,000: 04.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOCOR (simvastatin) tablets, film-coated (5mg, 10mg, 20mg, 40mg, 80mg). USFDA approved
	Me-too status	Simcol-20 Tablets. Reg. No. 34642
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved.	
2385.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Simvas 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Simvastatin…40mg
	Diary No. Date of R& I & fee	Dy. No. 41861: 06.12.2018 Rs. 20,000: 04.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	ZOCOR (simvastatin) tablets, film-coated (5mg, 10mg, 20mg, 40mg, 80mg). USFDA approved
	Me-too status	Simvoget 40Mg Tablets. Reg. No. 39735
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved.	
2386.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Sulpi 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R& I & fee	Dy. No. 40854: 07.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Benzamides
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SOLIAN 50 amisulpride 50 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 50mg Tablet. Reg No. 76060
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved.	
2387.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Sulpi 200mg Tablet
	Composition	Each Tablet Contains: Amisulpride…200mg
	Diary No. Date of R& I & fee	Dy. No. 40855: 07.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Benzamides
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SOLIAN 200 amisulpride 200 mg uncoated tablet. TGA approved
	Me-too status	SOLIAN TABLETS 200MG. Reg No. 21112
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved.	
2388.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Lomewel 400mg Tablets
	Composition	Each Film Coated Tablet Contains: Lomefloxacin as HCl…400mg
	Diary No. Date of R& I & fee	Dy. No. 41763: 07.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Maxaquin® lomefloxacin (as hydrochloride) film-caoted tablets 400mg. TGA approved
	Me-too status	Lomedin Tablets 400mg. Reg No. 28668 (does not depict film-coating)
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018,

		wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2389.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Spasmark 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Otilonium Bromide…40mg
	Diary No. Date of R& I & fee	Dy. No. 40864: 06.12.2018 Rs. 20,000: 04.12.2018
	Pharmacological Group	Synthetic anticholinergics, quaternary ammonium compounds
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Otilonio Stada 40 mg film-coated tablets. CIMA approved
	Me-too status	Otomin 40mg tablet. Reg. No. 59407
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2390.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Folinic 15mg Tablets
	Composition	Each Tablet Contains: Calcium folinate eq. to folinic acid….15 mg
	Diary No. Date of R& I & fee	Dy. No. 41763: 07.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Synthetic anticholinergics, quaternary ammonium compounds
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DBL LEUCOVORIN CALCIUM folinic acid 15 mg (as calcium folinate 16.2mg) uncoated tablet. TGA approved
	Me-too status	KUNYRIN TABLETS 15mg. Reg. No. 20666 (does not depict calcium salt)
	GMP status	The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	• The reference product contains calcium folinate eq. to folinic acid….15 mg. The firm revised the label claim form "Leucovorin Calcium Eq. to Folinic Acid…15mg" to "calcium folinate eq. to folinic acid….15 mg" in line with the reference product. • Adjust the weight of API as per accurate salt factor in master formula.
	Decision: Deferred for following submissions: • **Fee for revision of formulation** • **Submission of revised master formulation containing weight of API as per the salt factor.**	
2391.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Levetam 100mg/ml Oral Solution
	Composition	Each ml Contains: Levetiracetam…100mg
	Diary No. Date of R& I & fee	Dy. No. 32758; 02-10-2018, PKR: 20,000/-; 01-10-2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml; As per SRO

	Approval status of product in Reference Regulatory Authorities.	6 Kevtam Oral levetiracetam 100 mg/mL amber glass bottle. TGA approved
	Me-too status	Evic Solution 100mg/ml. Reg. No. 82629
	GMP status	The firm was inspected on 04.07.2018, wherein GMP level was rated GOOD.
	Remarks of the Evaluator.	•
	Decision: Approved.	
2392.	Name and address of manufacturer / Applicant	**M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan**
	Brand Name +Dosage Form + Strength	Delor 2.5mg/5ml Syrup
	Composition	Each 5ml Contains: Desloratadine…2.5mg
	Diary No. Date of R& I & fee	Dy. No. 32759; 02-10-2018, PKR: 20,000/-; 01-10-2018
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AERIUS FOR CHILDREN SYRUP desloratadine 2.5mg/5mL oral liquid bottle. TGA approved
	Me-too status	Neolor 0.5mg/ml Syrup. Reg. No. 82713
	GMP status	The firm was inspected on 04.07.2018, wherein GMP level was rated GOOD.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specification.	
2393.	Name and address of manufacturer / Applicant	**M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan**
	Brand Name +Dosage Form + Strength	Zufikast 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Zafirlukast …10mg
	Diary No. Date of R& I & fee	Dy. No. 32760; 02-10-2018, PKR: 20,000/-; 01-10-2018
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 20's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACCOLATE® (zafirlukast) TABLETS 10mg, 20mg film coated tablet. USFDA approved
	Me-too status	Xasthma 20mg Tablet. Reg. No. 53059
	GMP status	The firm was inspected on 04.07.2018, wherein GMP level was rated GOOD.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specification.	
2394.	Name and address of manufacturer / Applicant	**M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan**
	Brand Name +Dosage Form + Strength	Panto 40mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Pantoprazole as Sodium Sesquihydrate…40mg
	Diary No. Date of R& I & fee	Dy. No. 32761; 02-10-2018, PKR: 20,000/-; 01-10-2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROTONIX (pantoprazole sodium) delayed-release tablets 40mg, for oral use. USFDA approved
	Me-too status	PROTIUM GASTRO RESISTANT TABLETS 40mg. Reg.

		No. 21039
	GMP status	The firm was inspected on 04.07.2018, wherein GMP level was rated GOOD.
	Remarks of the Evaluator.	•
	Decision: Approved.	
2395.	Name & address of Manufacturer	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Predno 0.1% w/w Cream
	Composition	Each gram contains: Methylprednisolone Aceponate…1mg
	Diary No. Date of R & I & fee	44269; 28.12.2018 Rs. 20000; 28.12.2018
	Pharmacological form	Corticosteroids, potent (group III)
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities	ADVANTAN methylprednisolone aceponate 1mg/g cream tube. TGA approved
	Me-too Status	Zema 1mg/g Cream. Reg. No. 81508
	GMP Status	As above
	Remarks of the evaluator	•
	Decision: Approved with innovator's specification.	
2396.	Name and address of manufacturer/ Applicant	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.
	Brand Name + Dosage Form + Strength	Introgen 5mg/5ml Injection
	Composition	Each 5ml Contains: Tropisetron HCL Eq. to Tropisetron…5mg
	Diary No. Date of R & I & fee	Dy. No.37383; 12.11.2018 PKR. 20,000/-; 12.11.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	5ml ampule; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TROPISETRON-AFT tropisetron (as hydrochloride) 5 mg/5 mL solution for injection ampoule. TGA approved
	Me-too status	Emestron 5mg Injection (5ml). Reg. No. 66755
	GMP status	The firm was inspected on 20.12.2017 with the following conclusion: "Reference to previous inspection it was found that the firm rectified most of the shortcomings pointed out during last inspection. Panel advised the firm to continue the up gradation of building and system to maintain the GMP, which is a continuous process. Firm undertook to further upgrade the manufacturing & QC facility and documentation in the light of advices given by inspecting panels of experts. The panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest."
	Remarks of the Evaluator	•
	Decision: Deferred since the last GMP inspection report dated 20.12.2017 did not confirm GMP status for liquid injectable section and the firm was advised to provide liquid particle counter and TOC at the earliest.	
2397.	Name and address of manufacturer/ Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Clomi Star 50mg Tablets
	Composition	Each Tablet Contains: Clomiphene Citrate…50mg

	Diary No. Date of R & I & fee	Dy. No.39447; 30.11.2018 PKR. 20,000/-; 30.11.2018
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	GENRX CLOMIPHENE clomifene citrate 50mg tablet, un-coated. **TGA** approved
	Me-too status	OVA-MIT TABLETS. Reg. No. 20404
	GMP status	The firm was last inspected on 27.06.2019, wherein GMP was rated satisfactory.
	Remarks of the Evaluator	• The reference product is uncoated tablet. The firm has applied for film-coated tablet. Upon clarification, the firm submitted Rs. 5000/- but did not revise the manufacturing outlines in line with the reference product. Moreover, they have still mentioned film-coated tablet as dosage form.
	Decision: Deferred for revision of formulation along with outline of method of manufacturing as per the reference product.	
2398.	Name and address of manufacturer/ Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Diltaia-alt 60mg Tablet
	Composition	Each Tablet Contains: Diltiazem Hydrchloride…60mg
	Diary No. Date of R & I & fee	Dy. No.39446; 30.11.2018 PKR. 20,000/-; 30.11.2018
	Pharmacological Group	Calcium channel blocker
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	DILTIAZEM HYDROCHLORIDE TABLETS 60mg uncoated prolonged release tablet. **MHRA** approved
	Me-too status	Myozem Tablets 60mg. Reg. No. 41982 (does not reveal prolonged release)
	GMP status	The firm was last inspected on 27.06.2019, wherein GMP was rated satisfactory.
	Remarks of the Evaluator	• The reference product is uncoated prolonged release tablet. The firm has applied for film-coated tablet. The firm revised the formulation (label claim, composition) to uncoated (not pronlonged rlease) tablet along with submission of applicable fee. Moreover, they have still mentioned film-coated tablet as dosage form.
	Decision: Deferred for revision of formulation as per the reference product along with submission of fee for revision of formulation.	
2399.	Name and address of manufacturer/ Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name + Dosage Form + Strength	Aultafen 145mg Tablets
	Composition	Each Film Coated Tablet Contains: Fenofibrate…145mg
	Diary No. Date of R & I & fee	Dy. No.39445; 30.11.2018 PKR. 20,000/-; 30.11.2018
	Pharmacological Group	Fibrates
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	FENOFIBRATE BIOGARAN 145 mg, comprimé uncoated.

	Regulatory Authorities.	ANSM approved
	Me-too status	Fenoget 145mg Tablet. Reg. No. 58480
	GMP status	The firm was last inspected on 27.06.2019, wherein GMP was rated satisfactory.
	Remarks of the Evaluator	• The reference product is uncoated tablet. The firm revised the formulation (label claim, composition) in line with the reference product along with submission of applicable fee. Moreover, they have still mentioned film-coated tablet as dosage form.
	Decision: Deferred for revision of formulation as per the reference product along with submission of fee for revision of formulation.	
2400.	Name and address of manufacturer/ Applicant	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke, Sheikhupura
	Brand Name + Dosage Form + Strength	Meglumine Sodium Diatrizoate Injection
	Composition	Each ml contains: Diatrizoate sodium…0.1g Diatrizoate meglumine…0.66g
	Diary No. Date of R & I & fee	Dy. No. 44451; 31.12.2018 PKR. 20,000/-; 31.12.2018
	Pharmacological Group	Contrast media for x-rays of high osmolarity, water-soluble and nephrotropic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	20ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	UROGRAFIN® 76% Sodium amidotrizoate / Amidotrizoate meglumine Injection (**50ml, 100ml**). TGA approved UROGRAFIN 76% (20ml ampule, 50ml bottle, 100ml bottle). CIMA approved
	Me-too status	UROGRAFIN 76% INJ . Reg. No. 00080 (the composition are not mentioned)
	GMP status	Last inspection report conducted on 21-02-2018 with following conclusion: "Overall hygienic condition of firm was satisfactory at time of inspection. They were advised to improve further their documentation as mentioned in above. They agreed."
	Remarks of the Evaluator	
	Decision: Approved.	
2401.	Name and address of manufacturer/ Applicant	M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan
	Brand Name + Dosage Form + Strength	Bloterol 5mg/5ml Syrup
	Composition	Each 5ml Contains: Bambuterol HCl…5mg
	Diary No. Date of R & I & fee	Dy. No.37401; 12.11.2018 PKR. 20,000/-; 12.11.2018
	Pharmacological Group	Other systemic drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bambuterol Juice 1mg/ml/ Germany approved.
	Me-too status	Bambuzaf 5mg/5ml Syrup. Reg. No. 70491
	GMP status	The inspection report dated 07.04.2018 concluded that Overall the firm was operating under good level of CGMP.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2402.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Beta-C Cream

	Composition	Each Gram Contains: Betamethasone as dipropionate…0.05% Clotrimazole…1%
	Diary No. Date of R& I & fee	Dy. No. 40882: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Antifungal with corticosteroids
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5g, 10g, 15g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities	LOTRISONE® (clotrimazole and betamethasone dipropionate) cream, for topical use (1%/0.05%). USFDA Approved
	Me-too status	Holfungin Cream. Reg. No. 67598
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	Undertaking at the end of Form 5 has not been signed by the production manager and QCM by the QCM and production manager. Brand name and dosage form has not been mentioned in the fee challan.
	Decision: Deferred for following: • **Submission of undertaking of Form 5 signed by production incharge and QC incharge.** • **Clarification why the brand name and dosage form is not mentioned on fee challan.**	
2403.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Burn-Off Cream
	Composition	Each Gram Contains: Silver sulphadiazine…1%w/w
	Diary No. Date of R& I & fee	Dy. No. 40884: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Sulfonamides
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5g, 10g, 15g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities	Flamazine Cream 1.0%w/w. MHRA approved
	Me-too status	SILZIN CREAM Reg. No. 21193
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	Undertaking at the end of Form 5 has not been signed by the production manager and QCM by the QCM and production manager. Brand name and dosage form has not been mentioned in the fee challan.
	Decision: Deferred for following: • **Submission of undertaking of Form 5 signed by production incharge and QC incharge.** • **Clarification why the brand name and dosage form is not mentioned on fee challan.**	
2404.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Vomiron 4mg Tablets
	Composition	Each Tablet Contains: Ondansetron HCL…4mg
	Diary No. Date of R& I & fee	Dy. No. 40266: 05.12.2018 Rs. 20,000: 05.12.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO

	Approval status of product in Reference Regulatory Authorities	Ondansetron 4 mg Film-coated Tablets. MHRA approved
	Me-too status	Ondan Tablet film-coated 4mg. Reg No. 82656
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	• You have mentioned coating composition in the master formula. Revise the label claim accordingly. • Revise "Ondansetron HCl as dihydrate" to "Ondansetron as HCl dihydrate" in the label claim. Correction is also required in the master formula along with adjustment of weight of API as per salt factor. • Justify the addition of overage.
	Decision: Deferred for following: • **Revision of formulation as per the reference product along with submission of fee for revision of formulation** • **Submission of undertaking of Form 5 signed by production incharge and QC incharge.** • **Justification of addition of overage**	
2405.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Rash-Care Cream
	Composition	Each gram contains: Zinc oxide…8.5% w/w Benzalkonium chloride…0.1% w/w
	Diary No. Date of R& I & fee	Dy. No. 40884: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Anti-rash preparation
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	5g, 10g, 15g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	RASHNIL CRM (8.5%/1%). Reg. No. 6356
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Brand name and dosage form has not been mentioned in the fee challan.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Clarification why the brand name and dosage form is not mentioned on fee challan.**	
2406.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Olimag-F Capsule
	Composition	Each hard gelatin capsule contains: Fluoxetine as Hydrochloride…25mg Olanzapine…12mg
	Diary No. Date of R& I & fee	Dy. No. 40881: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO

	Approval status of product in Reference Regulatory Authorities	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by US-FDA
	Me-too status	Olanco Capsules. Reg. No. 79387
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	• Undertaking at the end of Form 5 has not been signed by the production manager and QCM. • Brand name and dosage form has not been mentioned in the fee challan.
	Decision: Deferred for following: • **Submission of undertaking of Form 5 signed by production incharge and QC incharge.** • **Clarification why the brand name and dosage form is not mentioned on fee challan.**	
2407.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ompro-S Capsule
	Composition	Each hard gelatin capsule contains: Omeprazole…20mg Sodium Bicarbonate…1100mg
	Diary No. Date of R& I & fee	Dy. No. 40880: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Proton pump inhibitors + antacid
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	14's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZEGERID® (omeprazole and sodium bicarbonate) capsules (20/1100mg and 40/1100mg) capsule. USFDA approved
	Me-too status	Zogital 20mg Capsules (omeprazole base). Reg. No. 64391
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	• Undertaking at the end of Form 5 has not been signed by the production manager and QCM. • Brand name and dosage form has not been mentioned in the fee challan.
	Decision: Deferred for following: • **Submission of undertaking of Form 5 signed by production incharge and QC incharge.** • **Clarification why the brand name and dosage form is not mentioned on fee challan.**	
2408.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ompro-S Plus Capsule
	Composition	Each hard gelatin capsule contains: Omeprazole…40mg Sodium Bicarbonate…1100mg
	Diary No. Date of R& I & fee	Dy. No. 40879: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Proton pump inhibitors + antacid
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	14's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	ZEGERID® (omeprazole and sodium bicarbonate) capsules (20/1100mg and 40/1100mg) capsule. USFDA approved
	Me-too status	Omfast 40/1100mg Capsule. Reg. No. 82717
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	• Brand name and dosage form has not been mentioned in the fee challan. • Undertaking at the end of Form 5 has not been signed

		by the production manager and QCM by the porudction manager and QCM.
	Decision: Deferred for following: • **Submission of undertaking of Form 5 signed by production incharge and QC incharge.** • **Clarification why the brand name and dosage form is not mentioned on fee challan.**	
2409.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ometro 40mg Capsule
	Composition	Each hard gelatin capsule contains: Omeprazole…40mg
	Diary No. Date of R& I & fee	Dy. No. 40267: 05.12.2018 Rs. 20,000: 05.12.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Losec 40 mg hard gastro-resistant capsules. Approved by MHRA
	Me-too status	Omecap Capsule. Reg. No. 84494
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	• The label claim is "Each hard gelatin capsule contains: Omeprazole…40mg". The reference product is hard gastro-resistant capsules. The firm was asked to submit source, GMP of source and COA and stability data of three batches of pellets conducted in zone IV-A. The firm did not submit the same.
	Decision: Deferred for following: • **Source of pellets, along with stability studies data, GMP certificate of pellets manufacturer and differential fee in case of import of pellets.** • **Revision of label claim as per the reference product.**	
2410.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Lorncam 8mg Tablets
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy. No. 40885: 06.12.2018 Rs. 20,000: 06.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids (oxicams)
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	• Undertaking at the end of Form 5 has not been signed by the production manager and QCM. • Dosage form has not been mentioned in the fee challan.
	Decision: Deferred for following: • **Submission of undertaking of Form 5 signed by production incharge and QC incharge.** • **Clarification why the brand name and dosage form is not mentioned on fee challan.**	

2411.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Caraceclo 100mg Tablets
	Composition	Each film-coated tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Dy. No. 40268: 05.12.2018 Rs. 20,000: 05.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's, 20's, 30's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Aceclofenac 100 mg film-coated Tablets (aceclofenac). MHRA approved
	Me-too status	Acenac 100Mg Tablets. Reg. No. 39336
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	• The firm revised the salt form to aceclofenac from aceclofenac sodium without submission of applicable fee. • The firm has applied for film-coated tablet. The firm revised the label claim and mentioned the coating composition in master formula.
	Decision: Deferred for revision of formulation as per the reference product along with submission of fee for revision of formulation.	
2412.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Schizonil 200mg Tablets
	Composition	Each film-coated tablet Contains: Quetiapine as fumarate…200mg
	Diary No. Date of R& I & fee	Dy. No. 40268: 05.12.2018 Rs. 20,000: 05.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's, 5x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine (as fumarate) 200mg Film-coated Tablets. MHRA approved
	Me-too status	Etal 200mg Tablet Tablet. Reg. No. 80380
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	The firm revised "quetiapine" to "quetiapine as fumarate" without submission of fee. The firm had applied for film-coated tablet. The firm revised the label claim and mentioned the coating composition in master formula. Brand name and dosage form has not been mentioned in the fee challan.
	Decision: Deferred for following: • **Revision of formulation as per the reference product along with submission of fee for revision of formulation.** • **Clarification why the brand name and dosage form is not mentioned on fee challan.**	
2413.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Noxi Tablet 8mg
	Composition	Each film coated tablet contains Lornoxicam….8mg

	Diary No. Date of R & I & fee	41340; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Antiinflammatory and antirheumatic products, non-steroids (oxicams)
	Type of form	Form 5
	Finished Product Specification	In house
	Pack Size & Demanded Price	1x10's; As per SRO
	Approval Status of product in Reference Regulatory Authorities	NOXON 8 mg film-coated tablets. **AIFA** approved
	Me-too Status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	• Name of signatory is missing on Form 5. • Strength has not been mentioned on fee challan
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2414.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Fenticon Cream 2%w/w
	Composition	Each gram of Cream contains Feticonazole Nitrate(BP)…2%w/w
	Diary No. Date of R & I & fee	41325; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Imidazole and triazole derivatives
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	20g, 40g; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Falvin 2% crema. AIFA approved
	Me-too Status	Fentyzole Cream 2%. Reg. No. 70054
	GMP Status	The firm was Inspected on 22-01-2019. The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	• Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2415.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Fenticon V Cream 2%w/w
	Composition	Each gram of Cream contains Fenticonazole Nitrate…2% w/w
	Diary No. Date of R & I & fee	41324; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Imidazole and triazole derivatives
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	20g, 40g; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Falvin 2% crema vaginale. AIFA approved
	Me-too Status	Fentyzole-V Cream 2%. Reg. No. 70055
	GMP Status	The firm was Inspected on 22-01-2019. The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	• Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	

2416.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Salact Lotion 16.7% w/w
	Composition	Each Gram of Lotion Contains Salicylic Acid….16.7%w/w Lactic Acid…16.7% w/w
	Diary No. Date of R & I & fee	41334; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Antiinfectives and antiseptics, excl. combinations with corticosteroids + Antiinflammatory agents, non-steroids
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	60ml, 120ml; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Salactol Collodion. MHRA Approved
	Me-too Status	Verrucum Liquid. Reg. No. 20574
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	Name of signatory is missing on Form 5. The international reference product is in the form of collodion. The firm has applied for lotion.
	Decision: Deferred for following: • **Revision of formulation as per the reference product along with submission of fee for revision of formulation.** • **Consideration on its turn since the differential fee 12,000/- was submitted after September 2015.**	
2417.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Cinpride Oral Solution 1mg/5ml
	Composition	Each 5ml of Oral Solution Contains: Cinitapride Hydrogen Tartrate Eq. to Cinitapride….1mg
	Diary No. Date of R & I & fee	41327; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Drugs for functional gastrointestinal disorders, Propulsives
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	60ml, 120ml; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Cidine 1 mg / 5 ml Oral solution by ALMIRALL, SA CIMA Approved
	Me-too Status	Cinipride 1mg/5ml Syrup. Reg No. 73656
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2418.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Uristat Tablet 40mg
	Composition	Each film coated tablet contains: Febuxostat…. 40mg
	Diary No. Date of R & I & fee	41341; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Preparations inhibiting uric acid production
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	20's, As Per SRO

	Approval Status of product in Reference Regulatory Authorities	ULORIC (febuxostat) tablet for oral use. USFDA approved
	Me-too Status	Febulos 40mg Tablet. Reg. No. 82694
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2419.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Uristat Tablet 80mg
	Composition	Each Film coated tablet contains: Febuxostat…. 80mg
	Diary No. Date of R & I & fee	41337; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Preparations inhibiting uric acid production
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	20's, As Per SRO
	Approval Status of product in Reference Regulatory Authorities	ULORIC (febuxostat) tablet for oral use. USFDA approved
	Me-too Status	Febulos 80mg Tablet. Reg. No. 82695
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2420.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Coxib Capsule 200mg
	Composition	Each Capsule Contains: Celecoxib….200mg
	Diary No. Date of R & I & fee	41339; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Antiinflammatory and antirheumatic products, non-steroids
	Type of form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	10's, 14's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Celebrex 200 mg capsules. MHRA approved
	Me-too Status	Bexicox 200 Capsule. Reg. No. 23947
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2421.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Etorib Tablet 60mg
	Composition	Each Film coated tablet contains Etoricoxib….60mg
	Diary No. Date of R & I & fee	41333; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Coxibs
	Type of form	Form-5
	Finished Product Specification	The firm has claimed in-house specifications

	Pack Size & Demanded Price	20's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Etoricoxib 60 mg Film-coated Tablets. MHRA approved
	Me-too Status	Eto 60 mg Tablet. Reg. No. 78176
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2422.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Paradol Tablet 325mg/37.5mg
	Composition	Each Film coated tablet contains: Paracetamol….325mg Tramadol HCl….37.5mg
	Diary No. Date of R & I & fee	41330; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Opioids in combination with non-opioid analgesics
	Type of form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's , As per SRO
	Approval Status of product in Reference Regulatory Authorities	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms US-FDA approved
	Me-too Status	Tril-P Tablet. Reg. No. 78181
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2423.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Ivadine Tablet 5mg
	Composition	Each film-coated tablet Contains: Ivabradine as HCl…..5mg
	Diary No. Date of R & I & fee	41336; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Other cardiac preparations
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	10's, 14's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	CORLANOR film-coated tablets, for oral use. USFDA approved
	Me-too Status	Ivatab 5mg Tablet. Reg. No. 76154
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	• Name of signatory is missing on Form 5. • The firm revised the formulation to film-coated tablet without submission of fee. • The firm revised the API to Ivabradine as HCl without submission of fee. Revision of the same in master formula and adjust its weight in master formula as per salt factor along with submission of applicable fee is still required.
	Decision: Deferred for following: • **Revision of formulation as per the reference product along with submission of fee for revision of formulation.** • **Consideration on its turn since differential fee 12,000/- was submitted after September 2015.**	

2424.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Ivadine Tablet 7.5mg
	Composition	Each film-coated tablet Contains: Ivabradine as HCl…..7.5mg
	Diary No. Date of R & I & fee	41330; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Other cardiac preparations
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	10's, 14's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	CORLANOR film-coated tablets, for oral use. USFDA approved
	Me-too Status	Ivatab 7.5mg Tablet. Reg. No. 76155
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	• Name of signatory is missing on Form 5. • The firm revised the formulation to film-coated tablet without submission of fee. • The firm revised the API to Ivabradine as HCl without submission of fee. Revision of the same in master formula and adjust its weight in master formula as per salt factor along with submission of applicable fee is still required.
	Decision: Deferred for following: • **Revision of formulation as per the reference product along with submission of fee for revision of formulation.** • **Consideration on its turn since the differential fee 12,000/- was submitted after September 2015.**	
2425.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Itotec Tablet 50mg
	Composition	Each film coated tablet contains: Itoprode HCl….50mg
	Diary No. Date of R & I & fee	41337; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Gastroprokinetic
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	20's, As per SRO
	Approval Status of product in Reference Regulatory Authorities	Ganaton 50mg tablet film-coated (PMDA) Japan Approved
	Me-too Status	ITP of M/s Sami Pharmaceuticals
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	• Name of signatory is missing on Form 5.
	Decision: Deferred for consideration on its turn since the differential fee 12,000/- was submitted after September 2015.	
2426.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Nicarb Lotion 0.25% w/w
	Composition	Each Gram of Lotion Contains: Prednicarbate….0.25%w/w
	Diary No. Date of R & I & fee	41335; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Corticosteroids, plain

	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	10g, 20g; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Cabedin Lotion 0.25% w/w. Reg. No. 55451
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	• Name of signatory is missing on Form 5. • Proof of international availability of same formulation, same strength and same filled volume in reference regulatory authorities as defined in 275th meeting of the registration board is required.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Consideration on its turn since the differential fee 12,000/- was submitted after September 2015.**	
2427.	Name & address of Manufacturer	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21 km Ferozpur Road Lahore-Pakistan.
	Brand Name + Dosage Form + Strength	Kotaz Lotion 2%w/w
	Composition	Each Gram of Lotion Contains: Ketoconazole….2%w/w
	Diary No. Date of R & I & fee	41328; 07.12.2018 Rs. 8000; 27.10.2010 and Rs. 12000; 07.12.2018
	Pharmacological form	Imidazole and triazole derivatives
	Type of form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	60ml; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Myxole 20 mg/g Lotion. Reg. No. 68611
	GMP Status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the evaluator	• Name of signatory is missing on Form 5. • Proof of international availability of same formulation, same strength and same filled volume in reference regulatory authorities as defined in 275th meeting of the registration board is required. • The product is available as SEBIZOLE ketoconazole 20 mg/g application bottle (Topical, clear, pink coloured liquid with a fragrance smell). TGA Approved. Howevber, the JP has separate monograph for lotion and solution.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Consideration on its turn since the differential fee 12,000/- was submitted after September 2015.**	
2428.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Cinol Injection 40mg/0.04mg
	Composition	Each ampoule contains: Phloroglucinol Dihydrate…40mg Trimethylphloroglucinol…0.04mg
	Diary No. Date of R & I & fee	Dy. No. 8540; 26.02.2019

		PKR. 20,000/-; 26.02.2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	4ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	SPASFON, solution injectable en ampoule (4ml). ANSM approved
	Me-too status	Spadix Injection. Reg. No. 29528
	GMP status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the Evaluator	• Name of signatory is missing on Form 5.
	Decision: Approved with innovator's specifications.	
2429.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Tizax Tablet 2mg
	Composition	Each Tablet Contains: Tizanidine as HCl…2mg
	Diary No. Date of R & I & fee	Dy. No. 8541; 26.02.2019 PKR. 20,000/-; 26.02.2019
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Tizanidine 4mg Tablets, uncoated. MHRA approved
	Me-too status	Tizanaflex Tablets 2mg. Reg. No. 35655
	GMP status	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.
	Remarks of the Evaluator	• Name of signatory is missing on Form 5.
	Decision: Approved.	
2430.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Sactum 500mg Injection
	Composition	Each Vial Contains: Cefoperazone as sodium…250mg Sulbactum as sodium…250mg
	Diary No. Date of R& I & fee	Dy. No. 39648: 03.12.2018 Rs. 20,000: 03.12.2018
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	1's, 20's, 30's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Sulperazon Injection 0.5 g (0.25g/0.25g). PMDA Approved
	Me-too status	Perabactum Injection 500mg IV/IM. Reg. No. 80380
	GMP status	The firm was inspected on 26.02.2019 with GOOD GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved.	
2431.	Name and address of manufacturer/ Applicant	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Mectasure 3g Sachet
	Composition	Each Sachet Contains: Dioctahedral Smectite…3g
	Diary No. Date of R & I & fee	Dy. No. 44515; 31.12.2018 PKR. 20,000/-; 31.12.2018

	Pharmacological Group	Intestinal Adsorbents
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diosmectal 3g powder of Diosmectite for oral suspension, approved by Italian Medicines Agency
	Me-too status	Semetamed 3.0g Sachets. Reg. No. 61925
	GMP status	The firm was inspected on 28.06.2018 with GOOD level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2432.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Royfer Injection 100mg/5ml
	Composition	Each 5ml ampoule contains: Iron sucrose eq to Elemental iron…100mg
	Diary No. Date of R & I & fee	39687; 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Iron preparations
	Type of form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	5ml; As per SRO
	Approval Status of product in Reference Regulatory Authorities	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too Status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP Status	Applicant: The firm was inspected on 17.12.2019, wherein the FID concluded that the firm requires to improve the pharmaceutical quality system in general, howver, basic elements of GMP compliance reference to schedule B-II are in place and complied with. Manufacturer: The firm was inspected on 19.09.2018 with the following recopmmendation: Keeping in view the above facts on record, the panel unanimously recommends the approval of various sections to M/s Rotex. The panel did not recommend the Gel preparations/products in Cream/Ointment (Gen) and Topical (Steroid) sections since the firm didont possess required machinery and equipments for said purpose.
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the doumnets. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2433.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals.Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	E-son 40mg Injection
	Composition	Each Vial Contains:

		Esomeprazole as sodium…40mg
	Diary No. Date of R & I & fee	39695; 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Proton pump inhibitors
	Type of form	Form 5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities	NEXIUM IV esomeprazole 40mg (as sodium) powder for injection vial. **TGA** approved
	Me-too Status	Pep-Ease Injection 40mg. Reg. No. 67428
	GMP Status	As above
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the documents. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2434.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Marsa 1gm Injection
	Composition	Each Vial Contains: Vancomycin as Hydrochloride…1gm
	Diary No. Date of R & I & fee	39699; 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Glycopeptide antibacterials
	Type of form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities	VANCOCIN CP vancomycin 1g (1,000,000IU as hydrochloride) powder for injection vial. TGA approved
	Me-too Status	Vanzy 1g Injection. Reg. No. 81902
	GMP Status	As above
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the doumnets. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2435.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals.Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd.Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Marsa 500mg Injection
	Composition	Each Vial Contains: Vancomycin as Hydrochloride…500mg

	Diary No. Date of R & I & fee	39698; 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Glycopeptide antibacterials
	Type of form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities	VANCOCIN CP vancomycin 500mg (as hydrochloride) powder for injection vial. TGA approved
	Me-too Status	Vanzy 500mg Injection. Reg. No. 81901
	GMP Status	As above
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the doumnets. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2436.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Zapra Injection 40mg
	Composition	Each Vial Contains: Omeprazole as sodium
	Diary No. Date of R & I & fee	396891 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Proton pump inhibitors
	Type of form	Form 5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial. TGA approved
	Me-too Status	Somezol Injection. Reg. No. 45386
	GMP Status	As above
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the doumnets. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2437.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Ryean Injection 75mg/3ml
	Composition	Each 3ml ampoule contains:

		Diclofenac sodium…75mg
	Diary No. Date of R & I & fee	39692; 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Acetic acid derivatives and related substances
	Type of form	Form 5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	3ml; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Diclofenac Sodium 75 mg/3 ml Solution for Injection
	Me-too Status	Adfenac Injection 75mg/3ml/ Reg. No. 78635
	GMP Status	As above
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the doumnets. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2438.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	RY-VIT-D Injection IM/Oral
	Composition	Each 1ml ampoule contains: Cholecalciferol (Vit D3)…5mg
	Diary No. Date of R & I & fee	39694; 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Vitamin D and analogues
	Type of form	Form 5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	1ml; As per SRO
	Approval Status of product in Reference Regulatory Authorities	VITAMIN D3 GOOD 200 000 IU / 1 ml, oral solution in ampoule. VITAMINE D3 BON 200 000 U.I. / 1 ml, solution injectable IM en ampoule. **ANSM** approved
	Me-too Status	Accu-D Injection. Reg. No. 79755
	GMP Status	As above
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the doumnets. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2439.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals.Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad

	Brand Name + Dosage Form + Strength	RY-HIT 100mg Injection
	Composition	Each Vial Contains: Hydrocortisone as sodium Succinate…100mg
	Diary No. Date of R & I & fee	39696; 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Glucocorticoids
	Type of form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities	Hydrocortisone (as sodium succinate) 100 mg, powder for solution for injection/infusion. MHRA approved
	Me-too Status	Cortizone 100mg Injection. Reg. No. 91898
	GMP Status	As above
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the doumnets. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2440.	Name & address of Manufacturer	M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	RY-HIT 250mg Injection
	Composition	Each Vial Contains: Hydrocortisone as sodium Succinate…250mg
	Diary No. Date of R & I & fee	39697; 03.12.2018 Rs. 50000; 03.12.2018
	Pharmacological form	Glucocorticoids
	Type of form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities	SOLU-CORTEF (hydrocortisone as sodium succinate for injection, USP) For Intravenous or Intramuscular Administration. USFDA approved
	Me-too Status	Cortizone 250mg Injection. Reg. No. 91899
	GMP Status	As above
	Remarks of the evaluator	• Scanned signature of production manager and QCM are placed on the doumnets. • The firm submitted list of 04 approved section of M/s Karson Pharmaceuticals. • The firm submitted that 06 product are approved of M/s Karson Pharmaceuticals for contract manufacturing. • The firm submitted that 13 applications are currently submitted and under review for registration.
	Decision: Approved.	
2441.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	AMISYTE 50mg Tablet
	Composition	Each tablet Contains:

		Amisulpride……50mg
	Diary No. Date of R& I & fee	Dy. No. 39953: 04.12.2018 Rs, 20,000/- : 04.12.2018
	Pharmacological Group	Benzamides
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	SOLIAN 50 amisulpride 50 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 50mg Tablet. Reg No. 76060
	GMP status	The firm was inspected on 17.01.2019 with the following conclusion: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic: 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator	The firm revised the formulation to uncoated tablet in line with the reference product along with submission of Rs. 5000/- fee.
	Decision: Approved.	
2442.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	ROXAB 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban……..2.5mg
	Diary No. Date of R& I & fee	Dy. No. 40703: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto Film Coated Tablet (2.5mg, 10mg, 15mg, 20mg). EMA approved
	Me-too status	XARELTO 2.5MG TABLETS. Reg. no. 74794
	GMP status	As above
	Remarks of the Evaluator	• The firm has changed the address in Form 5 from Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan to Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan without submission of any fee.
	Decision: Deferred for clarification since the initial application was submitted by Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila which is a separate licensed manufacturer.	
2443.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	BISBETOL 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate USP……2.5mg
	Diary No. Date of R& I & fee	Dy. No. 39970: 04.12.2018.

		Rs. 20,000/- : 04.12.2018.
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Bisoprolol 2.5 mg Film-coated Tablet. MHRA approved
	Me-too status	Bisfat Tablets 2.5mg. Reg. No. 77054
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2444.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	BISBETOL 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate …….5mg
	Diary No. Date of R& I & fee	Dy. No. 39971: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Beta blocking agents, selective.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Bisoprolol 5 mg Film-coated Tablet. MHRA approved
	Me-too status	Bisfat Tablets 5mg. Reg. No. 77052
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2445.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	BISBETOL 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate …….10mg
	Diary No. Date of R& I & fee	Dy. No. 39772: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Beta blocking agents, selective.
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Bisoprolol 10 mg Film-coated Tablet. MHRA approved
	Me-too status	Bisolol 10 mg tablet. Reg. No. 79559
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2446.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	WALVUS-M 50/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……..50mg Metfromin HCl ……850mg
	Diary No. Date of R& I & fee	Dy. No. 39968: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Dy. No. 39969: 04.12.2018

		Rs. 20,000/- : 04.12.2018
	Type of Form	Combinations of oral blood glucose lowering drugs
	Finished product Specification	Form-5
	Pack size & Demanded Price	Innovator's Specification
	Approval status of product in Reference Regulatory Authorities	10's, 14's & 30's; as per SRO
	Me-too status	GALVUMET 50/850 vildagliptin 50 mg/metformin hydrochloride 850 mg film coated tablet. TGA approved
	GMP status	GALVUS MET 50MG/850MG TABLETS. Reg. No. 66106
	Remarks of the Evaluator	• The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
2447.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	WALVUS-M 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin……..50mg Metfromin HCL ……500mg
	Diary No. Date of R& I & fee	Dy. No. 39968: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 14's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	GALVUMET 50/500 vildagliptin 50 mg/metformin hydrochloride 500 mg film coated tablet by Novartis Pharmaceuticals Australia Pty Ltd. TGA approved
	Me-too status	Galmet 50mg/500mg Tablet by Vision Pharma. Reg No. 81905
	GMP status	AS ABOVE
	Remarks of the Evaluator	The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
2448.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	VORIVA 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Voriconazole…….50mg
	Diary No. Date of R& I & fee	Dy. No. 39988: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	10's, 14'& 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Voriconazole 50mg Film coated Tablet. MHRA approved
	Me-too status	Vorif tablets 50mg (Reg. # 069765)
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2449.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	PENCID 40mg Tablet
	Composition	Each delayed released Tablet Contains:

		Pantoprazole as Sodium Sesquihydrate……40mg
	Diary No. Date of R& I & fee	Dy. No. 39950: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	PROTONIX (pantoprazole sodium) delayed-release tablets 40mg, for oral use. USFDA approved
	Me-too status	PROTIUM GASTRO RESISTANT TABLETS 40mg. Reg. No. 21039
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2450.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	ACEPRIDE 1mg Tablet
	Composition	Each film-coated ablet Contains: Cinitapride as hydrogen Tartrate……..1mg
	Diary No. Date of R& I & fee	Dy. No. 39957: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Cinitapride Cinfa 1 mg uncoated tablets (Spain Approved)
	Me-too status	Cidine 1mg tablet by highnoon laboratories
	GMP status	AS ABOVE
	Remarks of the Evaluator	• The firm revised the formulation to uncoated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved.	
2451.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	NALTREX 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Naltrexone HCl……50mg
	Diary No. Date of R& I & fee	Dy. No. 39957: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Drugs used in alcohol dependence
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's,, 30's & 100's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Adepend 50 mg filmcoated tablets. MHRA approved
	Me-too status	Nulify Tablets 50mg. Reg. No. 034394
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2452.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 33, Sunder industrial Estate, Lahore Pakistan
	Brand Name +Dosage Form + Strength	WALVUS 50mg Tablet
	Composition	Each tablet Contains: Vildagliptin……..50mg

	Diary No. Date of R& I & fee	Dy. No. 39967: 04.12.2018 Rs. 20,000/- : 04.12.2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's, 14's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Galvus® 50 mg tablets. EMA approved
	Me-too status	Glavil 50mg Tablet. Reg. No. 067245
	GMP status	AS ABOVE
	Remarks of the Evaluator	• The firm revised the formulation to uncoated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved.	
2453.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	Staar Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium……20mg
	Diary No. Date of R& I & fee	Dy. No. 40685: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 20mg film-coated tablets. MHRA approved
	Me-too status	Rostat 20mg Tablet. Reg. No. 55731
	GMP status	The firm (M/s walt danzey) was inspected on 25.06.2018 with the following conclusion Keeping in view the above facts, detailed visit of establishment and supporting documents provided by the management and verification of rectification of plan/action with reference to previous shortcomings identified and company has shown good response and rectified the problems and has shown good compliance as per schedule B-II.
	Remarks of the Evaluator	• .
	Decision: Approved.	
2454.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	Staar Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium……10mg
	Diary No. Date of R& I & fee	Dy. No. 40684: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 10mg film-coated tablets. MHRA approved
	Me-too status	Aurora Tablets 10mg. Reg. No. 046872.
	GMP status	AS ABOVE
	Remarks of the Evaluator	• .
	Decision: Approved.	

2455.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	Staar Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium……5mg
	Diary No. Date of R& I & fee	Dy. No. 40683: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 5mg film-coated tablets. MHRA approved
	Me-too status	Aurora Tablets 5mg. Reg. No. 046873
	GMP status	AS ABOVE
	Remarks of the Evaluator	• .
	Decision: Approved.	
2456.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	Zoblin Capsule 50mg
	Composition	Each capsule contains: Pregabalin……50mg
	Diary No. Date of R& I & fee	Dy. No. 40692: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 14's, 20's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Alzain 75 mg Capsules, Hard. MHRA approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	AS ABOVE
	Remarks of the Evaluator	.
	Decision: Approved.	
2457.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	Zoblin Capsule 75mg
	Composition	Each capsule contains: Pregabalin……75mg
	Diary No. Date of R& I & fee	Dy. No. 40693: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 14's, 20's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Alzain 75 mg Capsules, Hard. MHRA approved
	Me-too status	Scirica 75mg Capsule. Reg. No. 82186
	GMP status	AS ABOVE
	Remarks of the Evaluator	.
	Decision: Approved.	
2458.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	Fleet Plus 75/75mg Tablet
	Composition	Each Film Coated Tablet Contains: Clopidogrel as bisulphate……75mg

		Aspirin……..75mg
	Diary No. Date of R& I & fee	Dy. No. 40691: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	APO-CLOPIDOGREL/ASPIRIN 75 mg / 75 mg film-coated tablets. TGA approved
	Me-too status	Lowplat Plus 75 Tablet. Reg. no. 47177
	GMP status	OKK
	Remarks of the Evaluator	• The firm has mentioned clopidogrel as bilsulfate in the cover letter, but the dossier does not depict the same elsewhere. Upon clarification the firm revised clopidogrel to clopidogrel as bisulfate without submission of any fee. • Submit manufacturing method in line with the international reference product, as the reference product is manufactured by wet granulation of clopidogrel, dry granulation of acetylsalicylic acid, mixing, compression and film-coating, and blistering.
	Decision: Deferred for following: • **Submission of fee for revision / correction of salt form of the API.** • **Submission of revised manufacturing method in line with that of the reference product.**	
2459.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	RAFAZIN Tablet 200mg
	Composition	Each Film Coated Tablet Contains: Rifaximin…….200mg
	Diary No. Date of R& I & fee	Dy. No. 40681: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	XIFAXAN® (rifaximin) 200mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Nimixa 200mg Tablet film-coated. Reg. No. 70734
	GMP status	AS ABOVE
	Remarks of the Evaluator	• . • The manufacturing outlines were meant for cream. The firm revised the manufacturing outlines.
	Decision: Deferred for submission of manufacturing method of the applied product.	
2460.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	RAFAZIN Tablet 550mg
	Composition	Each Film Coated Tablet Contains: Rifaximin…….550mg
	Diary No. Date of R& I & fee	Dy. No. 39682: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Antibotics
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	XIFAXAN® (rifaximin) 550mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Nimixa 550mg Tablet film-coated. Reg. No. 70733
	GMP status	AS ABOVE

	Remarks of the Evaluator	• The manufacturing outlines were meant for cream. The firm revised the manufacturing outlines.
	Decision: Deferred for submission of manufacturing method of the applied product.	
2461.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	SERRATOL Capsule 20mg
	Composition	Each capsule contains: - Fluoxetine (as hydrochloride) …….20mg
	Diary No. Date of R& I & fee	Dy. No. 40694: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Fluoxetine 20 mg Capsules. MHRA approved
	Me-too status	Deprifex Capsule 20mg. Reg. No. 041334
	GMP status	AS ABOVE
	Remarks of the Evaluator	• .
	Decision: Approved.	
2462.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	REDRINE Tablet 450/35mg
	Composition	Each Uncoated Tablet Contains: Paracetamol…….450mg Orphenadrine citrate…….35mg
	Diary No. Date of R& I & fee	Dy. No. 40690: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Orphenadrine, combinations
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	NORGESIC paracetamol orphenadrine citrate uncoated. TGA approved
	Me-too status	Orasic Tablets. Reg. No. 27027
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2463.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	Fleet 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Clopidogrel as bisulphate…….75mg
	Diary No. Date of R& I & fee	Dy. No. 40686: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Clopidogrel 75 mg film-coated tablets. MHRA approved
	Me-too status	Clavix Tablet 75mg. Reg. No. 035838
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	

2464.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	DITS-S Capsule 40/1100mg
	Composition	Each capsule contains: - Omeprazole…….40mg Sodium bicarbonate…….1100mg
	Diary No. Date of R& I & fee	Dy. No. 40696: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Proton pump inhibitors + antacids
	Type of Form	Form-5
	Finished product Specification	Innovators Specifications
	Pack size & Demanded Price	2x7's; as per SRO
	Approval status of product in Reference Regulatory Authorities	ZEGERID® (omeprazole and sodium bicarbonate) capsules (20/1100mg and 40/1100mg) capsule. USFDA approved
	Me-too status	Omega Rapid Capsules 40/1100mg. Reg. No. 60279
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2465.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	LYSINE 300mg Capsule
	Composition	Each Capsule Contains: 408mg of Lymecycline Equivalent to 300mg Tetracycline Base (BP Specifications)
	Diary No. Date of R& I & fee	Dy. No. 42053: 07.12.2018 Rs. 20,000/- : 07.12.2018
	Pharmacological Group	Tetracyclines
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 14's, 20's, 28's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Tetralysal 300 mg Hard Capsules. MHRA Approved
	Me-too status	Macyline Capsule 300mg. Reg. No.
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of label claim.	
2466.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	TUKOL CR 25mg Tablet
	Composition	Each Enteric Coated Controlled Release Tablet Contains: Paroxetine as HCl hemihydrate……25mg
	Diary No. Date of R& I & fee	Dy. No. 40487: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR (paroxetine) extended-release tablets,enteric coated (12.5mg, 25mg, 37.5mg). USFDA approved
	Me-too status	Approved
	GMP status	AS ABOVE
	Remarks of the Evaluator	• The firm did not mention seal coating and enteric coating separately in the master formula as well as manufacturing outlines. • The firm revised the folrmualtion to Enteric Coated Controlled Release Tablet along without submission of fee.

	Decision: Deferred for following: • **Submission of fee for revision of formulation.** • **Submission of revised master formulation and manufacturing method in line with that of the reference product.**	
2467.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	TUKOL 20mg Tablet
	Composition	Each film-coated Tablet Contains: Paroxetine as HCl hemihydrate……20mg
	Diary No. Date of R& I & fee	Dy. No. 40488: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Paroxetine 20 mg film-coated tablets. MHRA approved
	Me-too status	Pexeva Tablets 20mg. Reg. No. 76916
	GMP status	AS ABOVE
	Remarks of the Evaluator	• The firm revised the formulation to film-coated Tablet along with submission of Rs. 5000/- fee.
	Decision: Approved.	
2468.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	DOSTERIL Tablet 37.5/325mg
	Composition	Each Film Coated Tablet Contains: Tramadol Hydrochloride……37.25mg Paracetamol……..325mg
	Diary No. Date of R& I & fee	Dy. No. 40689: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use US-FDA approved
	Me-too status	Tril-P Tablet by Linta Pharmaceuticals. Reg. No. 78181
	GMP status	AS ABOVE
	Remarks of the Evaluator	.
	Decision: Approved.	
2469.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	LEVOLAX Tablet 250mg
	Composition	Each Film Coated Contains: Levofloxacin as Hemihydrate……250mg
	Diary No. Date of R& I & fee	Dy. No. 40710 : 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Floroquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Evoxil 250 mg film-coated tablets. MHRA approved
	Me-too status	Levolis 250mg Tablets. Reg. No. 85178

	GMP status	
	Remarks of the Evaluator	.
	Decision: Approved.	
2470.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	LEVOLAX Tablet 500mg
	Composition	Each Film Coated Contains: Levofloxacin as Hemihydrate……500mg
	Diary No. Date of R& I & fee	Dy. No. 40711: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Floroquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Evoxil 500 mg film-coated tablets. MHRA approved
	Me-too status	Levoquin 500mg Tablet. Reg. No. 85206
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved.	
2471.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	CIPRIZON Tablet 250mg
	Composition	Each Film Coated tablet Contains: Ciprofloxacin as HCL……..250mg
	Diary No. Date of R& I & fee	Dy. No. 40708: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Floroquinolones
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	CIPRO® 250mg film-coated tablets. USFDA approved
	Me-too status	Cipra 250mg Tablet. Reg. No. 82229
	GMP status	AS ABOVE
	Remarks of the Evaluator	.
	Decision: Approved.	
2472.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	CIPRIZON Tablet 500mg
	Composition	Each Film Coated Contains: Ciprofloxacin as HCL…….500mg
	Diary No. Date of R& I & fee	Dy. No. 40709: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Floroquinolones
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin 500 mg film-coated Tablets. MHRA approved
	Me-too status	Cibo 500mg Tablet. Reg. No. 81583
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	

2473.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	RIVAZONE Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…….10mg
	Diary No. Date of R& I & fee	Dy. No. 40702: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 14's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Rivaroxaban 10 mg film-coated tablets by Milpharm Limited. MHRA approved
	Me-too status	Xaroban 10mg Tablet. Reg. No. 76284
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2474.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	RIVAZONE Tablet 15mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…….15mg
	Diary No. Date of R& I & fee	Dy. No. 40703: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 14's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Rivaroxaban 15 mg film-coated tablets by Milpharm Limited. MHRA approved
	Me-too status	Rivaxo 15mg film-coated Tablet. Reg. No. 80790
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2475.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	RIVAZONE Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…….20mg
	Diary No. Date of R& I & fee	Dy. No. 40704: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, 14's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Rivaroxaban 20 mg film-coated tablets. MHRA approved
	Me-too status	Rivaxo 20mg film-coated Tablet. Reg. No. 80791
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2476.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	MUCOGIN 4mg Capsule

	Composition	Each Capsule Contains: Thiocholchicoside…….4mg
	Diary No. Date of R& I & fee	Dy. No. 40695: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	MIOREL 4 mg capsule. ANSM approved
	Me-too status	Muscucoside capsule 4mg. Reg. No. 81656
	GMP status	
	Remarks of the Evaluator	
	Decision: Approved.	
2477.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	LANSZONE Injection 30mg
	Composition	Each Vial Contains: Lansoprazole (Lyophilized Sterile Powder)…..30mg
	Diary No. Date of R& I & fee	Dy. No. 40712: 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Propton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	1's; as per SRO
	Approval status of product in Reference Regulatory Authorities	PREVACID® I.V. (LANSOPRAZOLE) 3mg (lyophilized powder) for Injection. Not discontinued or withdrawn for safety or efficacy reasons in USFDA.
	Me-too status	Anso Injection. Reg. No. 069893
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of manufacturing facility.	
2478.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	LEZOXIB 100mg Capsule
	Composition	Each Capsule Contains: Celecoxib…….100mg
	Diary No. Date of R& I & fee	Dy. No. : 06.12.2018 Rs. 20,000/- : 06.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	20's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Celebrex 100 mg capsules. MHRA approved
	Me-too status	Bexicox 100 Capsule. Reg. No. 23946
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2479.	Name and address of manufacturer / Applicant	Horizon Health care Private Limited Plot No 35, Small industrial Estate, Taxila Pakistan
	Brand Name +Dosage Form + Strength	LEZOXIB 200mg Capsule
	Composition	Each Capsule Contains: Celecoxib…….200mg
	Diary No. Date of R& I & fee	Dy. No. 40696: 06.12.2018 Rs. 20,000/- : 06.12.2018

	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Celebrex 200 mg capsules. MHRA approved
	Me-too status	Bexicox 200 Capsule. Reg. No. 23947
	GMP status	AS ABOVE
	Remarks of the Evaluator	
	Decision: Approved.	
2480.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Irosuc 20mg/ml Injection
	Composition	Each injection contains: Iron sucrose …20mg
	Diary No. Date of R& I & fee	Dy. No. 40713: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml ampule x 5's, As per SRO
	Approval status of product in Reference Regulatory Authorities	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	**Applicant**: 19-09-2018 ad 03-10-2018 Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	• The firm revised 'iron sucrose' to 'iron (III)-hydroxide-sucrose eq. to elemental iron' without submission of applicable fee. • Adjustment of weight of API as per salt factor is required in master formula. • Proof of international availability of same formulation, same strength and same filled volume in reference regulatory authorities as defined in 275th meeting of the registration board is required. Otherwise, revise the strength in line with the reference product along with submission of applicable fee. • The firm submitted list of 10 approved sections of M/s Roryan Phamaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Phamaceuticals for contract manufacturing.
	Decision: Deferred for following: • **Submission of fee for revision of formulation** • **Adjustment of weight of API in the master formulation** • **capacity assessment of m/s Welmark**	
2481.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Anmol 40mg Injection

	Composition	Each Vial Contains: Omeprazole sodium (Iyophilized powder) …40mg
	Diary No. Date of R& I & fee	Dy. No. 40718: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial. TGA approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	**Applicant**: 19-09-2018 ad 03-10-2018 Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	• The firm has applied for Omeprazole as sodium (as per master formula). The firm revised Omeprazole to Omeprazole sodium in the label claim. • The firm submitted list of 10 approved sections of M/s Roryan Phamaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Phamaceuticals for contract manufacturing.
	Decision: Deferred for submission of fee for revision of formulation and capacity assessment of m/s welmark.	
2482.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Calcifed 5mg Injection
	Composition	Each injection contains: Cholecalciferol…5mg
	Diary No. Date of R& I & fee	Dy. No. 40716: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Vitamin D and analogues
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3 GOOD 200 000 IU / 1 ml, oral solution in ampoule. VITAMINE D3 BON 200 000 U.I. / 1 ml, solution injectable IM en ampoule. ANSM approved
	Me-too status	Accu-D Injection. Reg. No. 79755
	GMP status	**Applicant**: 19-09-2018 ad 03-10-2018 Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	• The firm submitted list of 10 approved sections of M/s Roryan Phamaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Phamaceuticals for contract manufacturing.
	Decision: Deferred for capacity assessment of m/s welmark.	

2483.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Esoyan 40mg Injection
	Composition	Each Vial Contains: Esomeprazole sodium (lyophilized powder)…40mg
	Diary No. Date of R& I & fee	Dy. No. 40717: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	NEXIUM IV esomeprazole 40mg (as sodium) powder for injection vial. TGA approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	**Applicant**: 19-09-2018 ad 03-10-2018 Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	• The firm has applied for esomeprazole as sodium (as per master formula). The firm revised esomeprazole to esomeprazole sodium in the label claim. • The firm submitted list of 10 approved sections of M/s Roryan Phamaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Phamaceuticals for contract manufacturing.
	Decision: Deferred for capacity assessment of m/s Welmark.	
2484.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	ME LOXIT 500mg Injection
	Composition	Each ml contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy. No. 40714: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Mecobalamin injection 500μg (1ml). PMDA approved
	Me-too status	Balco 500mcg IM/IV Injection (1ml). Reg. No. 81484
	GMP status	**Applicant**: 19-09-2018 ad 03-10-2018 Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	• The firm submitted list of 10 approved sections of M/s Roryan Phamaceuticals. • The firm submitted list of 11 approved products of M/s

		Roryan Phamaceuticals for contract manufacturing.
	Decision: Deferred for capacity assessment of m/s welmark.	
2485.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Mospro 80mg/ml Injection
	Composition	Each injection contains: Artemether…80mg
	Diary No. Date of R& I & fee	Dy. No. 40715: 06.12.2018 Rs. 50,000: 06.12.2018
	Pharmacological Group	Artemisinin and derivatives, plain
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Artemether 80mg/ml solution for injection (1ml). PMDA approved
	Me-too status	Malasan Injection (1ml). Reg. No. 30366
	GMP status	**Applicant**: 19-09-2018 ad 03-10-2018 Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP certificate **Manufacturer**: The firm was inspected on 04.09.2018 and 26.09.2018, wherein the panel renewal of DML was recommended.
	Remarks of the Evaluator	• The firm submitted list of 10 approved sections of M/s Roryan Phamaceuticals. • The firm submitted list of 11 approved products of M/s Roryan Phamaceuticals for contract manufacturing.
	Decision: Deferred for capacity assessment of m/s welmark.	
2486.	Name and address of manufacturer/ Applicant	M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi
	Brand Name + Dosage Form + Strength	Seizlac 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R & I & fee	Dy. No. 3669; 28.01.2019 PKR. 20,000/-; 18.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Aspire 50 mg film-coated tablets. MHRA Approved
	Me-too status	Lalap 50mg tablet. Reg. No. 70470
	GMP status	The firm was inspected on 26.09.2018, wherein the following conclusion was made. The building facilities and procedure demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moroever, firm should focus on above mentioned observations and comply with them on priority.
	Remarks of the Evaluator	•
	Decision: Approved.	
2487.	Name and address of manufacturer/ Applicant	M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi
	Brand Name+Dosage Form+ Strength	Seizlac 100mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Lacosamide…100mg
	Diary No. Date of R & I & fee	Dy. No. 3669; 28.01.2019 PKR. 20,000/-; 18.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 100mg Tablet film-coated. Reg. No. 83976
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2488.	Name and address of manufacturer/ Applicant	M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi
	Brand Name + Dosage Form + Strength	Seizlac 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…150mg
	Diary No. Date of R & I & fee	Dy. No. 3671; 28.01.2019 PKR. 20,000/-; 18.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lalap 150mg Tablet. Reg. No. 70472
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2489.	Name and address of manufacturer/ Applicant	M/s Platinum Pharmaceuticals Pvt Ltd A-20, North western Industrial Zone, Bin Qasim Karachi
	Brand Name + Dosage Form + Strength	Seizlac 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…200mg
	Diary No. Date of R & I & fee	Dy. No. 3672; 11.01.2019 PKR. 20,000/-; 11.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lalap 200mg Tablet. Reg. No. 70473
	GMP status	As above
	Remarks of the Evaluator	
	Decision: Approved.	
2490.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Oxapine 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Oxcarbazepine…600mg
	Diary No. Date of R & I & fee	Dy. No. 6350; 13.02.2019 PKR. 20,000/-; 13.02.2019

	Pharmacological Group	Carboxamide derivatives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Oxcarbazepine Mylan 600 mg Film-coated Tablets. MHRA approved
	Me-too status	Oxcarbalepsy tablet 600mg. Reg. No. 81655
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator	•
	Decision: Approved.	
2491.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Oxapine 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Oxcarbazepine…300mg
	Diary No. Date of R & I & fee	Dy. No. 6349; 13.02.2019 PKR. 20,000/-; 13.02.2019
	Pharmacological Group	Carboxamide derivatives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Oxcarbazepine Mylan 300 mg Film-coated Tablets. MHRA approved
	Me-too status	Oxcarbalepsy tablet 300mg. Reg. No. 81654
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator	•
	Decision: Approved.	
2492.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Misfenac 50mg/200mcg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac Sodium (enteric coated)…50mg Misoprostol…200mcg
	Diary No. Date of R & I & fee	Dy. No. 8749; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	Prostaglandins + NSAIDs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diclofenac sodium and misoprostol 50 mg/200 micrograms uncoated modified release tablets. MHRA approved ARTHROTEC (diclofenac sodium and misoprostol tablets) film-coated. USFDA approved
	Me-too status	Itami plus Tablet. Reg. No. 81170
	GMP status	The firm was inspected on 07.12.2017 with the following

		conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator	•
	Decision: Deferred for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.	
2493.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Valzide 80/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R & I & fee	Dy. No. 8748; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Co-Diovan 80mg/12.5mg film-coated tablets. Approved by MHRA
	Me-too status	Valzar Plus 80/12.5 Tablets. Reg. No. 50901
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator	•
	Decision: Approved.	
2494.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Amlozide 5/160/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R & I & fee	Dy. No. 8746; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets. **US-FDA** approved
	Me-too status	Exforge HCT 5/160/12.5MG film coated tablet Reg.No.69548
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator	•
	Decision: Approved.	

2495.	Name and address of manufacturer/ Applicant	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Baluchistan
	Brand Name + Dosage Form + Strength	Baclovant 10mg Tablet
	Composition	Each Uncoated Tablet Contains: Baclofen…10mg
	Diary No. Date of R & I & fee	Dy. No. 6350; 27.02.2019 PKR. 20,000/-; 27.02.2019
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Baclofen 10mg Tablets. MHRA approved
	Me-too status	LIORESAL 10MG TAB. Reg No. 7822
	GMP status	The firm was inspected on 07.12.2017 with the following conclusion: "All the observations pointed out during the inspection were discussed with management and they assured for early compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator	•
	Decision: Approved.	
2496.	Name and address of manufacturer/ Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name + Dosage Form + Strength	Fostro Sachet
	Composition	Each Sachet Contains: Fosfomycin Trometamol Eq. to Fosfomycin…3gm
	Diary No. Date of R & I & fee	Dy. No. 4665; 01.02.2019 PKR. 20,000/-; 01.02.2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	2=1's, 10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fosfomycin 3g granules for oral solution by Exeltis Poland Sp. z o.o., approved by MHRA
	Me-too status	Fomy-C Sachet by Kohinoor Industries, Sahiwal. Reg. No. 80117
	GMP status	The firm was inspected on 16.02.2018, with the following conclusion: "In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other cGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at an satisfactory level of compliance with cGMP guidelines as of today. The management was also suggested to further strengthen stability and analytical sections."
	Remarks of the Evaluator	•
	Decision: Approved.	
2497.	Name and address of manufacturer/ Applicant	M/s Fozan Pharmaceutical. 36-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name + Dosage Form + Strength	Marpolatis 10mg
	Composition	Each Film Coated Tablet Contains: Escitalopram as oxalate…10mg

	Diary No. Date of R & I & fee	Dy. No. 3351; 10.01.2019 PKR. 20,000/-; 09.01.2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipralex 10 mg film-coated tablets (**MHRA** Approved)
	Me-too status	Lexopram Tablets 10 mg by Evolution pharma
	GMP status	The firm was inspected on 25.05.2018 with the conclusion that overall the GMP compliance of the firm is satisfactory.
	Remarks of the Evaluator	•
	Decision: Approved.	
2498.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Solicin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…5mg
	Diary No. Date of R & I & fee	Dy. No. 1461; 11.01.2019 PKR. 20,000/-; 11.01.2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VESIcare (solifenacin succinate) film-coated 5mgtablets. **USFDA** approved
	Me-too status	Solfine film-coated Tablet 5mg. Reg No. 81958
	GMP status	The firm was inspected on 13.09.2019 the following recommendations: The panel of inspector recommends the renewal of M/s Pharmix Laboratories Pvt Ltd. Located at 21 Km, Ferozepur Road, Lahore bearing DML No. 000397 subject to verification of all approved sections by the licensing division, DRAP, Islamabad.
	Remarks of the Evaluator	• The firm was asked to submit properly filled enclosure of Form 5 (26 points) along with signed undertaking at the end of Form 5. The firm submitted undertaking only.
	Decision: Deferred for submission of complete Form 5.	
2499.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Solicin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin succinate…10mg
	Diary No. Date of R & I & fee	Dy. No. 1462; 11.01.2019 PKR. 20,000/-; 11.01.2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VESIcare (solifenacin succinate) film-coated 10mg tablets. **USFDA** approved
	Me-too status	Solfine film-coated Tablet 10mg. Reg No. 81959
	GMP status	As for above case
	Remarks of the Evaluator	• The firm was asked to submit properly filled enclosure of Form 5 (26 points) along with signed

		undertaking at the end of Form 5. The firm submitted undertaking only.
	Decision: Deferred for submission of complete Form 5.	
2500.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Prelin 50mg Capsule
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R & I & fee	Dy. No. 1460; 11.01.2019 PKR. 20,000/-; 11.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 50 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	As for above case
	Remarks of the Evaluator	• The firm was asked to submit properly filled enclosure of Form 5 (26 points) along with signed undertaking at the end of Form 5. The firm submitted undertaking only.
	Decision: Deferred for submission of complete Form 5.	
2501.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Alcox 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R & I & fee	Dy. No. 4422; 31.01.2019 PKR. 20,000/-; 31.01.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ARCOXIA etoricoxib 60mg film-coated tablet. **TGA** approved
	Me-too status	Gencox 60mg Tablets film-coated. Reg. No. 78839
	GMP status	As for above case
	Remarks of the Evaluator	• The firm was asked to submit properly filled enclosure of Form 5 (26 points) along with signed undertaking at the end of Form 5. The firm submitted undertaking only.
	Decision: Deferred for submission of complete Form 5.	
2502.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Acefin 1gm/100ml Infusion
	Composition	Each 100ml Vial Contains: Paracetamol…1gm
	Diary No. Date of R & I & fee	Dy. No. 1004 10.01.2019 PKR. 20,000/-; 09.01.2019
	Pharmacological Group	Anilides
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	100ml; Rs. 100/-
	Approval status of product in Reference	MHRA approved.

	Regulatory Authorities.	
	Me-too status	Provas Infusion 10mg/ml. No. 53223 (filled volume not specified)
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.	
2503.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Carpenem 1gm Injection
	Composition	Each Vial Contains: Meropenem as Trihydrate…1gm
	Diary No. Date of R & I & fee	Dy. No. 993: 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; Rs. 2100/-
	Approval status of product in Reference Regulatory Authorities.	MERREM® IV (meropenem for injection) 1g, for intravenous use. **US-FDA** approved
	Me-too status	Meropeon Injection 1g. Reg. No. 78145
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications. • Provide proof of approval of the relevant section.
	Decision: Deferred for following: • **Submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.** • **Evidence of approval of requisite manufacturing facility / section from Licensing Division.**	
2504.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Carpenem 500mg Injection
	Composition	Each Vial Contains: Meropenem as Trihydrate…500mg

	Diary No. Date of R & I & fee	Dy. No. 1000; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; Rs. 1300/-
	Approval status of product in Reference Regulatory Authorities.	MERREM® IV (meropenem for injection) 500mg, for intravenous use. **US-FDA** approved
	Me-too status	Engpan Injection 500mg. Reg. No. 64555
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications. • Provide proof of approval of the relevant section.
	Decision: Deferred for following: • **Submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.** • **Evidence of approval of requisite manufacturing facility / section from Licensing Division.**	
2505.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Dololac 30mg Injection
	Composition	Each 1ml Injection Contains: Ketorolac Trometamol…30mg
	Diary No. Date of R & I & fee	Dy. No. 1006; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5's; Rs. 500/-
	Approval status of product in Reference Regulatory Authorities.	TORADOL ketorolac trometamol 30mg/1mL injection ampoule. TGA approved
	Me-too status	Syntor 30 mg Injection IV/IM. Reg. No.83365
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing	

	outlines, environmental control and finished product specifications.	
2506.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Dololac 10mg Injection
	Composition	Each 1ml Injection Contains: Ketorolac Trometamol…10mg
	Diary No. Date of R & I & fee	Dy. No. 992; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5's; Rs. 300/-
	Approval status of product in Reference Regulatory Authorities.	TORADOL ketorolac trometamol 10mg/1mL injection ampoule. TGA approved
	Me-too status	Syntor 10 mg Injection IV/IM. Reg. No.83364
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.	
2507.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Florocin 125mg/5ml Suspension
	Composition	Each 5ml Contains: Ciprofloxacin as Hcl…125mg
	Diary No. Date of R & I & fee	Dy. No. 996; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Floruoquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml; Rs. 100/-
	Approval status of product in Reference Regulatory Authorities.	Already approved by Board in its 269th meeting
	Me-too status	Novidat suspension by Sami
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.

	Decision: Deferred for following: • **Submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.** • **Revision of formulation as per the reference product along with submission of fee.**	
2508.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Florocin 250mg/5ml Suspension
	Composition	Each 5ml Contains: Ciprofloxacin as Hcl…250mg
	Diary No. Date of R & I & fee	Dy. No. 997; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Floruoquinolones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CIPRO Oral Suspension 5%w/v (base only). USFDA approved
	Me-too status	Novidat suspension
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for following: • **Submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.** • **Revision of formulation as per the reference product along with submission of fee.**	
2509.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Listin 80mg Injection
	Composition	Each Vial Contains: Colistimethate Sodium (lyophilized powder) …80mg
	Diary No. Date of R & I & fee	Dy. No. 1009; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Polymyxins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; Rs. 2100/-
	Approval status of product in Reference Regulatory Authorities.	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection (lyophilized powder in glass vial). Approved by **MHRA**
	Me-too status	Colistat powder for Injection. Reg. No. 76160
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person.

		Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications and confirmation of manufacturing facility.	
2510.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Protohib 40mg Injection
	Composition	Each Vial Contains: Esomeprazole as Sodium (lyophilized powder)…40mg
	Diary No. Date of R & I & fee	Dy. No. 999; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1's; Rs. 350/-
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for injection vial. **TGA** approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications and confirmation of manufacturing facility.	
2511.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Rab 50mg Injection
	Composition	Each Vial Contains: Tigecycline (lyophilized powder)…50mg
	Diary No. Date of R & I & fee	Dy. No. 1007 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1's; Rs. 4500/-
	Approval status of product in Reference Regulatory Authorities.	TYGACIL® (tigecycline) for injection, for intravenous use (lyophilized powder or cake for reconstitution). USFDA

		approved
	Me-too status	Tigewel 50mg Injection. Reg. No. 82530
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications and confirmation of manufacturing facility.	
2512.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Stan 500mg Injection
	Composition	Each Vial Contains: Thiopental Sodium (lyophilized powder)…500mg
	Diary No. Date of R & I & fee	Dy. No. 1008; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Barbiturates, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; Rs. 100/-
	Approval status of product in Reference Regulatory Authorities.	Thiopental Sodium 500mg Powder for Solution for Injection. MHRA approved
	Me-too status	Thiopental 500mg Injection. Reg. No. 68879
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications and confirmation of manufacturing facility.	
2513.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	V-Mycin 1gm Injection IV
	Composition	Each Injection Contains: Vancomycin as Hcl…1gm
	Diary No. Date of R & I & fee	Dy. No. 1002; 09.01.2019 PKR. 20,000/-; 07.01.2019

	Pharmacological Group	Glycopeptide antibacterials
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; Rs. 1600/-
	Approval status of product in Reference Regulatory Authorities.	VANCOCIN CP vancomycin 1g (1,000,000IU as hydrochloride) powder for injection vial. TGA approved
	Me-too status	Vanzy 1g Injection. Reg. No. 81902
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications and confirmation of manufacturing facility.	
2514.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	V-Mycin 500mg Injection
	Composition	Each Injection Contains: Vancomycin as Hcl…500mg
	Diary No. Date of R & I & fee	Dy. No. 1001; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Glycopeptide antibacterials
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; Rs. 1000/-
	Approval status of product in Reference Regulatory Authorities.	VANCOCIN CP vancomycin 500mg (as hydrochloride) powder for injection vial. TGA approved
	Me-too status	Vanzy 500mg Injection. Reg. No. 81901
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications and confirmation of manufacturing facility.	

2515.	Name and address of manufacturer/ Applicant	M/s Lahore Chemical & Pharmaceutical Works Pvt Ltd. 137-Ferozepur Road, Lahore
	Brand Name + Dosage Form + Strength	Zadine Eye Drops 0.2%
	Composition	Olopatadine as HCL…0.2%
	Diary No. Date of R & I & fee	Dy. No. 1004; 09.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Other antiallergics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Pataday once daily relief / Patanol (olopatadine hydrochloride ophthalmic solution) 0.2%. USFDA approved.
	Me-too status	Eyepat Ophthalmic Solution 2%. Reg. No. 76592
	GMP status	The firm was inspected on 19.09.2019, wherein renewal of DML has been recommended
	Remarks of the Evaluator	• Name of signatory is missing on Form 5. However, the signature is matching with that of qualified person. Make sure that first page of Form is signed by the concerned person. • The firm was asked to submit supporting documents for the requirement of Form 5, including finished product specifications. The firm did not submit the same. There is no detail about the compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications.
	Decision: Deferred for submission of complete Form 5 signed by authorized person along with relevant supporting documents including compositions / master formula, complete manufacturing outlines, environmental control and finished product specifications and confirmation of manufacturing facility.	
2516.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Fencab 10mg Tablet
	Composition	Each tablet contains: Baclofen…10mg
	Diary No. Date of R & I & fee	Dy. No. 3464; 25.01.2019 PKR. 20,000/-; 24.01.2019
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Baclofen 10mg Tablets. MHRA approved
	Me-too status	LIORESAL 10MG TAB. Reg No. 7822
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2517.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Fexos 60mg/120mg Tablet
	Composition	Each film-coated tablet contains: Fexofenadine Hcl…120mg Pseudoophedrine Hcl…160mg

	Diary No. Date of R & I & fee	Dy. No. 3465; 25.01.2019 PKR. 20,000/-; 24.01.2019
	Pharmacological Group	pseudoephedrine, combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 20's, 30's, 40's, 50's, 60's, 70's, 80's, 80's, 90's, 100's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA-D 12 HOUR Extended-Release Tablets. **USFDA** approved
	Me-too status	Fexet-D 60Mg/120Mg film-coated Tablets. Reg No. 39099
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	• The reference product is in the form of two layer film-coated extended release tablet. Provide proof of reference product in reference regulatory agencies as defined in 275th meeting of the registration Board. The firm didnot revise the formulation (composition and manufacturing outlines) accordingly. However, the firm submitted Rs. 5000/- fee. • Theavailability of bilayermachine may be verified.
	Decision: Deferred for following: • **Revision of formulation as per the reference product.** • **Evidence of requisite manufacturing facility i.e. bilayer tablet machine.**	
2518.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Lizolid 400mg Tablet
	Composition	Each Film-coated tablet contains: Linezolid…400mg
	Diary No. Date of R & I & fee	Dy. No. 65; 01.01.2019 PKR. 20,000/-; 01.01.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	Innovator specifications
	Pack size & Demanded Price	5's, 20's 12's, 14's, 2x6; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) tablets (film-coated) for oral use by Pharmacia and Upjohn. **not discontinued or withdrawn by US-FDA for safety or efficacy reasons**
	Me-too status	Enliv 400mg Tablet by PharmEvo (Pvt.) Ltd. Reg No. 58096
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2519.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850,
	Brand Name + Dosage Form + Strength	Lizolid 600mg Tablet
	Composition	Each Film-coated tablet contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 66; 01.01.2019 PKR. 20,000/-; 01.01.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	Innovator specifications
	Pack size & Demanded Price	5's, 20's 12's, 14's, 2x6; as per SRO

	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) tablets (film-coated) for oral use by Pharmacia and Upjohn. **USFDA approved**
	Me-too status	Ozlin 600 mg Tablet by Linta Pharmaceuticals. Reg No. 78179
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2520.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Lizolid suspensio 100mg/5ml
	Composition	Each 5ml reconstituted suspension contains: Linezolid…100mg
	Diary No. Date of R & I & fee	Dy. No. 3467; 25.01.2019 PKR. 20,000/-; 24.01.2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished product Specification	Innovators specifications
	Pack size & Demanded Price	60ml, 120ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) 100mg/5ml for suspension. **USFDA approved**
	Me-too status	Adyzil Dry Suspension 100mg/5ml. Reg No.85090
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2521.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Oxicam 4mg Tablet
	Composition	Each Film-coated tablet contains: Lornoxicam…4mg
	Diary No. Date of R & I & fee	Dy. No. 3472; 25.01.2019 PKR. 20,000/-; 24.01.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	5's, 10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 4 mg Filmtabletten (Swiss Medic approved)
	Me-too status	Noxilor Tablet. Reg. No. 84039
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2522.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Oxicam 8mg Tablet
	Composition	Each Film-coated tablet contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 3473; 25.01.2019 PKR. 20,000/-; 24.01.2019

	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications.
	Pack size & Demanded Price	5's, 10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2523.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Mexocam 7.5mg Tablet
	Composition	Each tablet contains: Meloxicam…7.5mg
	Diary No. Date of R & I & fee	Dy. No. 3468; 25.01.2019 PKR. 20,000/-; 24.01.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Meloxicam 7.5 mg Tablets, uncoated. MHRA approved
	Me-too status	Mevox 7.5mg Tablets. Reg No. 23928
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2524.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850,
	Brand Name + Dosage Form + Strength	Mexocam 15mg Tablet
	Composition	Each tablet contains: Meloxicam…15mg
	Diary No. Date of R & I & fee	Dy. No. 3469; 25.01.2019 PKR. 20,000/-; 24.01.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Meloxicam 15 mg Tablets, uncoated. MHRA approved
	Me-too status	Mevox 15mg Tablets. Reg No. 23929
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2525.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850,
	Brand Name + Dosage Form + Strength	Semotem 50/500 mg Tablet
	Composition	Each Film-coated tablet contains: Sitagliptin as Phosphate monohydrate…50mg Metformin Hcl…500mg

	Diary No. Date of R & I & fee	Dy. No. 62; 01.01.2019 PKR. 20,000/-; 01.01.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovators specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/500mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/500mg Tablets. Reg. No. 53099 (does not depict hydrate form).
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2526.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Semotem 50/1000 mg Tablet
	Composition	Each Film-coated tablet contains: Sitagliptin as Phosphate monohydrate …50mg Metformin Hcl…1000mg
	Diary No. Date of R & I & fee	Dy. No. 63; 01.01.2019 PKR. 20,000/-; 01.01.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/1000mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/1000mg Tablets. Reg. No. 53100 (does not depict hydrate form).
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2527.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Vidaglip-M 50/500 mg Tablet
	Composition	Each Film-coated tablet contains: Vildagliptin…50mg Metformin HCL…500mg
	Diary No. Date of R & I & fee	Dy. No. 61; 01.01.2019 PKR. 20,000/-; 01.01.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	14's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/500 vildagliptin 50 mg/metformin hydrochloride 500 mg film coated tablet. TGA approved
	Me-too status	Galmet 50mg/500mg Tablet by Vision Pharma. Reg No. 81905
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	• The approved shelf-life of the product in 18 months in

		TGA
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
2528.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Tranex 250mg Capsule
	Composition	Each Capsule Contains: Tranexamic Acid…250mg
	Diary No. Date of R & I & fee	Dy. No. 3470; 25.01.2019 PKR. 20,000/-; 24.01.2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	20's, 100's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	TRANEX 250mg capsule. AIFA approved
	Me-too status	Tranza 250mg capsules. Reg No. 85769
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2529.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Karachi-75850, Pakistan
	Brand Name + Dosage Form + Strength	Tranex 500mg Capsule
	Composition	Each Capsule Contains: Tranexamic Acid…500mg
	Diary No. Date of R & I & fee	Dy. No. 3464; 25.01.2019 PKR. 20,000/-; 24.01.2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	20's, 100's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	TRANEX 500mg capsule. AIFA approved
	Me-too status	Sotran 500 Capsule. Reg No. 80350
	GMP status	The firm was inspected on 04.07.2018 with the following conclusion: Based on above observations their current GMP compliance level is rated as GOOD.
	Remarks of the Evaluator	•
	Decision: Approved.	
2530.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Calson- B Ointment
	Composition	Each Gram Contains: Calcipotriol as monohydrate…0.05mg Betamethasone as Dipropionate…0.5mg
	Diary No. Date of R & I & fee	Dy. No. 14282; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Calcipotriol, Combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	30g; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Calcipotriol (as monohydrate) /Betamethasone (as dipropionate) Sandoz 50 micrograms per g / 500 micrograms per g ointment.

		MHRA approved
	Me-too status	Calbet Ointment. Reg. No. 84025
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved.	
2531.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Napoxi 8mg Tablets
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 41261; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids (oxicams)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's,30's,50's,100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
2532.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Dicrin 50mg Capsule
	Composition	Each Capsule Contains: Diacerein…50mg
	Diary No. Date of R & I & fee	Dy. No. 41293; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovators specifications.
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ART 50 mg capsule. ANSM approved
	Me-too status	Diora 50mg Capsule. Reg. No. 67631
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved.	

2533.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Carbiz 200mg Tablets
	Composition	Each Tablet Contains: Carbamazepine…200mg
	Diary No. Date of R & I & fee	Dy. No. 41259; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 15's, 20's, 21's, 25's, 28's, 30's, 50's, 56's, 60's, 84's, 90's, 100's, 112's, 120's, 168's, 180's, 250's, 500's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Carbagen 200 mg tablets. MHRA approved
	Me-too status	TEGRETOL 200MG TAB. Reg. No. 636
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved.	
2534.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Neumid 100mg Tablet
	Composition	Each Tablet Contains: Nimesulide…100mg
	Diary No. Date of R & I & fee	Dy. No. 41275; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form-5
	Finished product Specification	Innovator's
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMA approved
	Me-too status	Alsolide Tablets 100mg. Reg. No. 38179 (Does not depict coating)
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved.	
2535.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Febxo 40mg Tablets
	Composition	Each Film Coated Tablet Contains: Febuxostat…40mg
	Diary No. Date of R & I & fee	Dy. No. 41263; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Preparations inhibiting uric acid production

	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	10's, 20's, 30's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ULORIC (febuxostat) tablet, film-coated for oral use. USFDA approved
	Me-too status	Febulos 40mg Tablet. Reg. No. 82694
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2536.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Meloci 15mg Tablet
	Composition	Each Tablet Contains: Meloxicam…15mg
	Diary No. Date of R & I & fee	Dy. No. 41265; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Non-steroidal anti-inflammatory drugs (NSAIDs)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 500's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MOBIC® (meloxicam) uncoated Tablets 15 mg by M/s Boehringer Ingelheim Pharmaceuticals, Inc. USFDA Approved.
	Me-too status	Mexiran Tablets 15mg by M/s Akson Pharmaceutical (Pvt) Ltd, Reg. No. 29846
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2537.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Lacosin 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R & I & fee	Dy. No. 41270; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	14's, 28's, 56's, 168's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 100mg Tablet film-coated. Reg. No. 83976
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded

		that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2538.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Coxito 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R & I & fee	Dy. No. 41274; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Coxibs
	Type of Form	Form-5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Etoricoxib 60 mg Film-coated Tablets. MHRA approved
	Me-too status	Eto 60 mg Tablet. Reg. No. 78176
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2539.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Liglip 50/1000mg Tablets
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…1000mg
	Diary No. Date of R & I & fee	Dy. No. 41260; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's, 30's, 60's, 120's, 180's, 360's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/1000 vildagliptin 50 mg/metformin hydrochloride 1000 mg film coated tablet. TGA approved
	Me-too status	Valiant-M Tablets by Ferozsons Labs., Nowshehra. Reg No. 77485
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
2540.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Lupride 2mg Capsule

	Composition	Each Capsule Contains: Loperamide HCL…2mg
	Diary No. Date of R & I & fee	Dy. No. 41281; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Antipropulsives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 50's, 100's, 200's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GASTRO-STOP loperamide hydrochloride 2mg capsules. TGA approved
	Me-too status	IMODIUM 2MG Capsule. Reg. No. 6159
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved.	
2541.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Speedo Sachet
	Composition	Each Sachet Contains: Macrogol 3350…13.125g Sodium Chloride…0.3507g Potassium Chloride…0.0466g Sodium Bicarbonate…0.1785g
	Diary No. Date of R & I & fee	Dy. No. 41295; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Osmotic laxative
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Movicol 13.8g sachet, powder for oral solution. Approved by MHRA
	Me-too status	Forlax Sachet. Reg. No. 82099
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2542.	Name and address of manufacturer/ Applicant	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Fedione-K 10mg/ml Injection
	Composition	Each ampoule contains: Phytomenadione…10mg
	Diary No. Date of R & I & fee	Dy. No. 41283; 07.12.2018 PKR. 20,000/-; 07.12.2018
	Pharmacological Group	Vitamin k and other hemostatics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Phytomenadione 10 mg/1 ml solution for injection (ampule). Approved by MHRA
	Me-too status	Kayvit Injection 10mg/ml. Reg. No. 65656
	GMP status	The firm was inspected on 18.07.2017 with the following conclusion: Based on the physical inspection of the unit, the technical personal met and the documents evaluated the panel concluded that the firm neutron pharma Lahore has maintained a fair level of GMP compliance as per schedule B-II of the Drugs Licensing registration and advertisement rules 1976.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
2543.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Ivaprolol 50/5 mg Tablet
	Composition	Each tablet contains: Metoprolol Tartrate…50mg Ivabradine as Hcl…5mg
	Diary No. Date of R & I & fee	Dy. No. 748; 07.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Implicor (25mg/5mg, 25mg/7.5mg, 50mg/5mg, 50mg/7.5mg) film-coated tablets. Germany approved
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator	• Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2544.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Ivaprolol 50/7.5 mg Tablet
	Composition	Each tablet contains: Metoprolol Tartrate…50mg Ivabradine as Hcl…7.5mg
	Diary No. Date of R & I & fee	Dy. No. 749; 07.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Implicor (25mg/5mg, 25mg/7.5mg, 50mg/5mg, 50mg/7.5mg) film-coated tablets. Germany approved
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator	• Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2545.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Lacosil 10mg/ml Oral Solution

	Composition	Each ml Contains: Lacosamide…10mg
	Diary No. Date of R & I & fee	Dy. No. 3710; 23.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VIMPAT oral solution contains 10 mg of lacosamide per mL. USFDA approved
	Me-too status	Lalap syrup 10mg/ml by Genix Pharma (Reg #089376)
	GMP status	GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator	•
	Decision: Approved.	
2546.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Lacosil 50mg Tablet
	Composition	Each film-coated tablet contains: Lacosamide…50mg
	Diary No. Date of R & I & fee	Dy. No. 3711; 23.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Aspire 50 mg film-coated tablets. MHRA Approved
	Me-too status	Lalap 50mg tablet. Reg. No. 70470
	GMP status	GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2547.	Name and address of manufacturer/ Applicant	M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Lacosil 100mg Tablet
	Composition	Each film-coated tablet contains: Lacosamide…100mg
	Diary No. Date of R & I & fee	Dy. No. 3712; 23.01.2019 PKR. 20,000/-; 07.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 100mg Tablet film-coated. Reg. No. 83976
	GMP status	GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2548.	Name and address of manufacturer/ Applicant	M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Omora Insta 40/1680 mg Sachet
	Composition	Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg
	Diary No. Date of R & I & fee	Dy. No. 1681; 14.01.2019 PKR. 20,000/-; 14.01.2019

	Pharmacological Group	USP
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole and sodium bicarbonate (Packet) for oral suspension. Approved by US-FDA
	Me-too status	Risek Insta Sachet by Getz Pharma (Pvt.) Ltd., Karachi Reg. No. 58548
	GMP status	The firm has been issued GMP certificate on the bsis of inspection dated 21.05.2019.
	Remarks of the Evaluator	• The firm has added 3% overage of Omeprazole with the justification to compensate loss during manufacturing.
	Decision: Deferred for scientific rationale for addition of 3% overage.	
2549.	Name and address of manufacturer/ Applicant	M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Hemobex-F Syrup
	Composition	Each 5ml Contains: Iron Polymaltose complex…50mg Folic Acid…0.35mg
	Diary No. Date of R & I & fee	Dy. No. 1683; 14.01.2019 PKR. 20,000/-; 14.01.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ferosoft-FA Syrup. Reg. No. 45110
	GMP status	The firm has been issued GMP certificate on the bsis of inspection dated 21.05.2019.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2550.	Name and address of manufacturer/ Applicant	M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Pizobex Syrup
	Composition	Each 5ml contains: Pizotifen as hydrogen maleate…0.25mg
	Diary No. Date of R & I & fee	Dy. No. 1684; 14.01.2019 PKR. 20,000/-; 14.01.2019
	Pharmacological Group	Other antimigraine preparations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	SANOMIGRAN **Elixir** 0.25mg/5ml (syrup). **MHRA** approved
	Me-too status	Aptigar Syrup (0.5mg/10ml). Reg. No. 54398
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 21.05.2019.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2551.	Name and address of manufacturer/ Applicant	M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Nymbex Forte 35/450 mg Tablet
	Composition	Each Tablet Contains: Orphenadrine Citrate…35mg Paracetamol…450mg

	Diary No. Date of R & I & fee	Dy. No. 1682; 14.01.2019 PKR. 20,000/-; 14.01.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	NORGESIC paracetamol orphenadrine citrate uncoated. TGA approved
	Me-too status	Orasic Tablets. Reg. No. 27027
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 21.05.2019.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2552.	Name and address of manufacturer/ Applicant	M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan
	Brand Name + Dosage Form + Strength	Ketafen Gel Extra
	Composition	Contains: Diclofenac diethylamine…2.32%
	Diary No. Date of R & I & fee	Dy. No. 2902; 22.01.2019 PKR. 20,000/-; 21.01.2019
	Pharmacological Group	Other dermatologicals
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	VOLTAROL EXTRA STRENGTH EMULGEL 2.32% GEL. MHRA approved VOLTAREN EMULGEL JOINT PAIN EXTRA STRENGTH (11.6% w/w, 2.32 w/w). Health Canada approved
	Me-too status	Sofac Gel 2% (DiclofenacDiethylamine23.20mgeq.toDiclofenac…20mg). Reg. No. 60356
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 21.05.2019.
	Remarks of the Evaluator	• The firm revised the label claim from Diclofenac diethylamine…2% to Diclofenac diethylamine…2.32%, and claimed submission of Rs. 5000/- fee. The fee challan and ndorsement form STO is missing. The fee for revision of strength may also be clarified by the registration Board. • Clarify whether the strength is w/w or w/v.
	Decision: Deferred for submission of fee for revision of formulation.	
2553.	Name and address of manufacturer/ Applicant	M/s Ethical Loboratories Pvt Ltd, 14 KM, Multan Road, Lahore
	Brand Name + Dosage Form + Strength	OLO 0.1% eye drop solution
	Composition	Each ml contains: Olopatadine HCL…1mg
	Diary No. Date of R & I & fee	Dy. No. 3456; 25.01.2019 PKR. 20,000/-; 25.01.2019 PKR. 20,000/-; 07.05.2020
	Pharmacological Group	Other antiallergics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Pataday twice daily relief / Patanol (olopatadine hydrochloride ophthalmic solution) 0.1%. USFDA approved.
	Me-too status	Ogate 0.1% Ophthalmic Solution. Reg. No. 75915
	GMP status	The firm was inspected on 21.11.2017, wherein renewal of DML was recommended.

	Remarks of the Evaluator	• The firm revised the dosage form in line with the reference product with submission of Rs. 20000/- fee. The fee challan has not been endorsed by the Division of Budget and accounts. • Undertaking at the end of Form 5 is missing.
	Decision: Deferred for following: • **Submission of fee for revision of formulation after getting endorsement from Budget and Account Division.** • **Submission of undertaking of Form 5.**	
2554.	Name and address of manufacturer/ Applicant	M/s Ethical Loboratories Pvt Ltd, 14 KM, Multan Road, Lahore
	Brand Name + Dosage Form + Strength	Nepafenac 0.1% suspension
	Composition	Each ml contains: Nepafenac…1mg
	Diary No. Date of R & I & fee	Dy. No. 3456; 25.01.2019 PKR. 20,000/-; 25.01.2019
	Pharmacological Group	Antiinflammatory agents, non-steroids
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	NEVANAC™ (nepafenac ophthalmic suspension) 0.1%. USFDA approved
	Me-too status	Pafnac Sterile Ophthalmic Suspension 0.1%. Reg. No. 76374
	GMP status	The firm was inspected on 21.11.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator	• Undertaking at the end of Form 5 is missing.
	Decision: Deferred for submission of undertaking of Form 5.	
2555.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Axalor Oral Syrup (5mg/5mL)
	Composition	Each 5mL syrup contains; Loratadine……5mg
	Diary No. Date of R&I& fee	Dy.No. 41450 :07.12.2018 Rs.20,000/- :06-12-2018
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	60ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Loratadine 5 mg/ 5 ml syrup. MHRA approved
	Mee too Status	Histagon Syrup 5mg/5ml. Reg. No. 28188
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2556.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Emaldine-V Tablet (5mg/160mg)
	Composition	Each film-coated tablet contains; Amlodipine (as Besylate)….5mg Valsartan……..160mg
	Diary No. Date of R&I& fee	Dy.No. : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Antihypertensives

	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 5/160. USFDA approved
	Mee too Status	VALTAN -M 165 PLUS TABLET. Reg. No. 77206
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2557.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Emaldine-V Tablet (5mg/80mg)
	Composition	Each Film coated tablet contains; Amlodipine (as Besylate)….5mg Valsartan……..80mg
	Diary No. Date of R&I& fee	Dy.No.41452 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Sepecification	USP
	Pack Size & Demanded Price	28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE 5/80 amlodipine 5mg (as besilate)/valsartan 80mg film-coated tablet. TGA approved
	Mee too Status	Amsart Plus 10mg/160mg Tablet by Macter International Karachi. Reg. No. 79547
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2558.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Emaldine-V Tablet (10mg/160mg)
	Composition	Each Film coated tablet contains; Amlodipine (as Besylate)….10mg Valsartan……..160mg
	Diary No. Date of R&I& fee	Dy.No. 41453 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Calcium channel antagonist/Angiotensin II antagonist
	Type of Form	Form-5
	Finished product Sepecification	USP
	Pack Size & Demanded Price	28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE (amlodipine and valsartan) tablets, for oral use Novartis Pharmaceuticals Corporation. US-FDA approved
	Mee too Status	Amsart Plus 10mg/160mg Tablet by Macter International Karachi. Reg. No. 79547
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein

		Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2559.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Emaldine-VH Tablet (5mg/160mg/12.5mg)
	Composition	Each Film coated tablet contains; Amlodipine (as Besylate)….5mg Valsartan……..160mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R&I& fee	Dy.No. 41454 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. US-FDA approved
	Mee too Status	Exforge HCT 5/160/12.5MG film coated. Reg. No. 69548
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2560.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Emaldine-VH Tablet (5mg/160mg/25mg)
	Composition	Each Film coated tablet contains; Amlodipine (as Besylate)….5mg Valsartan……..160mg Hydrochlorothiazide…….25mg
	Diary No. Date of R&I& fee	Dy.No. 41455 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. US-FDA approved
	Mee too Status	Exforge HCT 5/160/25MG film coated tablets by Novatris Pharma. Reg. No. 69549
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2561.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Emaldine-VH Tablet (10mg/160mg/25mg)
	Composition	Each Film coated tablet contains; Amlodipine (as Besylate)….10mg Valsartan……..160mg Hydrochlorothiazide…….25mg

	Diary No. Date of R&I& fee	Dy.No. 41457 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. US-FDA approved
	Mee too Status	Exforge HCT 10/160/25MG film coated tablets by Novatris Pharma. Reg. No. 69551
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2562.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Emaldine-VH Tablet (10mg/160mg/12.5mg)
	Composition	Each Film coated tablet contains; Amlodipine (as Besylate)….10mg Valsartan……..160mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R&I& fee	Dy.No. 41456 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. US-FDA approved
	Mee too Status	Exforge HCT 10/160/12.5MG film coated tablets by Novatris Pharma. Reg. No. 69550
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2563.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Emaldine-VH Tablet (10mg/320mg/25mg)
	Composition	Each Film coated tablet contains; Amlodipine (as Besylate)….10mg Valsartan……..320mg Hydrochlorothiazide…….25mg
	Diary No. Date of R&I& fee	Dy.No. 41458 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. US-FDA approved

	Mee too Status	Exforge HCT 10/320/25MG film coated tablets. Reg. No. 69552
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2564.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Taldine Tablet (5mg/40mg)
	Composition	Each tablet contains; Amlodipine (as Besylate)……...5mg Telmisartan……..40mg
	Diary No. Date of R&I& fee	Dy.No. 41459 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (5/40mg). USFDA approved
	Mee too Status	Ezitab-AM Tablet. Reg. No. 082041
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2565.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Taldine Tablet (5mg/80mg)
	Composition	Each tablet contains; Amlodipine (as Besylate)….5mg Telmisartan……..80mg
	Diary No. Date of R&I& fee	Dy.No. 41466 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) tablets, for oral use (5/80mg). USFDA approved
	Mee too Status	Ezitab-AM Tablet. Reg. No. 082044
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2566.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Xolidine Capsule (30mg)
	Composition	Each capsule contains;

		Duloxetine as HCl (enteric coated pellets) ….30mg
	Diary No. Date of R&I& fee	Dy.No. 41461 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	USP
	Pack Size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Dutor 30 mg gastro-resistant capsules, hard. MHRA approved
	Mee too Status	Oxcym DR 30 mg Capsule. Reg. No. 53101
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier. (Source of pellets is Vision Pharmaceuticals)
	Decision: Approved.	
2567.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Xolidine Capsule (60mg)
	Composition	Each capsule contains; Duloxetine as HCl (enteric coated pellets) ….60mg
	Diary No. Date of R&I& fee	Dy.No. 41462 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	USP
	Pack Size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Dutor 60 mg gastro-resistant capsules, hard. MHRA approved
	Mee too Status	Duloxa 60mg Capsule. Reg. No. 82093
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier. Provide COA and stability data of three batches of pellets conducted in zone IV-A. (Source of pellets is Vision Pharmaceuticals)
	Decision: Approved.	
2568.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Xolidine Capsule (20mg)
	Composition	Each capsule contains; Duloxetine as HCl (enteric coated pellets) ….20mg
	Diary No. Date of R&I& fee	Dy.No. 41463 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	USP
	Pack Size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Duloxetine 20 mg gastro-resistant capsules, hard. MHRA approved

	Mee too Status	Ambalta 20mg Capsule. Reg. No. 76630
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier. Provide COA and stability data of three batches of pellets conducted in zone IV-A. (Source of pellets is Vision Pharmaceuticals)
	Decision: Approved.	
2569.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Vee-Tin Tablet (50mg)
	Composition	Each Tablet contains; Vildagliptin ….50mg
	Diary No. Date of R&I& fee	Dy.No. 41464 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator ‘s Specification
	Pack Size & Demanded Price	28’s; as per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUS vildagliptin 50 mg tablets un-coated by Novartis Pharmaceuticals Australia Pty Ltd. TGA approved
	Mee too Status	Glavil 50mg Tablet by Atco Laboratories. Reg. No. 67245
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2570.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Relin Tablet (2mg)
	Composition	Each Tablet contains; Repaglinide…….2mg
	Diary No. Date of R&I& fee	Dy.No. 41465 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Other blood glucose lowering drugs, excl. insulins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	30’s; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Repaglinide Tablet (0.5mg, 1mg, 2mg). USFDA approved
	Mee too Status	Novonorm Tablet 2mg. Reg. No. 23601
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	

2571.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Relin Tablet (1 mg)
	Composition	Each Tablet contains; Repaglinide…….. 1 mg
	Diary No. Date of R&I& fee	Dy.No. 41466 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Other blood glucose lowering drugs, excl. insulins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Repaglinide Tablet (0.5mg, 1mg, 2mg). USFDA approved
	Mee too Status	Novonorm Tablet 1mg. Reg. No. 23602
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2572.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Relin Tablet (0.5 mg)
	Composition	Each Tablet contains; Repaglinide…….0.5 mg
	Diary No. Date of R&I& fee	Dy.No. 41467 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Other blood glucose lowering drugs, excl. insulins
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Repaglinide Tablet (0.5mg, 1mg, 2mg). USFDA approved
	Mee too Status	Novonorm Tablet 0.5mg. Reg. No. 23603
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2573.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Axtron Tablet (80 mg)
	Composition	Each Tablet contains Gliclazide……..…80 mg
	Diary No. Date of R&I& fee	Dy.No. 41468 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form-5
	Finished product Specification	BP
	Pack Size & Demanded Price	20's; as per SRO

	Approval status of product in Reference Regulatory Authorities.	Gliclazide 80 mg Tablets. MHRA approved
	Mee too Status	Db-Zide Tablets. Reg. No. 25857
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2574.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Axinate Syrup (12.5mg/4mL)
	Composition	Each 4mL contains Dimenhydrinate……..12.5 mg
	Diary No. Date of R&I& fee	Dy.No. 41469 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Antiemetics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	60ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Mee too Status	Hydrinate Liquid 12.5mg/4ml. Reg. No. 25593
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier. The international reference product has been discontinued. Provide proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2575.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Glitaride Tablet (30mg/2mg)
	Composition	Each Tablet contains Pioglitazone (asHCl)……30mg Glimipiride…….2 mg
	Diary No. Date of R&I& fee	Dy.No. 41470 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	DUETACT (pioglitazone and glimepiride) tablets uncoated (30mg/2mg, 30mg/4mg). USFDA approved
	Mee too Status	Zoliget Tablet. Reg. No. 50713
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	• Form 5 has been signed by the Manager

		Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier. • The reference product is in the form of uncoated tablet. The firm revised the formulation from film-caoted to uncoated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved.	
2576.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Glitaride Tablet (30mg/4mg)
	Composition	Each Tablet contains Pioglitazone(as HCl)…….30mg Glimipiride…..……4 mg
	Diary No. Date of R&I& fee	Dy.No. 41471 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	DUETACT (pioglitazone and glimepiride) tablets uncoated (30mg/2mg, 30mg/4mg). USFDA approved
	Mee too Status	Zoliget Tablet. Reg. No. 50713
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	• Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier. • The reference product is in the form of uncoated tablet. The firm revised the formulation from film-caoted to uncoated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved.	
2577.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Glitamet Tablet (15mg)
	Composition	Each Tablet contains Pioglitazone (as HCl)……...15mg
	Diary No. Date of R&I& fee	Dy.No. 41472 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Thiazolidinedione
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ACTOS (pioglitazone) tablets uncoated (15mg, 30mg, 45mg). USFDA approved
	Mee too Status	Piokure 15mg Tablets. Reg. No. 32631
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory.

		Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2578.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Glitamet Tablet (30mg)
	Composition	Each Tablet contains Pioglitazone(as HCl)…….30mg
	Diary No. Date of R&I& fee	Dy.No. 41473 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Thiazolidinedione
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ACTOS (pioglitazone) tablets uncoated (15mg, 30mg, 45mg). USFDA approved
	Mee too Status	Piokure 30mg Tablets. Reg. No. 32632
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2579.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Glitamet Tablet (45mg)
	Composition	Each Tablet contains Pioglitazone(as HCl)……...45mg
	Diary No. Date of R&I& fee	Dy.No. 41474 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Thiazolidinedione
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ACTOS (pioglitazone) tablets uncoated (15mg, 30mg, 45mg). USFDA approved
	Mee too Status	Piokure 45mg Tablets. Reg. No. 32633
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2580.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Glitamet Plus Tablet (15mg/500mg)
	Composition	Each Film coated Tablet contains Pioglitazone(as HCl)……15mg Metformin- HCl…….500mg

	Diary No. Date of R&I& fee	Dy.No. 41475 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET (pioglitazone and metformin hydrochloride) tablets film-coated (15mg/500mg, 15mg/850mg). USFDA approved
	Mee too Status	Diaset Plus 15mg/500mg Tablet. Reg. No. 76238
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2581.	Name and address of manufacturer / Applicant	M/s. AXIS Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name + Dosage Form + Strength	Glitamet Plus Tablet (15mg/850mg)
	Composition	Each Film coated Tablet contains Pioglitazone(as HCl)……..15mg Metformin -HCl……..….850mg
	Diary No. Date of R&I& fee	Dy.No. 41476 : 07.12.2018 Rs.20,000/- : 07.12.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	USP
	Pack Size & Demanded Price	28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ACTOPLUS MET (pioglitazone and metformin hydrochloride) tablets film-coated (15mg/500mg, 15mg/850mg). USFDA approved
	Mee too Status	Muppet 15mg/850mg Tablet. Reg. No. 76217
	GMP Status	The firm was inspected on 19.09.18 & 03.10.18, wherein the panel recommends for grant of cGMP certificate.
	Remarks of Evaluator	Form 5 has been signed by the Manager Plant/Regulatory. Upon justification, the firm submitted letter dated 11.02.2020, wherein Mr. Ghulam Murtaza (Plant / regulatory manager has been authorized to sign and submit the drug registration dossier.
	Decision: Approved.	
2582.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winlor 8mg Injection
	Composition	Each Vial Contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy. No. 1153 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	XEFO 8 mg powder and solvent for solution for injection. ANSM approved

	Me-too status	Lenor 8mg Injection. Reg. No. 83160
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	The firm submitted list of 03 products registered for contract manufacturing.
	Decision: Deferred for following: • **confirmation of manufacturing requirement of product, facility by manufacturer and also whether firm is manufacturing for itself or otherwise.** • **DML status of M/s Alen**	
2583.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Winrose Injection 100mg/5ml
	Composition	Each ampoule contains: Iron sucrose…100mg
	Diary No. Date of R & I & fee	Dy. No. 1152 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Orsec Injection 100mg/5ml. Reg. No.82559
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• Revise the label claim and salt from in line with the reference product along with submission of applicable fee. • The firm submitted list of 03 products registered for contract manufacturing.
	Decision: Deferred for DML status of M/s Alen.	
2584.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Zolid 600mg/300ml Infusion
	Composition	Each Vial Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy. No. 1151 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Antibacterials for systemic use

	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX linezolid 600mg/300mL injection infusion bag. TGA approved
	Me-too status	Oxalid Infusion 600mg/300ml. Reg. No. 82579
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• The firm submitted list of 03 products registered for contract manufacturing.
	Decision: Deferred for DML status of M/s Alen Pharmaceuticals.	
2585.	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. by M/s Bio Labs Pvt Ltd.Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Locrim 400mg Infusion
	Composition	Each 250ml Vial Contains: Moxifloxacin as Hcl…400mg
	Diary No. Date of R & I & fee	Dy. No. 1154; 09.01.2019 PKR. 50,000/-; 07.01.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. **TGA** approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	Alen Pharma: Suspension of Production activities in all Sections on 15.01.2020. Biolab: The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	• The firm submitted list of 03 products registered for contract manufacturing.
	Decision: Deferred for DML status of M/s Alen.	
2586.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan. By M/s Fynk Pharmaceuticals. 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Hemso Dry Powder Injection
	Composition	Each Vial Contains: Esomeprazole as Sodium…40mg
	Diary No. Date of R & I & fee	Dy. No.37386; 12.11.2018 PKR. 50,000/-; 12.11.2018

	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for injection vial. **TGA** approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	Applicant: The inspection report dated 28.09.2019 recommends the renewal of DML for 13 section. Manufacturer: The inspection report dated 20.09.2017 concluded that: Overall hygienic condition of firm is SATISFACTORY and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory
	Remarks of the Evaluator	• The firm submitted that no product is approved for contract manufacturing. • The firm submitted list of 03 applied products of the applicant for contract manufacturing. • The inspection report dated 28.09.2019 recommends the renewal of DML for 13 section.
	Decision: Deferred for manufacturing facility of M/s Fynk.	
2587.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan. By M/s Fynk Pharmaceuticals., 19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Hamazol Dry Powder Injection
	Composition	Each Vial Contains: Omeprazole as Sodium…40mg
	Diary No. Date of R & I & fee	Dy. No.37387; 12.11.2018 PKR. 50,000/-; 12.11.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg Powder for Solution for Injection. **MHRA** approved
	Me-too status	RISEK 40MG INJECTION. Reg. No. 45617 (does not depict injection or for injection).
	GMP status	As above
	Remarks of the Evaluator	• As above
	Decision: Deferred for manufacturing facility of M/s Fynk.	
2588.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan. By M/s Fynk Pharmaceuticals.,19km G.T. Road Kalashah Kaku, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Penzol 40mg Dry Powder Injection
	Composition	Each Vial Contains: Pantoprazole Sodium Eq. to Pantoprazole…40mg
	Diary No. Date of R & I & fee	Dy. No.37385; 12.11.2018 PKR. 50,000/-; 12.11.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PRAZOLE pantoprazole (as pantoprazole sodium) 40 mg/vial powder for injection. **TGA** approved

	Me-too status	Panpak 40mg IV Injection (vial).. Reg. No. 82763
	GMP status	As above
	Remarks of the Evaluator	• As above
	Decision: Deferred for manufacturing facility of M/s Fynk.	
2589.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Delora 5mg Tablet
	Composition	Each film-coated tablet contains: Desloratadine……5mg
	Diary No. Date of R& I & fee	Dy No. 18883: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1x10's; As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Desloratadine 5 mg film-coated tablets. **MHRA** approved
	Me-too status	Larinex Tablets 5mg. Reg. No. 39175
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2590.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Amlo 5/80 mg Tablet
	Composition	Each film-coated tablet contains: Amlodipine as Besylate…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Dy No. 18890: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's; As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 5/80. **TGA** approved
	Me-too status	VALTAN -M 85 PLUS TABLET. Reg. No. 77204
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	•
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2591.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Amlo 5/160 mg Tablet
	Composition	Each film-coated tablet contains: Amlodipine as Besylate…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 18891: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's; As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 5/160. **USFDA** approved

	Me-too status	VALTAN -M 165 PLUS TABLET. Reg. No. 77206
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2592.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Amlo 10/160 mg Tablet
	Composition	Each film-coated tablet contains: Amlodipine as Besylate…10mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 18891: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's; As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Exforge film-coated tablet 10/160. **USFDA** approved
	Me-too status	VALTAN -M 170 PLUS TABLET. Reg. No. 77207
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2593.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Benclamet 5/500 mg Tablet
	Composition	Each film-coated tablet contains: Glibenclamide…5mg Metformin Hydrochloride…500mg
	Diary No. Date of R& I & fee	Dy No. 18889: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Blood glucose lowering drugs, excl. insulins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Glucovance 5/500mg tablet, film-coated. **TGA** approved
	Me-too status	Glucovance 500mg/5mg Tablets. Reg. No. 30008
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2594.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Benclamet 2.5/500 mg Tablet
	Composition	Each film-coated tablet contains: Glibenclamide…2.5mg Metformin Hydrochloride…500mg
	Diary No. Date of R& I & fee	Dy No. 18888: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Blood glucose lowering drugs, excl. insulins
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Glucovance 2.5/500mg tablet, film-coated. **TGA** approved
	Me-too status	Glucovance 500mg/2.5mg Tablets. Reg. No. 30009
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2595.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Tirem 250mg Tablets
	Composition	Each film-coated tablet contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Dy No. 18884: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 250 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 250mg Tablets. Reg. No. 84220
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2596.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Tirem 500mg Tablets
	Composition	Each film-coated tablet contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 18885: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 500 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 500mg Tablets. Reg. No. 84221
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2597.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Bentop 25mg Tablet
	Composition	Each film-coated tablet contains: Topiramate…25mg
	Diary No. Date of R& I & fee	Dy No. 18886: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Topamax® 25 mg film-coated tablets. **MHRA** approved
	Me-too status	Erbro 25mg Tablet Tablet. Reg. No. 80384
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2598.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals Pvt Ltd. Plot # 119, Street #8, Sector I-10/3, Industrial Triangle, Islamabad
	Brand Name +Dosage Form + Strength	Bentop 100mg Tablet
	Composition	Each film-coated tablet contains: Topiramate…100mg
	Diary No. Date of R& I & fee	Dy No. 18887: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Topamax® 100 mg film-coated tablets. **MHRA** approved
	Me-too status	Topister Tablet 100mg. Reg. No. 82549
	GMP status	The firm was inspected on 08-11-2018 & 13-11-2018, wherein the grant of DML was recommended.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification since the applicant firm has transferred the premises to another site, while the application is from the old premises.	
2599.	Name and address of manufacturer / Applicant	M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Brocifen 2gm Injection IV
	Composition	Each Vial Contains: Ceftriaxone as sodium…..2g
	Diary No. Date of R& I & fee	Dy No. 18880: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 2 g powder for solution for injection/infusion. MHRA approved
	Me-too status	Cefast 2g Injection I.V. Reg. No. 82281
	GMP status	The firm was inspected on 07.11.2018 with the following conclusion: As per available manufacturing, quality control and environmental facilities provided, documentation reviewed, technical/qualified personnel employed and observations made during inspection, the firm Wellborne Hattar is considered to be operating under satisfactory level of cGMP compliance and hence recommend for the grant of cGMP certificate.
	Remarks of the Evaluator.	•
	Decision: Approved.	
2600.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Acotin Capsules 10mg

	Composition	Each Capsule Contains: Acitretin…10mg
	Diary No. Date of R & I & fee	Dy. No. 8547; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Retinoids for treatment of psoriasis (under dermatologicals)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Acitretin 10 mg Capsules, hard gelatin capsule. MHRA approved
	Me-too status	Acetin Capsules 10mg. Reg. No. 64012
	GMP status	The firm was inspected on 18 & 23.04.2019 with the following conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and Drap, Act, 2012 and rules framed there under.
	Remarks of the Evaluator	•
	Decision: Approved.	
2601.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Baropac Tablets 20mg
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg
	Diary No. Date of R & I & fee	Dy. No. 7384; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Aniotensin receptor blockers.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Olmesartan 20 mg Film-coated tablets. MHRA approved
	Me-too status	Benicar Tablets 20mg, film-coated. Reg. No. 79706
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2602.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Baropac Tablets 40mg
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg
	Diary No. Date of R & I & fee	Dy. No. 7381; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Aniotensin receptor blockers.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Olmesartan 40 mg Film-coated tablets. MHRA approved
	Me-too status	Benicar Tablets 40mg, film-coated. Reg. No. 79711.
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2603.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Betabam 10mg Tablets

	Composition	Each tablet contains Bambuterol Hcl…10mg
	Diary No. Date of R & I & fee	Dy. No. 7383; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator specifications
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bambec Tablets 10mg, uncoated. MHRA approved
	Me-too status	Bambu 10mg Tablets. Reg. No. 68420
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2604.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bidilol Tablets 3.125mg
	Composition	Each Film Coated oral Tablet Contains: Carvedilol…3.125mg
	Diary No. Date of R & I & fee	Dy. No. 7389; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Carvedilol 3.125 mg Film-coated Tablets by Milpharm Limited. **MHRA** approved
	Me-too status	Delaware 3.125mg Tablet by Efroze Chemical Industries. Reg. No. 55009. **The data does not depict film-coating**
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2605.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bidilol Tablets 12.5mg
	Composition	Each Film Coated oral Tablet Contains: Carvedilol…12.5mg
	Diary No. Date of R & I & fee	Dy. No. 7385; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Carvedilol 12.5 mg Film-coated Tablets by Generics [UK] Limited t/a Mylan. MHRA approved
	Me-too status	Carlol 12.5mg Tablets by Nabiqasim Industries. Reg. No. 39708
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2606.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bidilol Tablets 25mg
	Composition	Each Film Coated oral Tablet Contains: Carvedilol…25mg

	Diary No. Date of R & I & fee	Dy. No. 7387; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Carvedilol 25 mg Film-coated Tablets by Generics [UK] Limited t/a Mylan. **MHRA** approved
	Me-too status	Carlol 25mg Tablets by Nabiqasim Industries. Reg. No. 39405
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2607.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bidilol Tablets 6.25mg
	Composition	Each Film Coated oral Tablet Contains: Carvedilol…6.25mg
	Diary No. Date of R & I & fee	Dy. No. 7386; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Carvedilol 6.25 mg Film-coated Tablets by Generics [UK] Limited t/a Mylan. MHRA approved
	Me-too status	Carlol 6.25mg Tablets by Nabiqasim Industries. Reg. No. 39707
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2608.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Biokast 10mg Tablet
	Composition	Each tablet contains Zafirlukast…10mg
	Diary No. Date of R & I & fee	Dy. No. 5673; 08.02.2019 PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator specifications
	Pack size & Demanded Price	28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACCOLATE® (zafirlukast) TABLETS 10mg, 20mg film coated tablet. USFDA approved
	Me-too status	"Upkast Tablets 10mg. Reg. No. 47419
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2609.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Biokast 20mg Tablet
	Composition	Each tablet contains Zafirlukast…20mg
	Diary No. Date of R & I & fee	Dy. No. 5674; 08.02.2019

		PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator specifications
	Pack size & Demanded Price	28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACCOLATE® (zafirlukast) TABLETS 10mg, 20mg film coated tablet. USFDA approved
	Me-too status	Xasthma 20mg Tablet. Reg. No. 53059
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2610.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bioromate 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate…100mg
	Diary No. Date of R & I & fee	Dy. No. 7391; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Topamax® 100 mg film-coated tablets. **MHRA** approved
	Me-too status	Topister Tablet 100mg. Reg. No. 82549
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2611.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bioromate 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate…200mg
	Diary No. Date of R & I & fee	Dy. No. 7392; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Topiramate Milpharm 200 mg film-coated tablets. **MHRA** approved
	Me-too status	Tics 200mg Tablet . Reg. No. 55478
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2612.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Biostan 160mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…160mg
	Diary No. Date of R & I & fee	Dy. No. 4888; 04.02.2019 PKR. 20,000/-; 04.02.2019

	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Valsartan 160mg Film-coated tablets. MHRA approved
	Me-too status	Valseta 160mg Tablet, film-coated. Reg. No. 83348
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2613.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bucef Capsules 400mg
	Composition	Each Capsule Contains: Ceftibuten dihydrate eq to Ceftibuten…400mg
	Diary No. Date of R & I & fee	Dy. No. 8547; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ISOCEF 400 mg (containing ceftibuten base) capsule rigide. approved by AIFA, Italy
	Me-too status	Zinir 400mg Capsule by S.J. & G. Fazul Ellahie (Pvt) Ltd. Reg. No. 80796
	GMP status	As above
	Remarks of the Evaluator	• Ceftibute 400 mg Capsule (Ceftibuten as dihydrate) of M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Lahore has been approved in 279th meeting of RB with the following facts: • Discontinued in USFDA. □ SMPC of CEDAX 400mg capsule in USFDA states API as Ceftibuten (as dihydrate) • Approved in ITALY □ SMPC of CEDAX 400mg capsule in Italy states API as Ceftibuten base • Manufacturers of product in both countries are different. □ SMPC of CEDAX 90mg/5ml and 180mg/5ml dry suspension which is discontinued in USFDA not for safety or efficacy reasons states API as Ceftibuten (as dihydrate)
	Decision: Deferred for clarification of applied formulation in the light of reference formulations approved by various reference regulatory authorities.	
2614.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Ciclorine Capsule 250mg
	Composition	Each Capsule Contains: Cycloserine…250mg
	Diary No. Date of R & I & fee	Dy. No. 5396; 07.02.2019 PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	USP

	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CYCLOSERINE 250mg capsule. MHRA approved
	Me-too status	Xerine 250mg Capsules. Reg. No. 84201
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved with protective measures for workers.	
2615.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Conazole 200mg Tablet
	Composition	Each Tablet Contains: Ketoconazole…200mg
	Diary No. Date of R & I & fee	Dy. No. 4896; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	Imidazole derivatives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NIZORAL® (KETOCONAZOLE) TABLETS, uncoated. USFDA approved
	Me-too status	Kenazol 200 mg Tablet. Reg. No. 81173
	GMP status	As above
	Remarks of the Evaluator	
	Decision: Deferred for regulatory status in reference regulatory authorities.	
2616.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Desfaxine 100mg Tablets
	Composition	Each extended release tablet contains Desvenlafaxine succinate…100mg
	Diary No. Date of R & I & fee	Dy. No. 8551; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pristiq extended release tablets 100mg (film-coated). USFDA approved
	Me-too status	Denla XR 100mg Tablet. Reg. No. 70434 (Does not depict coating)
	GMP status	As above
	Remarks of the Evaluator	• Revise Desvenlafaxine succinate to Desvenlafaxine as succinate monohydrate in the label claim
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2617.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Desfaxine 50mg Tablets
	Composition	Each extended release tablet contains Desvenlafaxine succinate…50mg
	Diary No. Date of R & I & fee	Dy. No. 8550; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications

	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pristiq extended release tablets 50mg (film-coated). USFDA approved
	Me-too status	Denla XR 50mg Tablet. Reg. No. 70433 (Does not depict coating)
	GMP status	As above
	Remarks of the Evaluator	• Revise Desvenlafaxine succinate to Desvenlafaxine as succinate monohydrate in the label claim
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2618.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	E-Steine Capsules 150mg
	Composition	Each Capsule Contains: Erdosteine…150mg
	Diary No. Date of R & I & fee	Dy. No. 8544; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Mucolytics
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ERDOTIN 150 MG CAPSULE RIGIDE. AIFA approved
	Me-too status	Dostin Capsules 150mg. Reg. No. 32332
	GMP status	As above
	Remarks of the Evaluator	
	Decision: Approved.	
2619.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Feloxacine Tablets 400mg
	Composition	Each film-coated tablet contains: Lomefloxacin Hcl…400mg
	Diary No. Date of R & I & fee	Dy. No. 7379; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Maxaquin® lomefloxacin (as hydrochloride) film-coated tablets 400mg. TGA approved
	Me-too status	Lomedin Tablets 400mg. Reg No. 28668 (does not depict film-coating)
	GMP status	As above
	Remarks of the Evaluator	• Revise Lomefloxacin Hcl to Lomefloxacin as Hcl in the label claim
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2620.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Fenozet Capsules 67mg
	Composition	Each Capsule Contains: Fenofibrate (micronized)…67mg
	Diary No. Date of R & I & fee	Dy. No. 8545; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Lipid modifying agents, plain

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fenofibrate (micronized) 67 mg capsules. MHRA approved
	Me-too status	Lipidof 67 Capsule. Reg. No. 33164
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2621.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Fixetin Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Fluoxetine as HCL…10mg
	Diary No. Date of R & I & fee	Dy. No. 8549; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SARAFEM (fluoxetine as hydrochloride 10mg, 15mg, 20mg uncoated tablets). USFDA approved
	Me-too status	Futine 10 mg Tab. Reg. No. 44602 (Fluoxetine HCL…10mg)
	GMP status	As above
	Remarks of the Evaluator	• Provide proof of reference product (film-coated tablet) in reference regulatory agencies as defined in 275th meeting of the registration Board. Otherwise, revise the formulation (label claim, composition and manufacturing outlines) to uncoated tablet, along with submission of applicable fee. • Provide proof of approval of me-too product (name and registration number) approved by DRAP.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2622.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Flunaz Capsules 50mg
	Composition	Each Capsule Contains: Fluconazole…50mg
	Diary No. Date of R & I & fee	Dy. No. 8547; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Triazole derivatives
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azocan 50mg Capsules. MHRA approved
	Me-too status	Fungon Capsules 50mg. Reg. No. 55352
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2623.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Levesei Tablets 1000mg
	Composition	Each Film Coated oral Tablet Contains: Levetiracetam…1000mg

	Diary No. Date of R & I & fee	Dy. No. 7388; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam Zentiva 1000 mg film-coated tablets. MHRA approved
	Me-too status	Elicia 1000mg Tablet, film-coated. Reg. No. 81157
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2624.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Levesei Tablets 750mg
	Composition	Each Film Coated oral Tablet Contains: Levetiracetam…750mg
	Diary No. Date of R & I & fee	Dy. No. 7380; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 750 mg film-coated tablets. **MHRA** approved
	Me-too status	Levotam film-coated 750mg Tablets. Reg. No. 55641
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2625.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Macepril 1.25mg Tablet
	Composition	Each Tablet Contains: Ramipril…1.25mg
	Diary No. Date of R & I & fee	Dy. No. 4891; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ramipril 1.25 mg Tablets, uncoated. MHRA approved
	Me-too status	Lipra 1.25mg Tablet Reg. No. 67366
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2626.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Macepril 10mg Tablet
	Composition	Each Tablet Contains: Ramipril…10mg
	Diary No. Date of R & I & fee	Dy. No. 4892; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	ACE inhibitors, plain

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ramipril 10 mg Tablets, uncoated. MHRA approved
	Me-too status	Lipra 10mg Tablet Reg. No. 67369
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2627.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Macepril 2.5mg Tablet
	Composition	Each Tablet Contains: Ramipril…2.5mg
	Diary No. Date of R & I & fee	Dy. No. 4893; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ramipril 2.5 mg Tablets, uncoated. MHRA approved
	Me-too status	Lipra 2.5mg Tablet Reg. No. 67367
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2628.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Macepril 5mg Tablet
	Composition	Each Tablet Contains: Ramipril…5mg
	Diary No. Date of R & I & fee	Dy. No. 4894; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ramipril 5 mg Tablets, uncoated. MHRA approved
	Me-too status	Lipra 5mg Tablet Reg. No. 67368
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2629.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Mucosteine Capsules 375mg
	Composition	Each Capsule Contains: Carbocisteine…375mg
	Diary No. Date of R & I & fee	Dy. No. 8548; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Mucolytics
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Carbocisteine 375 mg Capsules. MHRA approved

	Me-too status	Carbocisteine 375 mg Capsules. Reg. No. 5112
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2630.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	P-Convul 400mg Capsules
	Composition	Each Capsule Contains: Piracetam…400mg
	Diary No. Date of R & I & fee	Dy. No. 8546; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	UCETAM CAPSULES 400MG. Reg. No. 21955
	GMP status	As above
	Remarks of the Evaluator	• Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2631.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Pinrole 0.25mg Tablet
	Composition	Each film coated release tablet contains: Ropinirole as HCl…0.25mg
	Diary No. Date of R & I & fee	Dy. No. 5400; 07.02.2019 PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	21's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	REQUIP (ropinirole) 0.25mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Balans 0.25mg Tablet. Reg No. 50557
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2632.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Pinrole 1mg Tablet
	Composition	Each film coated release tablet contains: Ropinirole as HCl…1mg
	Diary No. Date of R & I & fee	Dy. No. 5397; 07.02.2019 PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	21's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	REQUIP (ropinirole) 1mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Balans 1mg Tablet. Reg No. 50564

	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2633.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Pinrole 2mg Tablet
	Composition	Each film coated release tablet contains: Ropinirole as HCl…2mg
	Diary No. Date of R & I & fee	Dy. No. 5397; 07.02.2019 PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	21's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	REQUIP (ropinirole) 2mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Balans 2mg Tablet. Reg No. 50558
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2634.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Sarcard 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…150mg
	Diary No. Date of R & I & fee	Dy. No. 4895; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10,s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVAPRO® (irbesartan) uncoated tablets 75mg, 150mg, 300mg, for oral use. USFDA approved ABISART 150 irbesartan 75mg, 150mg and 300mg film-coated tablet blister pack. TGA approved.
	Me-too status	Irbisaff Tablet. Reg. No. 77189
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2635.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Sarcard 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…300mg
	Diary No. Date of R & I & fee	Dy. No. 4889; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10,s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVAPRO® (irbesartan) uncoated tablets 75mg, 150mg, 300mg, for oral use. USFDA approved ABISART 150 irbesartan 75mg, 150mg and 300mg film-coated tablet blister pack. TGA approved.
	Me-too status	Irbisaff Tablet 300mg. Reg. No. 77188

	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2636.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Sarcard 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…75mg
	Diary No. Date of R & I & fee	Dy. No. 4890; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10,s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVAPRO® (irbesartan) uncoated tablets 75mg, 150mg, 300mg, for oral use. USFDA approved ABISART 150 irbesartan 75mg, 150mg and 300mg film-coated tablet blister pack. TGA approved.
	Me-too status	Irbest Tablets 75mg. Reg. No. 59783
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2637.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Sivast 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Simvastatin…40mg
	Diary No. Date of R & I & fee	Dy. No. 4897; 04.02.2019 PKR. 20,000/-; 04.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 49's, 50's, 56's, 60's, 84's, 90's, 98's, 100's, 205's, 1000's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZOCOR (simvastatin) tablets, film-coated (5mg, 10mg, 20mg, 40mg, 80mg). USFDA approved
	Me-too status	Simvoget 40Mg Tablets. Reg. No. 39735
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2638.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Slimostat Capsules 60mg
	Composition	Each Capsule Contains: Orlistat…60mg
	Diary No. Date of R & I & fee	Dy. No. 8543; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	Peripherally acting antiobesity products
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Beacita 60mg Capsules, hard. **MHRA** approved
	Me-too status	OSKER 60mg Capsule. Reg. No. 66787
	GMP status	As above

	Remarks of the Evaluator	• Submit all the requirements of orlistat pellets including stability data.
	Decision: Deferred for further deliberation upon requirement of accelerated stability studies data of Orlistat IR pellets.	
2639.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	STC Tranxet Injection 500mg/5ml
	Composition	Each 5ml contains: Tranexamic Acid…500mg
	Diary No. Date of R & I & fee	Dy. No. 7382; 20.02.2019 PKR. 20,000/-; 19.02.2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	5ml (ampule) x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRANEXAMIC ACID IV APOTEX tranexamic acid 500 mg/5 mL solution for injection vial. TGA approved
	Me-too status	Enxamin Injection 500mg. Reg. No. 52925
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2640.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Sulpide 200mg Tablet
	Composition	Each Tablet Contains: Amisulpride…200mg
	Diary No. Date of R & I & fee	Dy. No. 5399; 07.02.2019 PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Benzamides
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SOLIAN 200 amisulpride 200 mg uncoated tablet. TGA approved
	Me-too status	SOLIAN TABLETS 200MG. Reg No. 21112
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2641.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Sulpide 400mg Tablet
	Composition	Each Tablet Contains: Amisulpride…400mg
	Diary No. Date of R & I & fee	Dy. No. 5398; 07.02.2019 PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Benzamides
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SOLIAN 200 amisulpride 200 mg **uncoated** tablet. TGA approved SOLIAN 400 amisulpride 400 mg **film-coated** tablet. TGA approved
	Me-too status	Amiride Tablet 400mg. Reg No. 63103

	GMP status	As above
	Remarks of the Evaluator	
	Decision: Approved.	
2642.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Sulpide 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R & I & fee	Dy. No. 5401; 07.02.2019 PKR. 20,000/-; 07.02.2019
	Pharmacological Group	Benzamides
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SOLIAN 50 amisulpride 50 mg uncoated tablet. TGA approved
	Me-too status	Ampisol 50mg Tablet. Reg No. 76060
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2643.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Torvastatin 40mg Tablets
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate…40mg
	Diary No. Date of R & I & fee	Dy. No. 8547; 26.02.2019 PKR. 20,000/-; 25.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
	Me-too status	Fatilor 40mg Tablet by Lisko Pakistan Ltd. Reg No. 58163 (does not depict film-coating)
	GMP status	As above
	Remarks of the Evaluator	•
	Decision: Approved.	
2644.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 5/10mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……5mg Atorvastatin as calcium trihydrate……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 40763 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg,

		10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Zodip Plus 10 Tablet. Reg. No. 59794
	GMP status	GMP Inspection of the firm was conducted on 04-03-2019 with the following conclusion: All the observations pointed out during inspection were discussed with the management of the firm and they were committed to overcome before next periodic inspection. Based on the above observations and keeping in view their attitude for better compliance, their current compliance level is rated as Good.
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Submission of complete outline of method of manufacturing** • **Revision of formulation as per the reference product along with submission of requisite fee.**	
2645.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 5/20mg
	Composition	Each film coated tablet contains Amlodipine as besylate……..5mg Atorvastatin as calcium trihydrate……..…20mg
	Diary No. Date of R& I & fee	Dy. No. 40764 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Zodip Plus 20 Tablet. Reg. No. 59795
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Submission of complete outline of method of manufacturing** • **Revision of formulation as per the reference product along with submission of requisite fee.**	
2646.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 5/40mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……5mg Atorvastatin as calcium trihydrate……40mg

	Diary No. Date of R& I & fee	Dy. No. 40765 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Co-Atorap 5/40 Tablet. Reg. No. 55142 (does not depict film-coating)
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Submission of complete outline of method of manufacturing** • **Revision of formulation as per the reference product along with submission of requisite fee.**	
2647.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 10/10mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……10mg Atorvastatin as calcium trihydrate……10mg
	Diary No. Date of R& I & fee	Dy. No. 40766 : 06.12.2018, Rs.20`,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Corsafe AT 10/10 Tablets. Reg. No. 68320
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Submission of complete outline of method of manufacturing** • **Revision of formulation as per the reference product along with submission of requisite fee.**	
2648.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 10/20mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……10mg Atorvastatin as calcium trihydrate……20mg
	Diary No. Date of R& I & fee	Dy. No. 40767 : 06.12.2018, Rs. 20,000: 06.12.2018

	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Corsafe AT 10/20 Tablets. Reg. No. 68321
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Submission of complete outline of method of manufacturing** • **Revision of formulation as per the reference product along with submission of requisite fee.**	
2649.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Liptramide Tablet 10/40mg
	Composition	Each Film coated tablet contains Amlodipine as besylate……10mg Atorvastatin as calcium trihydrate……40mg
	Diary No. Date of R& I & fee	Dy. No. 40768 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & 1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Co-Atorap 10/40 Tablet. Reg. No. 50589 (does not reveal film-coating)
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned atorvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Submission of complete outline of method of manufacturing** • **Revision of formulation as per the reference product along with submission of requisite fee.**	
2650.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Fludecan Injection 25mg/ml
	Composition	Each ml contains Fluphenazine decanoate ……25mg
	Diary No. Date of R& I & fee	Dy. No. 40766 : 06.12.2018, Rs. 20,000: 06.12.2018 Daed 06.12.2018
	Pharmacological Group	Phenothiazines with piperazine structure

	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml x 1's Ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	Modecate Injection 25mg/ml (0.5ml, 1ml, 2ml) for IM use. MHRA Approved
	Me-too status	Fenzitec Depot Injection. Reg. No. 73773
	GMP status	As above
	Remarks of the Evaluator	• Terminal sterilization process is missing in the manufacturing outlines.
	Decision: Deferred for submission of detailed method of sterilization.	
2651.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dibilo M 1/500 Tablet
	Composition	Each tablet contains Glimepride ……..……..1mg Metformin HCl……..……..500mg
	Diary No. Date of R& I & fee	Dy. No. 40769 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Sulfonylureas + Biguanides
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Diabold Plus Tablet (film-coated). Reg. No. 76011 GPRIDE-M SR 1/500mg tablet (bilayer). Reg. No. 76306
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim and submission of applicable is required. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2652.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dibilo M 2/500 Tablet
	Composition	Each tablet contains Glimepride ……..2mg Metformin HCl……..500mg
	Diary No. Date of R& I & fee	Dy. No. 40770 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Biguanide / Sulphonylurea
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Diabold Plus Tablet (film-coated). Reg. No. 76012 GPRIDE-M SR 2/500mg tablet (bilayer). Reg. No. 76307
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim and submission of applicable is required. • Blistering and packing process is missing in the manufacturing outlines.

	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2653.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aretemac Injection 30mg
	Composition	Each vial of dry substance contains: Artesunate……..…30mg
	Diary No. Date of R& I & fee	Dy. No. 40771 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Artemisinin and derivatives, plain
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified
	Me-too status	Artebrain Injection 30mg. Reg. No. 85071
	GMP status	As above
	Remarks of the Evaluator	
	Decision: Approved.	
2654.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aretemac Injection 120mg
	Composition	Each vial of dry substance contains Artesunate…….……..……120mg
	Diary No. Date of R& I & fee	Dy. No. 40772 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Artemisinin and derivatives, plain
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO Approved formulation
	Me-too status	Artebrain Injection 120mg. Reg. No. 85069
	GMP status	As above
	Remarks of the Evaluator	
	Decision: Approved.	
2655.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sodium Chloride 0.9% w/v 10ml Ampoules
	Composition	Each 10ml contains Sodium Chloride……..…90mg
	Diary No. Date of R& I & fee	Dy. No. 40773 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10mlx1's As per SRO
	Approval status of product in Reference Regulatory Authorities	Sodium Chloride Injection BP 0.9% w/v in type I clear glass ampoules (2ml, 5ml, 10ml and 20ml). MHRA approved
	Me-too status	Soride of M/s Bosch Pharma
	GMP status	As above
	Remarks of the Evaluator	• Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for submission of detailed method of sterilization.	

2656.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sodium Chloride 0.9% w/v 2.5ml Ampoules
	Composition	Each 2.5ml contains Sodium Chloride……22.5mg
	Diary No. Date of R& I & fee	Dy. No. 40774 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Sodium Chloride 0.9% Injection (10ml). Reg. No. 84871
	GMP status	As above
	Remarks of the Evaluator	Provide evidence of approval of applied formulation (same filled volume) in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of detailed method of sterilization.**	
2657.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sericalm Injection 50mg/ml
	Composition	Each ml contains Haloperidol as decanoate……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 40775 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Butyrophenone derivatives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's Ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	HALDOL® 50, 100 (haloperidol as decanoate) For IM Injection Only (1ml ampule). USFDA Approved with box warning
	Me-too status	Seredol Depot Injection (1ml). Reg. No. 60600
	GMP status	As above
	Remarks of the Evaluator	• Revise "Haloperidol decanoate" to "Haloperidol as decanoate" in the label claim • Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of detailed method of sterilization.**	
2658.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lorsafe Tablet 4mg
	Composition	Each film coated tablet contains Lornoxicam……4mg
	Diary No. Date of R& I & fee	Dy. No. 40777 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Oxicams

	Type of Form	Form 5
	Finished product Specification	In house
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg Filmtabletten (Swiss Medic approved)
	Me-too status	Noxilor Tablet. Reg. No. 84039
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	
2659.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lorsafe Tablet 8mg
	Composition	Each film coated tablet contains Lornoxicam……..…8mg
	Diary No. Date of R& I & fee	Dy. No. 40778 : 06.12.2018, Rs. 20,000: 06.12.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished product Specification	In house
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Film tabletten. Swiss Medic Approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	
2660.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	S Vant Tablet 8mg
	Composition	Each Tablet contains Candesartan Cilexetil……..…8mg
	Diary No. Date of R& I & fee	Dy. No. 41953: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Angiotensin II antagonists, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND® (candesartan cilexetil) 8 mg non-film-coated tablets, for oral use by ANI Pharms Inc. US-FDA approved
	Me-too status	Cansart 8mg Tablets by CCL Pharma. Reg. No. 82665
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	
2661.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	S Vant Tablet 16mg
	Composition	Each Tablet contains Candesartn Cilexetil……..…16mg
	Diary No. Date of R& I & fee	Dy. No. 41954: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Angiotensin II antagonists, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 14's As per SRO

	Approval status of product in Reference Regulatory Authorities	ATACAND® (candesartan cilexetil) 16 mg non-film-coated tablets, for oral use. US-FDA approved
	Me-too status	Cansart Tablets by CCL Pharma. Reg. No. 33953
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	
2662.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Beca Tablet 60mg
	Composition	Each Tablet contains: Etoricoxib……60mg
	Diary No. Date of R& I & fee	Dy. No. 41955: 07.12.2018 Rs. 20,000
	Pharmacological Group	Coxibs
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Etoricoxib 60 mg Film-coated Tablets. MHRA approved
	Me-too status	Eto 60 mg Tablet. Reg. No. 78176
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Provide finished product specifications. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of finished product specification.** • **Submission of complete outline of method of manufacturing.**	
2663.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Samide Tablet 50mg
	Composition	Each Tablet contains Lacosamide……50mg
	Diary No. Date of R& I & fee	Dy. No. 41956: 07.12.2018 Rs. 20,000
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	Lacosamide Aspire 50 mg film-coated tablets by Aspire Pharma Limited. MHRA Approved
	Me-too status	Lalap 50mg tablet. Reg. No. 70470
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.**	

	• **Submission of complete outline of method of manufacturing.**	
2664.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Samide Tablet 100mg
	Composition	Each Tablet contains Lacosamide……100mg
	Diary No. Date of R& I & fee	Dy. No. 41956: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Sodium Channel Inactivator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 100mg Tablet film-coated. Reg. No. 83976
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2665.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Kulb Plus Tablet 50mg/12.5mg
	Composition	Each Tablet contains Losartan Potassium ……..……50mg Hydrochlorothiazide……..…12.5mg
	Diary No. Date of R& I & fee	Dy. No. 41959: 07.12.2018 Rs.20,000: 07.12.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	FORTZAAR 50 mg / 12.5 mg film-coated tablets. ANSM approved
	Me-too status	Rosar-H Tablets. Reg. No. 64218
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2666.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	R-Tatin Tablet 5mg
	Composition	Each Film coated tablet contains Rosuvastatin (as calcium)……5mg
	Diary No. Date of R& I & fee	Dy. No. 41960: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 5mg film-coated tablets. MHRA approved
	Me-too status	Rostat 5mg Tablet. Reg. No. 55729
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned rosuvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2667.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	R-Tatin Tablet 10mg
	Composition	Each Film coated tablet contains Rosuvastatin (as calcium)……10mg
	Diary No. Date of R& I & fee	Dy. No. 41961: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 10mg film-coated tablets. MHRA approved
	Me-too status	Rosan 10mg Tablet. Reg. No. 81462
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned rosuvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2668.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	R-Tatin Tablet 20mg
	Composition	Each Film coated tablet contains Rosuvastatin (as calcium)……20mg
	Diary No. Date of R& I & fee	Dy. No. 41962: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 20mg film-coated tablets. MHRA approved
	Me-too status	Rostat 20mg Tablet. Reg. No. 55731
	GMP status	As above
	Remarks of the Evaluator	Adjust the weight of APIs as per salt factor in master formula only. Provide finished product specifications. Blistering and packing process is missing in the manufacturing

		outlines. The firm has mentioned rosuvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.** • **Submission of finished product specification** • **Submission of master formulation in line with the reference product**	
2669.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	R-Tatin Tablet 40mg
	Composition	Each Film coated tablet contains Rosuvastatin (as calcium)……..…40mg
	Diary No. Date of R& I & fee	Dy. No. 41963: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 40mg film-coated tablets. MHRA approved
	Me-too status	Rosugen Tablet 40mg. Reg. No. 84109
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines. • The firm has mentioned rosuvastatin (base) in Form 5. However, the correct salt form has been mentioned in composition and master formula.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2670.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Thicoside Capsule 4mg
	Composition	Each capsule contains Thiocolchicoside……..…4mg
	Diary No. Date of R& I & fee	Dy. No 41964: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	MIOREL 4 mg capsule. ANSM approved
	Me-too status	Muscucoside capsule 4mg. Reg. No. 81656
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	
2671.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Iron Fort Syrup
	Composition	Each 5ml contains Ferric Ammonium citrate …1000mg

		Folic Acid……..11mg Pyridoxine HCl....……...48mg Thiamine HCl…….…..…...24mg Nicotinamide……..……220mg
	Diary No. Date of R& I & fee	Dy. No. 41965: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Iron with multi-Vitamins
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	200ml Bottle 1's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	As above
	Remarks of the Evaluator	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Provide proof of approval of me-too product (name registration number and name of company) with same composition same strength and same salt form(s) by DRAP. • Packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Submission of complete outline of method of manufacturing.**	
2672.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Cerin Capsule 50mg
	Composition	Each Capsule contains Diacerein……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 41966: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	ART 50 mg capsule. ANSM approved
	Me-too status	Diora 50mg Capsule. Reg. No. 67631
	GMP status	As above
	Remarks of the Evaluator	• Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	
2673.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ocedophine Tablet 400/60mg
	Composition	Each Tablet contains Ibuprofen……..……...400mg Pseudoephedrine……60mg
	Diary No. Date of R& I & fee	Dy. No. 41967: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic Acid and sympathomimetics
	Type of Form	Form-5
	Finished product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lasynac Max Strength 400mg/60mg film coated tablets. MHRA Approved
	Me-too status	Irofen Forte Tablets. Reg. No. 42233
	GMP status	As above
	Remarks of the Evaluator	• The firm revised "Pseudoephedrine" to "Pseudoephedrine HCl" in composition. Revision of label claim is required along with submission of applicable fee. • Revision of formulation to film-coated tablet is required. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2674.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Gaba Capsule 100mg
	Composition	Each capsule contains Gabapentin……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 41968: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 100mg Capsules. MHRA approved
	Me-too status	Pentowan 100mg Capsule. Reg. No. 79688
	GMP status	As above
	Remarks of the Evaluator	Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	
2675.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Gaba Capsule 300mg
	Composition	Each Capsule contains Gabapentin……..…300mg
	Diary No. Date of R& I & fee	Dy. No. 41969: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 300mg Capsules. MHRA approved
	Me-too status	Pentowan 300mg Capsule. Reg. No. 82103
	GMP status	As above
	Remarks of the Evaluator	Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	

2676.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Gaba Capsule 400mg
	Composition	Each Capsule contains Gabapentin……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 41970: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Gabapentin 400mg Capsules. MHRA approved
	Me-too status	NEURONTIN CAPSULES 400mg. Reg. No. 16141
	GMP status	As above
	Remarks of the Evaluator	Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of complete outline of method of manufacturing.	
2677.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dexi Tablet 200mg
	Composition	Each film-coated tablet contains: Dexibuprofen ……200mg
	Diary No. Date of R& I & fee	Dy. No. 41971: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 200 mg film-coated tablets MHRA Approved
	Me-too status	Haltrin 200mg Tablet. Reg. No. 61068
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2678.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dexi Tablet 300mg
	Composition	Each film-coated tablet contains: Dexibuprofen ……300mg
	Diary No. Date of R& I & fee	Dy. No. 41972: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 300 mg film-coated tablets MHRA Approved
	Me-too status	Tercica 300mg Tablet. Reg. No. 58445
	GMP status	As above

	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2679.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dexi Tablet 400mg
	Composition	Each film-coated tablet contains: Dexibuprofen ……..…400mg
	Diary No. Date of R& I & fee	Dy. No. 41973: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 400 mg film-coated tablets MHRA Approved
	Me-too status	Tercica 400mg Tablet. Reg. No. 58446
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition and manufacturing outlines to film-coated tablet. Revision of label claim is required along with submission of applicable fee. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2680.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Dexi Syrup 100mg.5ml
	Composition	Each 5ml contains Dexibuprofen ……..…100mg
	Diary No. Date of R& I & fee	Dy. No. 41974: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	120ml & 60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	As above
	Remarks of the Evaluator	• Packing process is missing in the manufacturing outlines. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Provide proof of approval of me-too product (name registration number and name of company) with same formulation and same strength by DRAP.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies**	

	which were adopted by the Registration Board in its 275th meeting. • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Submission of complete outline of method of manufacturing.**	
2681.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ceral Tablet 6.4mg
	Composition	Each Film coated tablet contains Glycerol Trinitrate……..…6.4mg
	Diary No. Date of R& I & fee	Dy. No. 41975: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Organic nitrates
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Sustac 6.4mg prolonged release tablet. MHRA Approved
	Me-too status	Slotac S.Rtablet 6.4mg. Reg. No. 25168
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition to prolonged release tablet. Revision of label claim is required along with submission of applicable fee. • The firm revised glycerol to Glyceryl throughout the dossier. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2682.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ceral Tablet 2.6mg
	Composition	Each Film coated tablet contains Glycerol Trinitrate……..…2.6mg
	Diary No. Date of R& I & fee	Dy. No. 41976: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Organic nitrates
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Sustac 2.6mg prolonged release tablet. MHRA Approved
	Me-too status	Slotac S.Rtablet 6.4mg. Reg. No. 25167
	GMP status	As above
	Remarks of the Evaluator	• The firm revised the composition to prolonged release tablet. Revision of label claim is required along with submission of applicable fee. • The firm revised glycerol to Glyceryl throughout the dossier. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	

2683.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Soritic Tablet 20/12.5mg
	Composition	Each Tablet contains Lisinopril as dihydrate……..…20mg Hydrochlorothiazide……...12.5mg
	Diary No. Date of R& I & fee	Dy. No. 41978: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2 x 14's As per SRO
	Approval status of product in Reference Regulatory Authorities	Lisoretic 20 mg/12.5 mg Tablets, uncoated, MHRA approved
	Me-too status	Acinopril Plus Tablets. Reg. No. 76830
	GMP status	As above
	Remarks of the Evaluator	• Revise "Lisinopril dihydrate" to "Lisinopril as dihydrate" in the label claim. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2684.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sodium Bicarbonate 5% w/v Injection (0.5ml)
	Composition	Each 1ml contains Sodium Bicarbonate……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 41979: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	Electrolyte solutions
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	0.5ml Ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Sodium Bicarbonate Injection. Reg. No. 76428 (does not specify the pack volume)
	GMP status	As above
	Remarks of the Evaluator	• Provide evidence of approval of applied formulation (same filled volume) in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of detailed method of sterilization.**	
2685.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sodium Bicarbonate 5% w/v Injection (1ml)
	Composition	Each 1ml contains Sodium bicarbonate……50mg
	Diary No. Date of R& I & fee	Dy. No. 41980: 07.12.2018 Rs. 20,000: 07.12.2018

	Pharmacological Group	Electrolyte solutions
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml Ampoule As per SRO
	Approval status of product in Reference Regulatory Authorities	The product is present in 1ml pack size (50mg/ml) in combo pack of Artesunate injection. W.H.O. prequalified.
	Me-too status	Sodium Bicarbonate Injection. Reg. No. 76428 (does not specify the pack volume)
	GMP status	As above
	Remarks of the Evaluator	Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for submission of detailed method of sterilization.	
2686.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ezicoro 10/10 mg Tablet
	Composition	Each Tablet contains Ezetimibe……10mg Simvastatin……10mg
	Diary No. Date of R& I & fee	Form -5 Dy.No 41981: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN® (ezetimibe and simvastatin) tablets, uncoated-tablet (10mg/210mg, 10/20mg, 10/40mg, 10/80mg). TGA Approved
	Me-too status	NeoCom –S Tablets. Reg. No. 42397
	GMP status	As above
	Remarks of the Evaluator	• The firm has mentioned coating composition and process in the revised manufacturing outlines. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2687.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ezicoro 10/20 mg Tablet
	Composition	Each Tablet contains Ezitimbe ……10mg Simvastatin……20mg
	Diary No. Date of R& I & fee	Dy. No. 41982: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN® (ezetimibe and simvastatin) tablets, uncoated-tablet (10mg/210mg, 10/20mg, 10/40mg, 10/80mg). TGA Approved
	Me-too status	NeoCom –SD Tablets. Reg. No. 42398
	GMP status	As above
	Remarks of the Evaluator	• The firm has mentioned coating composition and process in the revised manufacturing outlines.

		• Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2688.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ezicoro 10/40 mg Tablet
	Composition	Each Tablet contains Ezitimbe ……..…….10mg Simvastatin……..…40mg
	Diary No. Date of R& I & fee	Dy. No. 42012: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN® (ezetimibe and simvastatin) tablets, uncoated-tablet (10mg/210mg, 10/20mg, 10/40mg, 10/80mg). TGA Approved
	Me-too status	NeoCom –ST Tablets. Reg. No. 42399
	GMP status	As above
	Remarks of the Evaluator	• The firm has mentioned coating composition and process in the revised manufacturing outlines. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	
2689.	Name and address of manufacturer / Applicant	M/s. SAFE Pharmaceuticals Pvt. Ltd Plot No. C.I-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ezicoro 10/80 mg Tablet
	Composition	Each Tablet contains Ezitimbe ……..….10mg Simvastatin……..…80mg
	Diary No. Date of R& I & fee	Dy. No. 42013: 07.12.2018 Rs. 20,000: 07.12.2018
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	VYTORIN® (ezetimibe and simvastatin) tablets, uncoated-tablet (10mg/210mg, 10/20mg, 10/40mg, 10/80mg). TGA Approved
	Me-too status	Neutrachol Plus Tablets. Reg. No. 59304
	GMP status	As above
	Remarks of the Evaluator	• The firm has mentioned coating composition and process in the revised manufacturing outlines. • Blistering and packing process is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Submission of complete outline of method of manufacturing.**	

2690.	Name and address of manufacturer/ Applicant	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Raze 6mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone…6mg
	Diary No. Date of R & I & fee	Dy. No. 2091; 17.01.2019 PKR. 20,000/-; 16.01.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	6's, 10's, 20's, 30's, 28's, 42's, 50's, 100's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Risperidone 6mg Film-coated Tablets; MHRA approved
	Me-too status	Could not be confirmed
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator	• Provide proof of me-too product (name and registration No.) with same strength and formulation approved by DRAP, otherwise, submit stability data of three batches conducted in zone IV-A.
	Decision: Deferred for updated GMP status of the firm from QA&LT division.	
2691.	Name and address of manufacturer/ Applicant	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Qutia XR 150mg Tablet
	Composition	Each Extended Release Tablet Contains: Quetiapine Fumarate Eq. to Qutiapine…150mg
	Diary No. Date of R & I & fee	Dy. No. 2089; 17.01.2019 PKR. 20,000/-; 16.01.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL XR® (quetiapine fumarate) extended-release tablets, 50mg, 150mg, 200mg, 300mg, 400mg). USFDA approved
	Me-too status	Ziapine XR150mg Oral Tablets Reg. No. 78755
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator	•
	Decision: Deferred for updated GMP status of the firm from QA&LT division.	
2692.	Name and address of manufacturer/ Applicant	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Brentil 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine Hydrobromide…5mg
	Diary No. Date of R & I & fee	Dy. No. 2092; 17.01.2019 PKR. 20,000/-; 16.01.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, 14's, 28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	TRINTELLIX (vortioxetine) tablets, 5mg, film-coated.; USFDA approved
	Me-too status	Could not be confirmed
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019.

	Remarks of the Evaluator	• Submit stability data of three batches conducted in zone IV-A.
	Decision: Deferred for submission of stability data as per requirement of Registration Board.	
2693.	Name and address of manufacturer/ Applicant	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Brentil 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine Hydrobromide…10mg
	Diary No. Date of R & I & fee	Dy. No. 2093; 17.01.2019 PKR. 20,000/-; 16.01.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, 14's, 28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	TRINTELLIX (vortioxetine) tablets, 10mg, film-coated.; USFDA approved
	Me-too status	Could not be confirmed
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator	• Submit stability data of three batches conducted in zone IV-A.
	Decision: Deferred for submission of stability data as per requirement of Registration Board.	
2694.	Name and address of manufacturer/ Applicant	M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Brentil 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine Hydrobromide…15mg
	Diary No. Date of R & I & fee	Dy. No. 2094; 17.01.2019 PKR. 20,000/-; 16.01.2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, 14's, 28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	TRINTELLIX (vortioxetine) tablets, 15mg, film-coated.; USFDA product was not discontinued or withdrawn for safety or efficacy reasons
	Me-too status	Could not be confirmed
	GMP status	Show cause Notice/Suspension of Production Orders issued on 21st May, 2019.
	Remarks of the Evaluator	• Submit stability data of three batches conducted in zone IV-A.
	Decision: Deferred for submission of stability data as per requirement of Registration Board.	
2695.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Asrovit 40mg Tablets
	Composition	Each film-coated tablet Contains: Atorvastatin as calcium…40mg
	Diary No. Date of R & I & fee	Dy. No. 7788; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved

	Me-too status	Fatilor 40mg Tablet by Lisko Pakistan Ltd. Reg No. 58163 (does not depict film-coating)
	GMP status	The firm was inspected on 07.10.2019, wherein the GMp was rated good.
	Remarks of the Evaluator	• The reference product is film-coated tablet. The firm has mentioned coating composition and process in the dossier. But the label claim was each tablet contains". Upon clarification the firm revised the label claim.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2696.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Asrovit 80mg Tablets
	Composition	Each film-coated tablet Contains: Atorvastatin as calcium…80mg
	Diary No. Date of R & I & fee	Dy. No. 7790; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
	Me-too status	Torvia 20mg Tablet by Pakistan Pharmaceutical Products. Reg No. 81161
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• The reference product is film-coated tablet. The firm has mentioned coating composition and process in the dossier. But the label claim was each tablet contains". Upon clairification the firm revised the label claim.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2697.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Bisop 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Bisoprolol fumarate…10mg
	Diary No. Date of R & I & fee	Dy. No. 7795; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Beta blocking agents, selective.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's; Rs. 296/-
	Approval status of product in Reference Regulatory Authorities.	Bisoprolol 10 mg Film-coated Tablet. MHRA approved
	Me-too status	Bisolol 10 mg tablet. Reg. No. 79559
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• .
	Decision: Approved.	

2698.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Bisop 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Bisoprolol fumarate…5mg
	Diary No. Date of R & I & fee	Dy. No. 7796; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Beta blocking agents, selective.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's; Rs. 159/-
	Approval status of product in Reference Regulatory Authorities.	Bisoprolol 5 mg Film-coated Tablet. MHRA approved
	Me-too status	Bisfat Tablets 5mg. Reg. No. 77052
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	
	Decision: Approved.	
2699.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Bisop 2.5mg Tablets
	Composition	Each Film Coated Tablet Contains: Bisoprolol fumarate…2.5mg
	Diary No. Date of R & I & fee	Dy. No. 7794; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Beta blocking agents, selective.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Bisoprolol 2.5 mg Film-coated Tablet. MHRA approved
	Me-too status	Bisfat Tablets 2.5mg. Reg. No. 77054
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	•
	Decision: Approved.	
2700.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Dopin 2.5mg Tablets
	Composition	Each Tablet Contains: Felodipine…2.5mg
	Diary No. Date of R & I & fee	Dy. No. 7786; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Dihydropyridine derivatives
	Type of Form	Form 5
	Finished product Specification	USP (as PR tablet)
	Pack size & Demanded Price	30's; Rs. 270/-
	Approval status of product in Reference Regulatory Authorities.	Vascalpha 2.5mg Prolonged Release tablets, film-coated (Felodipine). MHRA approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• The reference product is in the form of film-coated prolonged

		release tablet. • Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP. Otherwise, submit all the legal requirements meant for the product that requires the stability studies in zone IV-A.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of formulation as per reference product along with submission of requisite fee.**	
2701.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form +Strength	Dopin 5mg Tablets
	Composition	Each Tablet Contains: Felodipine…5mg
	Diary No. Date of R & I & fee	Dy. No. 7774; 21.02.2019PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Dihydropyridine derivatives
	Type of Form	Form 5
	Finished product Specification	USP (as PR tablet)
	Pack size & Demanded Price	30's; Rs. 325/-
	Approval status of product in Reference Regulatory Authorities.	Vascalpha 5mg Prolonged Release tablets, film-coated (Felodipine). MHRA approved
	Me-too status	Felpine 5mg Tablets. Reg. No. 52673 (does not depict SR/PR/ER/XR)
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• The reference product is in the form of film-coated prolonged release tablet. • Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP. Otherwise, submit all the legal requirements meant for the product that requires the stability studies in zone IV-A.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of formulation as per reference product along with submission of requisite fee.**	
2702.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Glazid 30mg Tablet
	Composition	Each Modified Release Tablet Contains: Gliclazide…30mg
	Diary No. Date of R & I & fee	Dy. No. 7781; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Sulfonylureas
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2x 10's; Rs. 231/-
	Approval status of product in Reference Regulatory Authorities.	PHARMACOR GLICLAZIDE MR gliclazide 30 mg modified release tablet. TGA approved
	Me-too status	Glinext MR Tablet 30mg. Reg. No. 84463
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.

	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2703.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Glazid 60mg Tablet
	Composition	Each Modified Release Tablet Contains: Gliclazide…60mg
	Diary No. Date of R & I & fee	Dy. No. 7780; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Sulfonylureas
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2x 10's; Rs.195/-
	Approval status of product in Reference Regulatory Authorities.	PHARMACOR GLICLAZIDE MR gliclazide 60 mg modified release tablet. TGA approved
	Me-too status	Glinext MR Tablet 60mg. Reg. No. 84469
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specification.	
2704.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Glazid 80mg Tablet
	Composition	Each Tablet Contains: Gliclazide…80mg
	Diary No. Date of R & I & fee	Dy. No. 7778; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Sulfonylureas
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2x 10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Gliclazide 80 mg Tablets, uncoated. MHRA approved
	Me-too status	Glizid Tablets 80mg. Reg. no. 31105
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• The firm revised the label claim from "Each modified release tablet contains" to "each tablet contains" without submission of fee.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2705.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Perido 2mg Tablets
	Composition	Each Tablet Contains: Perindopril…2mg
	Diary No. Date of R & I & fee	Dy. No. 7784; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	ACE inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference	Perindopril 2mg Tablets (perindopril tert-butylamine 2 mg),

	Regulatory Authorities.	uncoated. **MHRA** approved
	Me-too status	Dopril Tablets 2mg. No. 43470
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• Provide proof of reference product with same formulation, salt form and strength in reference regulatory agencies as defined in 275th meeting of the registration Board. Otherwise, revise the salt form in line with the reference product along with submission of applicable fee. • Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of formulation as per reference product along with submission of requisite fee.**	
2706.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Perido 4mg Tablets
	Composition	Each Tablet Contains: Perindopril…4mg
	Diary No. Date of R & I & fee	Dy. No. 7783; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	ACE inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Perindopril 4mg Tablets (perindopril tert-butylamine 2 mg), uncoated. **MHRA** approved
	Me-too status	Dopril Tablets 4mg. Reg. No. 43464
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• Provide proof of reference product with same formulation, salt form and strength in reference regulatory agencies as defined in 275th meeting of the registration Board. Otherwise, revise the salt form in line with the reference product along with submission of applicable fee. • Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of formulation as per reference product along with submission of requisite fee.**	
2707.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Perido 8mg Tablets
	Composition	Each Tablet Contains: Perindopril…8mg
	Diary No. Date of R & I & fee	Dy. No. 7782; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	ACE inhibitors

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Perindopril 8mg Tablets. **MHRA** approved
	Me-too status	Coversyl Tablets. Reg. No. 32260
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• Provide proof of reference product with same formulation, salt form and strength in reference regulatory agencies as defined in 275th meeting of the registration Board. Otherwise, revise the salt form in line with the reference product along with submission of applicable fee. • Provide proof of me-too product (name and registration number) with same formulation, salt form and strength already approved by DRAP.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of formulation as per reference product along with submission of requisite fee.**	
2708.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Rapril 10mg Tablets
	Composition	Each Tablet Contains: Ramipril…10mg
	Diary No. Date of R & I & fee	Dy. No. 7793; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x14's; Rs. 602/-
	Approval status of product in Reference Regulatory Authorities.	Ramipril 10 mg Tablets, uncoated. MHRA approved
	Me-too status	Lipra 10mg Tablet Reg. No. 67369
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	•
	Decision: Approved.	
2709.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Rapril 5mg Tablets
	Composition	Each Tablet Contains: Ramipril…5mg
	Diary No. Date of R & I & fee	Dy. No. 7792; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x14's; Rs. 445/-
	Approval status of product in Reference Regulatory Authorities.	Ramipril 5 mg Tablets, uncoated. MHRA approved
	Me-too status	Lipra 5mg Tablet Reg. No. 67368
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was

		rated good.
	Remarks of the Evaluator	•
	Decision: Approved.	
2710.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Rapril 2.5mg Tablets
	Composition	Each Tablet Contains: Ramipril…2.5mg
	Diary No. Date of R & I & fee	Dy. No. 7793; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	ACE inhibitors, plain
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x14's; Rs. 342/-
	Approval status of product in Reference Regulatory Authorities.	Ramipril 2.5 mg Tablets, uncoated. MHRA approved
	Me-too status	Lipra 2.5mg Tablet Reg. No. 67367
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	•
	Decision: Approved.	
2711.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Toprol 100mg Tablets
	Composition	Each Tablet Contains: Metoprolol Tartrate…100mg
	Diary No. Date of R & I & fee	Dy. No. 7779; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metoprolol Tartrate 100 mg Tablets, uncoated. MHRA approved Metoprolol Tartrate 100 mg Film-coated Tablets. MHRA approved MINAX 100 metoprolol tartrate 100mg tablet, uncoated. TGA approved
	Me-too status	Fynkard Tablets 100mg. Reg. No. 32246 Dronic 100mg Tablets, film coated. Reg. No. 81425
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	Both international and me-too product are available uncoated as well as film-coated tablet. The firm has label claim "each tablet contains" and has mentioned coating composition and process. Upon clarifcation, the firm claimed film-coated tablet. Now revision of the label claim as required.
	Decision: Approved.	
2712.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Toprol 50mg Tablets
	Composition	Each Tablet Contains: Metoprolol Tartrate…50mg

	Diary No. Date of R & I & fee	Dy. No. 7775; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metoprolol Tartrate 50 mg Tablets, uncoated. MHRA approved Metoprolol Tartrate 50 mg Film-coated Tablets. MHRA approved MINAX 50 metoprolol tartrate 100mg tablet, uncoated. TGA approved
	Me-too status	Metocard Tablets 50mg. Reg. No. 34755 Mepresor 50mg Tablets, film-coated. Reg. No. 36124
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	Both international and me-too product are available uncoated as well as film-coated tablet. The firm has label claim "each tablet contains" and has mentioned coating composition and process. Upon clarifcation, the firm claimed film-coated tablet. Now revision of the label claim as required.
	Decision: Approved.	
2713.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Toprol 25mg Tablets
	Composition	Each Tablet Contains: Metoprolol Tartrate…25mg
	Diary No. Date of R & I & fee	Dy. No. 7773; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metroprolol tartrate 25mg tablet. USFDA approved.
	Me-too status	Metrocard Tablets 25 mg. Reg. No. 40889 (does not depict film-coating)
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• The international product is available uncoated as well as film-coated tablet (50 mg and 100mg). The international reference product in USFDA is available as uncoated tablet (50 mg and 100mg). However, Metroprolol tartrate 25mg tablet, USFDA approved does not have any information in this regard. The firm has label claim "each tablet contains" and has mentioned coating composition and process. Upon clarifcation, the firm claimed film-coated tablet.
	Decision: Approved.	
2714.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Vastin 5mg Tablets
	Composition	Each film-coated tablet Contains: Rosuvastatin Calcium…5mg

	Diary No. Date of R & I & fee	Dy. No. 7785; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Crestor 10mg film-coated tablets. MHRA approved
	Me-too status	Aurora Tablets 5mg. Reg. No. 046873
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• The reference product is film-coated tablet. The firm has label claim "each tablet contains" and has mentioned coating composition and process. Upon clarifcation, the firm claimed film-coated tablet.
	Decision: Approved.	
2715.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Vastin 10mg Tablets
	Composition	Each film-coated tablet Contains: Rosuvastatin Calcium…10mg
	Diary No. Date of R & I & fee	Dy. No. 7787; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Crestor 10mg film-coated tablets. MHRA approved
	Me-too status	Aurora Tablets 10mg. Reg. No. 046872.
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• The reference product is film-coated tablet. The firm has label claim "each tablet contains" and has mentioned coating composition and process. Upon clarifcation, the firm claimed film-coated tablet.
	Decision: Approved.	
2716.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Vastin 20mg Tablets
	Composition	Each film-coated tablet Contains: Rosuvastatin Calcium…20mg
	Diary No. Date of R & I & fee	Dy. No. 7789; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Crestor 20mg film-coated tablets. MHRA approved
	Me-too status	Aurora Tablets 20mg. Reg. No. 046871
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	• The reference product is film-coated tablet. The firm

		has label claim "each tablet contains" and has mentioned coating composition and process. Upon clarifcation, the firm claimed film-coated tablet.
	Decision: Approved.	
2717.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Volvo 2.5mg Tablets
	Composition	Each Tablet Contains: Nebivolol Hcl Eq. to Nebivolol…2.5mg
	Diary No. Date of R & I & fee	Dy. No. 7777; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	14's; Rs. 102/-
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 2.5mg) tablets, for oral use by Allergan Sales LLC. **US-FDA** approved
	Me-too status	Bynevol 2.5mg Tablet by Atco Lab Karachi. Reg No. 81561
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	
	Decision: Approved.	
2718.	Name and address of manufacturer/ Applicant	M/s City Pharmaceutical Laboratories. Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi-Pakistan
	Brand Name + Dosage Form + Strength	Volvo 5mg Tablets
	Composition	Each Tablet Contains: Nebivolol Hcl Eq. to Nebivolol…5mg
	Diary No. Date of R & I & fee	Dy. No. 7776; 21.02.2019 PKR. 20,000/-; 20.02.2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	14's; Rs. 168/-
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 5mg) tablets, for oral use by Allergan Sales LLC. **US-FDA** approved
	Me-too status	Bynevol 5mg Tablet by Atco Lab Karachi. Reg No. 81099
	GMP status	The firm was inspected on 07.10.2019, wherein the GMP was rated good.
	Remarks of the Evaluator	
	Decision: Approved.	
2719.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma.** **Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name +Dosage Form + Strength	Alendovetor 10mg Tablet
	Composition	Each Tablet Contains: Alendronate sodium trihydrate eq to Alendronic acid…10mg
	Diary No. Date of R& I & fee	Dy.No 6304 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alendronic Acid 10mg tablets (uncoated) MHRA Approved

	Me-too status	Osteopor 10mg Tablet by Werrick Pharma (Reg # 027045)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2720.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma.** **Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name +Dosage Form + Strength	Eazyin 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin as dihydrate …250mg
	Diary No. Date of R& I & fee	Dy.No 6306 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zithromax film coated tablet (250mg & 500mg) by Pfizer, USFDA Approved.
	Me-too status	Zee Tablet 250 Mg by Danas Pharma, (Reg # 038687)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2721.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Devoter 5mg Tablet
	Composition	Each film coated tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy.No 6305 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antihistamines
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Desloratadine Mylan 5 mg film-coated tablets MHRA Approved.
	Me-too status	Desora 5mg tablet of S.J & G. Fazal Ellahie (Reg# 037421)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	• Firm has mentioned desloratadine 5mg in fee challan and covering letter, but mentioned desloratadine 10mg in form 5. Firm has submitted that it was due to a typographic mistake. Now firm has submitted revised form 5 and also submitted 5,000 fee for revision of formulation.
	Decision: Approved.	
2722.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Innostine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Dy.No 6311 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antihistamine

	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	EBASTINE ARROW 10 mg film-coated tablets ANSM Approved
	Me-too status	Atmos Tablets 10mg of Scotmann Pharma (Reg# 056116)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2723.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Innostine 5mg/5ml Syrup
	Composition	Each 5ml contains: Ebastine…5mg
	Diary No. Date of R& I & fee	Dy.No 6325 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CLEVER 1 mg / ml syrup AIFA Italy Approved
	Me-too status	Atmos Syrup of Scotmann Pharma (Reg# 059318)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	• Firm has oral liquid (General) section.
	Decision: Approved.	
2724.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Escovetor 10mg Tablet
	Composition	Each film coated tablet Contains: Escitalopram as Oxalate……10mg
	Diary No. Date of R& I & fee	Dy.No 6307 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipralex 10 mg film-coated tablets (MHRA Approved)
	Me-too status	Cipralex 10mg Tablets by Lundbeck (Reg # 028467)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2725.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Coxivetor 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy.No 6308 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Anti-inflammatory and Ant rheumatic Products

	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Arcoxia 60 mg Film-coated Tablets by MSD (**MHRA** Approved)
	Me-too status	Etoria 60mg Tablet of Hygeia Pharma (Reg.# 080818)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2726.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Gemivetor 320mg Tablet
	Composition	Each Film Coated Tablet Contains: Gemifloxacin as mesylate…320mg
	Diary No. Date of R& I & fee	Dy.No 6309 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Factive 320mg film-coated tablet of Oscient Pharmaceuticals (**USFDA** Approved)
	Me-too status	Gemox 320mg tablet by Genome Pharma (Reg# 053543)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2727.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Pridivetor 50mg Tablets
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R& I & fee	Dy.No 6318 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, (**AIFA** Italy Approved)
	Me-too status	Vesulpid Tablets 50mg by Martin Dow (Reg# 041012)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	• Firm has initially applied for film coated tablet, later the firm has revised their formulation to uncoated tablet as per the reference product. Firm has also submitted fee 5,000/- for revision of formulation.
	Decision: Approved.	
2728.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Pridivetor 25mg Tablets
	Composition	Each Tablet Contains: Levosulpiride…25mg

	Diary No. Date of R& I & fee	Dy.No 6317 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LEVOPRAID 25 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, (**AIFA** Italy Approved)
	Me-too status	Vesulpid Tablets 25mg by Martin Dow (Reg# 041008)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	• Firm has initially applied for film coated tablet, later the firm has revised their formulation to uncoated tablet as per the reference product. Firm has also submitted fee 5,000/- for revision of formulation.
	Decision: Approved.	
2729.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Linzovetor 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…400mg
	Diary No. Date of R& I & fee	Dy.No 6319 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antibiotics, Oxazolidinone
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX Tablets 400MG (film coated) USFDA approved but discontinued for reasons other than safety and efficacy. The FDA database declared the following: **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons*
	Me-too status	Barizold Tablet 400mg by Barrett Hodgson (Reg# 076342)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2730.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Hepakil 120ml Syrup
	Composition	Each 5ml contains: L-Ornithine L-Aspartate…300mg Nicotinamide…24mg Riboflavin Sodium phospate…0.24mg
	Diary No. Date of R& I & fee	Dy.No 8167 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Vitamins & amino acid supplement
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD

		compliance to GMP
	Remarks of the Evaluator[IX]	• Firm has submitted the request to revise their formulation to following composition: Each 5ml contains: L-Ornithine L-Aspartate…300mg Nicotinamide…24mg Riboflavin Sodium phospate…0.76mg • Firm has also submitted fee 20,000/- for revision of formulation • Me-too status of this formulation has been verified: Levijon Syrup by Sami Pharma (Reg # 015063) • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since the submitted reference of Germany could not be verified.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2731.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Inovelin 500mcg Tablet
	Composition	Each sugar Coated Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy.No 6320 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mecobalamin 500mcg sugar coated tablet **PMDA** Japan Approved
	Me-too status	Mecomed Tab 500 mcg by Global Pharma (Reg# 041670)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2732.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Inomin 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin hydrochloride…250mg
	Diary No. Date of R& I & fee	Dy.No 6312 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metformin Hydrochloride Tablets 250mg (Film coated) MT "DSPB" (**PMDA** Japan Approved)
	Me-too status	Glucophage 250mg TAB by Martin Dow (Reg# 013365)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	

2733.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Inomin 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin hydrochloride…500mg
	Diary No. Date of R& I & fee	Dy.No 6313 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metformin Hydrochloride Tablets 500mg (Film coated) (**USFDA** Approved)
	Me-too status	Glucophage 500mg TAB by Martin Dow (Reg# 000552)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2734.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Inomin 1g Tablet
	Composition	Each Film Coated Tablet Contains: Metformin hydrochloride ..…1g
	Diary No. Date of R& I & fee	Dy.No 6314 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metformin Hydrochloride Tablets 1g (Film coated) (**USFDA** Approved)
	Me-too status	Glucophage 1g TAB by Martin Dow (Reg# 025488)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2735.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Innopine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine …10mg
	Diary No. Date of R& I & fee	Dy.No 6310 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Olanzapine Accord 10 mg film-coated tablets (**MHRA** Approved)
	Me-too status	Zyprexa Tablets 10mg by Eli Lilly (Reg#023616)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	

2736.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Instron 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron (as hydrochloride dihydrate)….8mg
	Diary No. Date of R& I & fee	Dy.No 6316 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8 mg film-coated tablets (**MHRA** Approved)
	Me-too status	Ondonx Tablet 8mg by Genix Pharma (Reg# 081451)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2737.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Pantovetor 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Pantoprazole as sodium sesquihydrate…40mg
	Diary No. Date of R& I & fee	Dy.No 6321 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pantoprazole 40 mg gastro-resistant tablets (**MHRA** Approved)
	Me-too status	Protium Gastro Resistant Tablets 40mg by Abbott (Reg# 021039)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	• Firm has applied the formulation of film coated tablet since the reference product is gastro resistant tablet. Firm need to revise the formulation to gastro resistant tablet as per the reference product along with submission of requisite fee for revision of formulation.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2738.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Parovetor 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Paroxetine as hydrochloride…20mg
	Diary No. Date of R& I & fee	Dy.No 6322 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paroxetine 20 mg film-coated tablets (**MHRA** Approved)

	Me-too status	Neoxetine Tablets 20mg by Neomedix (Reg # 081407)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2739.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Parovetor 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Paroxetine as hydrochloride…40mg
	Diary No. Date of R& I & fee	Dy.No 6323 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paxil 40 mg film-coated tablets (**USFDA** Approved)
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm needs to be provided. • Submit complete form 5 for Parovetor 40mg Tablet, since the submitted form 5 is of Pantovetor 40mg Tablet.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Submission of complete form 5 for the applied product.**	
2740.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Inoxicam 20mg Tablet
	Composition	Each uncoated tablet contains: Piroxicam as betacyclodextrin…20mg
	Diary No. Date of R& I & fee	Dy.No 6315 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CYCLADOL 20 mg, scored tablet (**ANSM** France Approved)
	Me-too status	Pirujin Tablet by Jupiter Pharma (Reg # 081925)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2741.	Name and address of manufacturer / Applicant	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Brand Name +Dosage Form + Strength	Tizenivetor 2mg Tablet
	Composition	Each uncoated tablet contains: Tizanidine as hydrochloride…2mg

	Diary No. Date of R& I & fee	Dy.No 6324 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tizanidine 2mg Tablets (uncoated) (**MHRA** Approved)
	Me-too status	Movax 2mg Tablets by Sami Pharma (Reg # 025594)
	GMP status	Last GMP inspection report dated 03-09-2019 concludes GOOD compliance to GMP
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2742.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Plimox Dry Suspension 125mg/5ml
	Composition	Each 5ml of reconstituted suspension contains: Amoxicillin as trihydrate…125mg
	Diary No. Date of R& I & fee	Dy.No 8106 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antibiotic Penicillin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	90ml As per SRO
	Approval status of product in Reference Regulatory Authorities.	Amoxicillin 125 mg/5 ml Oral Suspension (**MHRA** Approved)
	Me-too status	Amoxilite Suspension 125mg by Elite Pharma (Reg# 040210)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Dry suspension (Penicillin) section as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2743.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Plimox Dry Suspension 250mg/5ml
	Composition	Each 5ml of reconstituted suspension contains: Amoxicillin as trihydrate…250mg
	Diary No. Date of R& I & fee	Dy.No 8105 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antibiotic Penicillin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	90ml As per SRO
	Approval status of product in Reference Regulatory Authorities.	Amoxicillin 250 mg/5 ml Oral Suspension (**MHRA** Approved)
	Me-too status	Amoxilite Suspension 125mg by Elite Pharma (Reg# 040211)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Dry suspension (Penicillin) section as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2744.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Plitant Capsule 40mg

	Composition	Each Capsule Contains: Aprepitant…40mg
	Diary No. Date of R& I & fee	Dy.No 8096 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	antiemetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Emend Capsule by Merck (**USFDA** Approved)
	Me-too status	Apreon Capsule 40mg by Ferozsons Lab (Reg. # 068201)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Capsule section (General) as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2745.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Diazip Tablet 5/2.5mg
	Composition	Each sugar coated tablet Contains: Chlordiazepoxide…5mg Clidinium Bromide…2.5mg
	Diary No. Date of R& I & fee	Dy.No 8104 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Benzodiazepine derivatives, Anxiolytic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Librax 5 mg + 2.5 mg sugar coated tablets (**AIFA** Italy Approved)
	Me-too status	Librax Tablets by Roche Pharmaceuticals (Reg#000568)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Tablet section (psychotropic) as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2746.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Colecol Injection 5mg
	Composition	Each 1ml contains: Cholecalciferol……5mg
	Diary No. Date of R& I & fee	Dy.No 8097 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Vitamin- D
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	1ml glass ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200,000 IU / 1 ml, IM solution for injection in ampoule & VITAMIN D3 GOOD 200,000 IU / 1 ml, oral solution in ampoule (**ANSM** France Approved)
	Me-too status	Drol- D injection by Regal Pharma (Reg. # 082005)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Liquid Injection (Vial / ampoule) SVP section as per the

		submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2747.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Clidron Dry Suspension 125mg/5ml
	Composition	Each 5ml of reconstituted suspension contains: Clarithromycin (as taste mask granules)…125mg Source of granules: Vision Pharmaceuticals Islamabad.
	Diary No. Date of R& I & fee	Dy.No 8111 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin granules for oral suspension 125mg/5ml (**USFDA** approved)
	Me-too status	Rethro 125mg /5ml by Regal Pharma (Reg# 081980)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Dry suspension (General) section as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2748.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Clidron Tablet 250mg
	Composition	Each film coated tablet Contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Dy.No 8109 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 250 mg film-coated tablets (**MHRA** Approved)
	Me-too status	Alercid Tablets 250mg by Alina Combine (Reg# 039595)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2749.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Clidron Tablet 500mg
	Composition	Each film coated tablet Contains: Clarithromycin…500mg
	Diary No. Date of R& I & fee	Dy.No 8108 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 500 mg film-coated tablets (**MHRA** Approved)

	Me-too status	Alercid Tablets 500mg by Alina Combine (Reg# 039596)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	•
	Decision: Approved.	
2750.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Cyanocobalamin Injection 500mcg IV
	Composition	Each 2ml contains: Cyanocobalamin …500mcg
	Diary No. Date of R& I & fee	Dy.No 8100 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	25 x 2ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Evidence of approval of applied formulation as 500mcg cyanocobalamin / 2ml ampoule in reference regulatory authorities which were adapted by Registration Board in its 275th meeting could not be confirmed • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2751.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Plironem Injection IV 1gm
	Composition	Each Vial Contains: Meropenem Trihydrat eq to Meropenem…1gm
	Diary No. Date of R& I & fee	Dy.No 8103 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antibiotic carbapenem
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meronem IV 1g Powder for solution for injection or infusion (**MHRA** Approved)
	Me-too status	Meronem 1g IV Injection by ICI (Reg# 018548)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Evidence of approval of carbapenem section is required. • Firm has submitted that carbapenem are beta lactam antibiotics. We have separate dedicated area for cephalosporin and penicillin. There it is requested to consider our application in our available section.

	Decision: Registration Board decided to reject the application since the firm does not have requisite manufacturing facility / section.	
2752.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Danse Injection 8mg
	Composition	Each 4ml contains: Ondansetron (as hydrochloride dihydrate) …8mg
	Diary No. Date of R& I & fee	Dy.No 8094 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Anti- emetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	4ml x 5 ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 2 mg/ml Solution for Injection (**MHRA** Approved)
	Me-too status	Adosetron 8mg Injection by Searle IV Solutions (Reg. # 078614)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Liquid Injection (Vial / ampoule) SVP section as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2753.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Danse Tablet 8mg
	Composition	Each film coated Tablet Contains: Ondansetron (as hydrochloride dihydrate)…8mg
	Diary No. Date of R& I & fee	Dy.No 8093 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8 mg film-coated tablets (**MHRA** Approved)
	Me-too status	Ondonx Tablet 8mg by Genix Pharma (Reg# 081451)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has initially applied for uncoated tablet, since the reference product is film coated tablet the firm revised their formulation to film coated tablet as per the reference product and submitted 5000/- fee for revision of formulation.
	Decision: Approved.	
2754.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Danse Oral Solution 4mg
	Composition	Each 5ml contains: Ondansetron (as hydrochloride dihydrate)..…4mg
	Diary No. Date of R& I & fee	Dy.No 8095 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	60ml amber glass bottle: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 4mg/5ml Oral Solution (**MHRA** Approved)
	Me-too status	Ondanles 4mg/5ml oral solution by NeoMedics (Reg# 066472)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Liquid Syrup (General) section as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2755.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Plidol CF Tablet
	Composition	Each Tablet Contains: Paracetamol…500mg Chlorpheniramine Maleate…4mg Pseudoephedrine HCL…60mg
	Diary No. Date of R& I & fee	Dy.No 8107 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Analgesic/Antihistamine
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Panadol CF Tablet by GSK (Reg# 013113)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting could not be confirmed
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2756.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Plinzo Injection IV 4.5gm
	Composition	Each Vial Contains: Piperacillin (as sodium)……4gm Tazobactam (as sodium)…500mg
	Diary No. Date of R& I & fee	Dy.No 8102 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin 4g / Tazobactam 500mg powder for solution for infusion vials (**MHRA** Approved)
	Me-too status	Tanzo Injection by Bosch (Reg# 039439)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Dry Powder Injectable (Penicillin) section as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2757.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan

	Brand Name +Dosage Form + Strength	Raniva Injection 50mg
	Composition	Each 2ml contains: Ranitidine (as hydrochloride)…50mg
	Diary No. Date of R& I & fee	Dy.No 8101 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	H2 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10ml x 2ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ranitidine 50mg/2ml Solution (ampoule) for Injection and Infusion (**MHRA** Approved)
	Me-too status	Ranigen 50mg/2ml Injection by Genix Pharma (Reg# 083773)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Registration Board in its 294th meeting has decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision. • Firm has Liquid Injection (Vial / ampoule) SVP section as per the submitted section approval letter dated 06-12-2019.
	Decision: Deferred in the light of decision of 294th meeting of Registration Board.	
2758.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Plima Injection 100mg
	Composition	Each 2ml contains: Tramadol hydrochloride…100mg
	Diary No. Date of R& I & fee	Dy.No 8110 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	5 x 2ml clear glass ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tramadol 50mg/ml Solution (2ml ampoule) for Injection or Infusion (**MHRA** Approved)
	Me-too status	Tramal Injection 100mg (Reg# 010172)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Liquid Injection (Vial / ampoule) SVP section as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2759.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Tropli Injection 5mg
	Composition	Each 5ml contains: Tropisetron (as hydrochloride)…5mg
	Diary No. Date of R& I & fee	Dy.No 8098 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Serotonin 5-HTreceptor antagonist
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	1x 1ml ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	TROPISETRON-AFT tropisetron (as hydrochloride) 5 mg/5 mL solution for injection ampoule (**TGA** Approved)
	Me-too status	Tropiset Injection of CCL Pharma (Reg#048023)

	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Liquid Injection (Vial / ampoule) SVP section as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	
2760.	Name and address of manufacturer / Applicant	M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan
	Brand Name +Dosage Form + Strength	Tropli capsule 5mg
	Composition	Each Capsule Contains: Tropisetron (as hydrochloride)…5mg
	Diary No. Date of R& I & fee	Dy.No 8099 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Serotonin 5-HTreceptor antagonist
	Type of Form	Form 5
	Finished Product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Navoban - 5 mg hard gelatin capsule (**Norway** Approved)
	Me-too status	Tropiset Capsules of CCL Pharma (Reg# 048028)
	GMP status	Panel inspection report dated 30-09-2019 recommended the renewal of DML.
	Remarks of the Evaluator[IX]	• Firm has Capsule section (General) as per the submitted section approval letter dated 06-12-2019.
	Decision: Approved.	

b. Deferred cases

2761.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mensodol Tablet 500/25mg
	Composition	Each film-coated tablet contains: Paracetamol…500mg Pamabrom…25mg
	Diary No. Date of R& I & fee	Dy No. 15549: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Anilides + Pamabrom (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	30's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Women's Tylol Caplets. Reg. No. 62787
	GMP status	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• Form 5 is different in some points from the approved one. • Justification is required about 3% excess. • Provide proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board. • The label claim in Form 5 is "Each tablet contains". However, coating composition have been mentioned in Master Formula. Justify/clarify.
	Previous decision	The Board in its 289th meeting deferred the case the following: • Justification is required about 3% excess.

		• Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board. • The label claim in Form 5 is "Each tablet contains". However, coating composition have been mentioned in Master Formula. Justify/clarify.
	Evaluation by PEC	• The firm submitted that the overage was mentioned mistakenly. • The firm submitted that the label claim is film-coated tablet. • Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.
	Previous decision	• The Board in its 292nd meeting deferred the case for Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.
	Evaluation by PEC	• The firm provided reference of "Back Aid Max, OTC product) which could be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
2762.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Dexsol 10% IV 1000ml Infusion
	Composition	Each 100ml Contains: Dextrose as monohydrate…10%
	Diary No. Date of R& I & fee	Dy No. 30211: 07.09.2018 PKR 20,000/-: 06.09.2018
	Pharmacological Group	Carbohydrates
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	1000ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GLUCOSE (as monohydrate) 10 % B.BRAUN, solution pour perfusion (infusion). 250ml, 500ml, 1000ml (in Polyethylene bottle). ANSM approved
	Me-too status	DEXTROSE (anhydrouvs) 10% INJ. Reg. No. 02355
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Revise "Dextrose as monohydrate" to Dextrose monohydrate in Master formula only.
	Previous decision	• The Board in its 293rd meeting deferred the case for revision of formulation from Dextrose as monohydrate to Dextrose monohydrate along with the submission of requisite fee
	Evaluation by PEC	• The firm revised Dextrose as monohydrate to Dextrose monohydrate in master formula.
	Decision: Approved.	
2763.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Dexsol 10% IV 500ml Infusion
	Composition	Each 100ml Contains: Dextrose as monohydrate…10%
	Diary No. Date of R& I & fee	Dy No. 30210: 07.09.2018 PKR 20,000/-: 06.09.2018
	Pharmacological Group	Carbohydrates + saline
	Type of Form	Form 5
	Finished Product Specification	BP

	Pack size & Demanded Price	500ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GLUCOSE (as monohydrate) 10 % B.BRAUN, solution pour perfusion (infusion). 250ml, 500ml, 1000ml (in Polyethylene bottle). ANSM approved
	Me-too status	GEE-SOL 10% IV Infusion (anhydrous) 500ml. Reg. No. 80419
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Revise "Dextrose as monohydrate" to Dextrose monohydrate in Master formula only.
	Previous decision	• The Board in its 293rd meeting deferred the case for revision of formulation from Dextrose as monohydrate to Dextrose monohydrate along with the submission of requisite fee
	Evaluation by PEC	• The firm revised Dextrose as monohydrate to Dextrose monohydrate in master formula.
	Decision: Approved.	
2764.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Dexsol DS $\frac{1}{2}$ IV 500ml Infusion
	Composition	Each 100ml Contains: Dextrose as monohydrate…5g Sodium chloride…….0.45g
	Diary No. Date of R& I & fee	Dy No. 30209: 07.09.2018 PKR 20,000/-: 06.09.2018
	Pharmacological Group	Carbohydrates + electrolytes
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	500ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sodium Chloride 0.45 % w/v and Glucose 5.0 % w/v Solution for Infusion BP (500ml, 1000ml) LDPE. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Evidence of me-too product with same strength and filled volume (name and registration number) approved by DRAP is required. • Revise "Dextrose as monohydrate" to Dextrose monohydrate in AMster formula only.
	Previous decision	The Board in its 293rd meeting deferred the case for the following • Revision of formulation from Dextrose as monohydrate to Dextrose monohydrate along with the submission of requisite fee. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	• The firm revised Dextrose as monohydrate to Dextrose monohydrate in master formula without submission of fee. • The firm provided me-too product, i.e., MEDISOL (+SET) INJ (Reg. No. 9728), which contains dextrose anhydrous and has filled volume of 1000ml.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2765.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Visolact-D IV 500ml Infusion

	Composition	Each 1000ml Contains: Calcium Chloride 2H2O…0.2g Potassium Chloride…0.3g Sodium Chloride…6g Sodium Lactate…3.1g Dextrose Anhydrous…50g
	Diary No. Date of R& I & fee	Dy No. 30206: 07.09.2018 PKR 20,000/-: 06.09.2018
	Pharmacological Group	Carbohydrates + electrolytes
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	500ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lactated Ringer's and 5% Dextrose Injection, USP (500ml, 1000ml). USFDA approved.
	Me-too status	SAFESOL RINGOLATE D.I.V.INFUSION (500ml). Reg. No. 9217 (contain dextrose anhydrous; and sodium chloride….0.6 g/1000ml)
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• The reference product contains dextrose hydrous. The firm has mentioned dextrose anhydrous.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of correct master formulation as per the reference product along with submission of requisite fee for revision of formulation.
	Evaluation by PEC	• The firm revised the dextrose anhydrous to dextrose hydrous without submission of any fee.
	Decision: Deferred for submission of requisite fee for revision of formulation.	
2766.	Name and address of manufacturer/ Applicant	M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan
	Brand Name + Dosage Form+ Strength	Easehale 0.025% Respules 1ml
	Composition	Each 1ml Contains: Ipratropium bromide as monohydrate…0.025%
	Diary No. Date of R & I & fee	Dy. No. 30195; 07.09.2018 PKR. 20,000/-; 07.09.2018
	Pharmacological Group	Anticholinergics
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	5'sx1ml (Polyethylene); As per SRO
	Approval status of product in Reference Regulatory Authorities	AERON 250 ipratropium bromide anhydrous 250 microgram/mL inhalation ampoule (LDPE). TGA approved, wherein active is ipratropium bromide monohydrate 261 microgram/mL. IPRATRIN UNI-DOSE ipratropium bromide monohydrate 250microgram/1mL inhalation ampoule. TGA approved
	Me-too status	Optra Nebuliser Solution. Reg. No. 57885
	GMP status	The firm was inspected on 03.04.2019, wherein **acceptable level** of GMP compliance was reported.
	Remarks of the Evaluator	• The firm was asked to revise label claim to "Ipratropium bromide as monohydrate. The firm did not revise the same.
	Previous decision	The Board in its 293rd meeting deferred the case for revision of label claim to Ipratropium bromide as monohydrate as per the label claim of the reference product.
	Evaluation by PEC	• The firm revised the label claim to Ipratropium bromide as monohydrate.

	Decision: Deferred for submission of requisite fee for revision of formulation.	
2767.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Sepgen 1000mg Dry Powder Injection
	Composition	Each Vial Contains: Cefepime as HCl monohydrate (with L-arginine)…1000mg
	Diary No. Date of R& I & fee	Dy No. 25675: 24.07.2018 PKR 20,000/-: 24.07.2018
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's glass vial; as per PRC
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use. **USFDA** approved
	Me-too status	Cefevial Injection 1.0gm IV. Reg. No. 80030 (does not depict L-argenine)
	GMP status	The firm was inspected on 19.09.2017, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	• The firm submitted revised Form 5, wherein name of signatory is not present on Form 5. • The reference product contains Cefepime as HCl monohydrate. Correction along with adjustment of its weight as per salt factor in Master Formula was asked from the firm. The firm did not revise the same.
	Previous decision	The Board in its 291st meeting deferred the case for revision of salt form in line with the reference product
	Evaluation by PEC	The firm did not revise the label claim meant for monohydrate salt form.
	Previous decision	The Board in its 293rd meeting deferred the case for revision of label claim along with submission of requisite fee.
	Evaluation by PEC	The firm revised "Cefepime as HCl and with L-arginine" to "Cefepime as HCl monohydrate (with L-arginine)". As per practice the Board usually does not demand fee for addition/deletion of hydrate form of API.
	Decision: Approved.	
2768.	Name and address of manufacturer / Applicant	Rock Pharmaceutical laboratories (Pvt.) Ltd., 134-B & 135-B Noweshera Industrial Estate, Risalpur
	Brand Name +Dosage Form + Strength	Zes Capsule 40mg
	Composition	Each capsule contains: Omeprazole (as enteric coated pellets)…..40mg
	Diary No. Date of R& I & fee	Dy No. 2675: 26.01.2017 PKR 100,000/-: 26.01.2017
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Losec 40 mg hard gastro-resistant capsules. Approved by **MHRA**
	Me-too status	Omecap Capsule. Reg. No. 84494
	GMP status	The firm was inspected on 18.07.2018, wherein grant of GMP certificate was recommended. Source of pellets: not provided
	Remarks of the Evaluator.	• The firm submitted stability data of imported pellets of Ocean Pharmacoat (Pvt) Ltd, Hyderabad, India, which has already been approved for Zes 20mg capsules. • Latest GMP of the source of pellets is required.

		• The pellets have been tested as per in-house specifications.
	Previous decision	The Board in its 291st meeting deferred the case for GMP certificate of the source of pellets and clarification regarding testing of pellets as per in-house specifications.
	Evaluation by PEC	• The firm submitted GMP certificate of the source of pellets. • The firm submitted that the testing of pellets is not available in pharmacopeia therefore the testing is performed as per testing method of manufacturer.
	Previous decision	The Board in its 293rd meeting deferred the case for clarification for testing the pellets according to In-House specifications while the product is pharmacopoeial.
	Evaluation by PEC	The firm submitted that: • Pharmacopeial method will be followed for the finished product • Delayed release pelelts is not available in USP. • The pharmcopiea only contains monograph for API and these specifications are not applicable to omeprazole pellets. Morover the monograph of omeprazole API does not metion dissolution test.
	Decision: Approved.	
2769.	Name and address of manufacturer/ Applicant	M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatabad
	Brand Name+ Dosage Form + Strength	Omecon 40mg Tablet
	Composition	Each Gastro-Resistant Tablet Contains: Omeprazole…..40mg
	Diary No. Date of R & I & fee	Dy. No.39298; 29.11.2018 PKR. 20,000/-; 29.11.2018 PKR. 5,000/-; 25.02.2020
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40 mg gastro-resistant tablets. MHRA approved
	Me-too status	Benzim 40 Tablet. Reg. No. 44599 (does not depict enteric coating
	GMP status	The firm was inspected on 26.07.2017, wherein the firm was rated at satisfactory level of cGMP.
	Remarks of the Evaluator	• Provide proof of availability of same formulation, same salt and same strength (name and registration number) approved by DRAP.
	Previous decision	The Board in its 293rd meeting deferred the case for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC	The firm revised "Each Gastro-Resistant Tablet Contains: Omeprazole as magnesium…..40mg' to "Each Gastro-Resistant Tablet Contains: Omeprazole…..40mg" along with submission of Rs. 5000/- fee.
	Decision: Approved.	
2770.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Adomet 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Methyldopa BP eq. to Anhydrous Methyldopa…250mg
	Diary No. Date of R& I & fee	Dy No. 25422: 23.07.2018 PKR 20,000/-: 23.07.2018

	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	100's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ALDOMET® (METHYLDOPA) film-coated. **MHRA** approved
	Me-too status	Dopamat 250mg Tablet. Reg. No. 56148
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Previous decision	The Board in its 292nd meeting deferred the case for correction of pharmacological group.
	Evaluation by PEC	The firm revised the pharmacological group.
	Decision: Approved.	
2771.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Danso 2mg/ml Injection
	Composition	Each ml Contains: Ondansetron as Hydrochloride dihydrate…2mg
	Diary No. Date of R& I & fee	Dy No. 25427: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	The claimed BP specifications. Available in USP
	Pack size & Demanded Price	4mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 2mg/ml Solution for Injection or Infusion (2ml, 4ml ampule). MHRA approved.
	Me-too status	Ondenles 8mg Injection (4ml). Reg. No. 80548 Adosetron 4mg Injection (2ml). Reg. No. 78789
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5. • The firm was asked to clarify the pack size as you can get one filled volume (either 4ml or 2 ml) per registration. The firm did not respond to the clarification. • Revise 'Ondansetron as Hydrochloride dihydrate' to "Ondansetron Hydrochloride dihydrate' in master Formula only.
	Previous decision	The Board in its 291st meeting deferred the case for • Clarification of the pack size as you can get one filled volume (either 4ml or 2 ml) per registration • Revisision 'Ondansetron as Hydrochloride dihydrate' to "Ondansetron Hydrochloride dihydrate' in master Formula only.
	Evaluation by PEC	The firm demanded 4ml filled volume and revised 'Ondansetron as Hydrochloride dihydrate' to "Ondansetron Hydrochloride dihydrate' in master Formula.
	Decision: Approved.	
2772.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Brand Name + Dosage Form+ Strength	Metscot XR 750mg Tablets
	Composition	Each Extended Release Tablet Contains: Metformin Hydrochloride…750mg
	Diary No. Date of R & I & fee	Dy. No. 30411; 10.09.2018

		PKR. 20,000/-; 10.09.2018
	Pharmacological Group	Biguanides
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's, 2x15's, 5x6's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Metabet SR 750mg Prolonged-Release Tablets. MHRA approved DIABEX XR 750 metformin hydrochloride 750 mg extended release tablets blister pack. TGA approved
	Me-too status	Xormet XR Tablets 750 mg. Reg. No. 77131
	GMP status	The firm was inspected on 10.10.2018 and 17.10.2018 wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator	• The firm has mentioned XR coating in the dossier. Upon clarification, the firm referred to the product in TGA which is white to off-white, capsule-shaped, biconvex tablet, debossed "750" on one side and "Merck", on the other side. • It is further submitted that the tablet in MHRA has no coating compositions and contain Hypromellose (E464), however, in the PAR of 500mg tablet, it is mentioned that the product is film-coated and the core does not contains any release retardant polymer.
	Previous decision	The Board in its 293rd meeting deferred the case for clarification of applied formulation with reference to the innovator's product, since the applied formulation has been coated with "extended release polymer" whereas the innovator product does not contain any such coating.
	Evaluation by PEC	The firm provided another reference product, i.e., Metforem 750 mg prolonged-release tablets, approved in **Finland,** wherein Hypromellose as used in the tablet core as well as in coating. It is pertinent to mention that metformin HCl Sr tablet in MHRA has film-caoting composed of Opadry white OY-7300 (hypromellose, titanium dioxide and macrogol 400).
	Decision: Approved.	
2773.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	**Glistat Tablet 4mg**
	Composition	Each tablet contains: Glimepiride…….. 4mg
	Dairy No. Date of R & I fee	Dy No. 7214: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	Glimepiride 4 mg tablets, uncoated (MHRA Approved)
	Me-too status	Glimar Tablets 4mg. Reg. No. 75958
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	The label claim was film-coated tablet, but coating composition and process are not mentioned in the application. The firm did not clarify the same.
	Previous decision	The Board in its 293rd meeting deferred the case for submission coating composition of the applied product and

		complete method of manufacturing with the detail of coating process.
	Evaluation by PEC	The firm submitted that the tablet is uncoated. It was a typo mistake in the label claim.
	Decision: Deferred for submission of requisite fee for revision of formulation.	
2774.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	**Glistat Tablet 3mg**
	Composition	Each film-coated tablet contains: Glimepiride…….. 3mg
	Dairy No. Date of R & I fee	Dy No. 7213: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	Glimepiride 3 mg tablets, uncoated (MHRA Approved)
	Me-too status	Evopride 3mg Tablet by M/s Pharmevo (Reg#29133)
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	The label claim was film-coated tablet, but coating composition and process are not mentioned in the application. The firm did not clarify the same.
	Previous decision	The Board in its 293rd meeting deferred the case for submission coating composition of the applied product and complete method of manufacturing with the detail of coating process.
	Evaluation by PEC	The firm submitted that the tablet is uncoated. It was a typo mistake in the label claim.
	Decision: Deferred for submission of requisite fee for revision of formulation.	
2775.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	**Zelotrine Tablet 5mg**
	Composition	Each film-coated tablet contains: Levocetirizine as dihydrochloride…..5mg
	Dairy No. Date of R & I fee	Dy No. 7214: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Piperazine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	XYZAL levocetirizine hydrochloride 5 mg film coated tablet blister pack. TGA approved
	Me-too status	Norzin 5 mg Tablets, film-coated. Reg. No. 77965
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	The firm was asked to revise 'Levoceterizine Dihydrochloride equivalent to Levoceterizine' to 'Levocetirizine Dihydrochloride' in the label claim and master formula. The firm neither revised the label claim nor revised the quantity of API to 5 mg in master formula.
	Previous decision	The Board in its 293rd meeting deferred the case for revision of

		formulation as per the reference product along with submission of requisite fee for revision of formulation.
	Evaluation by PEC	• The firm submitted that there is no need to change. • The firm needs to remove the equivalency in the label claim. • Regarding fee submission, the Registration Board is humbly requested to clarify the fee submission in case of pre-approval changes, as there is no written guidelines/rules for such fee. Cases of similar nature (adding or removing equivalency) have been approved without fee submission in various meetings.
	Decision: Deferred for revision of label claim and master formulation along with submission of requisite fee for revision of formulation.	
2776.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	**Zelotrine 2.5mg/5ml Syrup**
	Composition	Each 5ml contains: Levoceterizine as Dihydrochloride…..2.5mg
	Dairy No. Date of R & I fee	Dy No. 7202: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Piperazine derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack Size & Demanded Price	60ml amber coloured bottle , As per SRO
	Approval status of product in Reference Regulatory Authorities	XYZAL (levocetirizine dihydrochloride) oral solution 0.5mg/ml. USFDA approved
	Me-too status	T-Day Syrup 2.5mg/5ml. Reg. No. 83990
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	The firm was asked to revise 'Levoceterizine Dihydrochloride equivalent to Levoceterizine' to 'Levocetirizine Dihydrochloride' in the label claim and master formula. The firm neither revised the label claim nor revised the quantity of API to 5 mg in master formula.
	Previous decision	The Board in its 293rd meeting deferred the case for revision of formulation as per the reference product along with submission of requisite fee for revision of formulation.
	Evaluation by PEC	• The firm submitted that there is no need to change. • The firm needs to remove the equivalency in the label claim. • Regarding fee submission, the Registration Board is humbly requested to clarify the fee submission in case of pre-approval changes, as there is no written guidelines/rules for such fee. Cases of similar nature have been approved without fee submission in various meetings.
	Decision: Deferred for revision of label claim and master formulation along with submission of requisite fee for revision of formulation.	
2777.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	**Premsole Capsule 20mg**
	Composition	Each capsule contains: Enteric coated pellets of Esomeprazole Magnesium trihydrate equivalent to Esomeprazole ……. 20mg.
	Dairy No. Date of R & I fee	Dy No. 7205: 26.02.2018

		PKR 20,000/-: 22.02.2018
	Pharmacological Group	Proton pump Inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x7's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	Esomeprazole magnesium Capsule 20mg. USFDA Approved
	Me-too status	Esorid 20mg Capsules. Reg. No. 33097
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	• The source of pellets is Vision Pharmaceuticals, Islamabad. • The manufacturing outlines are not clear. The firm has referred to tablet manufacturing thereof. Submit complete manufacturing outlines.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of manufacturing outlines.
	Evaluation by PEC	The firm submitted that they have already submitted the manufacturing outlines.
	Decision: Approved.	
2778.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	**Premsole Capsule 40mg**
	Composition	Each Capsule contains: Enteric coated pellets of Esomeprazole Magnesium trihydrate equivalent to Esomeprazole ……. 40mg.
	Dairy No. Date of R & I fee	Dy No. 7206: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Proton pump Inhibitor
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack Size & Demanded Price	2x7's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	Esomeprazole magnesium Capsule 40mg. USFDA approved
	Me-too status	Espra Capsule 40mg. Reg. No. 33051
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	• The source of pellets is Vision Pharmaceuticals, Islamabad. • The manufacturing outlines are not clear. The firm has referred to tablet manufacturing thereof. Submit complete manufacturing outlines.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of manufacturing outlines.
	Evaluation by PEC	The firm submitted that they have already submitted the manufacturing outlines.
	Decision: Approved with innovator's specification.	
2779.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Spasnil Tablets
	Composition	Each tablet contains: Phloroglucinol…..80mg trimethylphloroglucinol ……..80mg
	Diary No. Date of R& I & fee	Dy No. 26908: 29.12.2017

		PKR 20,000/-: 29.12.2017
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PHLOROGLUCINOL / TRIMETHYLPHLOROGLUCINOL ACINO 62.233 mg / 80 mg, coated tablet by ACINO France SAS. Approved by **ANSM**
	Me-too status	Despasm Tablet by Irza Pharmaceuticals. Reg. No. 85210
	GMP status	The firm has been granted GMP inspection on the basis of inspection dated 24.12.2018.
	Remarks of the Evaluator.	• International availability is the form of sugar-coated tablet. The firm revised the formulation to sugar-coated tablet without submission of prescribed fee and correction of label. Morever, sugar/sucrose has not been mentioned in the composition of coating • The API 'Phloroglucinol' is the form of 'Phloroglucinol hydrate'. Necessary correction is required.
	Previous decision	The Board in its 289th meeting deferred the case for: • Submission of fee for revision of formulation. • Correction of label and composition of coating • Correction of'Phloroglucinol' to 'Phloroglucinol hydrate'
	Evaluation by PEC	• Now the firm submitted label claim for film-coated tablet along with submission of Rs. 5000/- fee and film-coating composition. The firm also revised Phloroglucinol' to 'Phloroglucinol hydrate'. • Correction of label to "each sugar-caoted tablet contains:" and composition meant of suger coating are required.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
2780.	Name and address of manufacturer/ Applicant	M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrial Area, Superhighway, Karachi
	Brand Name+ Dosage Form + Strength	Cibval-HA 160/10/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…160mg Amlodipine as besilate…10mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R & I & fee	Dy. No.39060; 29.11.2018 PKR. 20,000/-; 26.11.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. **US-FDA** approved
	Me-too status	Exforge HCT 10/160/12.5MG film coated tablets. Reg. No. 69550
	GMP status	The firm has been issued GMP certificate for export on the basis of inspection dated 07.08.2019.
	Remarks of the Evaluator	• The salt in master formula was amlodipine besilate. The firm revise amlodipine to amlodipine as besilate in Label claim.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of fee for revising the label claim.
	Evaluation by PEC	The firm submitted Rs. 20000/- fee dated 11.03.2020. The

		Board shall clarify the matter of fee, as there are no guidelines for fee in case of preapproval changes and in majority of the cases, the firms submit Rs. 5000/- fee for revision of salt form.
	Decision: Approved.	
2781.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Iborine Capsule 200mg
	Composition	Each capsule contains: Mebeverine HCl…….200mg
	Diary No. Date of R& I & fee	Dy No. 1735: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	COLOFAC® MR 200mg Capsules. **MHRA** approved
	Me-too status	Mebrest-200 Capsule. Reg. No. 80547
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same. • *The source of pellets is Vision Pharmaceuticals, Islamabad, wherein all the testing methods are under discussion.*
	Previous decision	The Board in its 289th meeting deferred the case for further delibration
	Evaluation by PEC	• The firm submitted that they use the testing method as specified by the manufacturer of the pellets.
	Previous decision	• The Board in its 291st meeting deferred the case for further delibration
	Evaluation by PEC	• The firm again submitted that they use the testing method as specified by the manufacturer of the pellets.
	Decision: Registration Board deferred the case for further delibration.	
2782.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, Khyber Pakhtunkhwa
	Brand Name +Dosage Form + Strength	Colomat 1 MIU Injection
	Composition	Each Vial Contains: Colistimethate Sodium (Lyophilized Powder)…1 MIU
	Diary No. Date of R& I & fee	Dy No. 25806: 26.07.2018 PKR 20,000/-: 26.07.2018
	Pharmacological Group	Polymyxins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection (lyophilized powder in glass vial). Approved by **MHRA**
	Me-too status	Colistat powder for Injection. Reg. No. 76160
	GMP status	The firm was last inspected on 13.02.2018, wherein it was

		concluded that "Overall the firm was in good working condition with proper documentation, adequate Equipments both in production and quality control and qualified staff for performing the manufacturing and analysis of the manufactured products in accordance with the cGMP guidelines. Some of the minor shortcomings as described above were identified to the firm for immediate rectification. Based on the premises inspected, the qualified staff met and documentation reviewed, it is concluded that M/s Aulton Pharma Industrial Estate Hatter operate at good level of compliance with cGMP guidelines".
	Remarks of the Evaluator.	Undertaking was not signed. The firm submitted duly signed form 5.
	Prevoius decision	The Board in its 291st meeting deferred the case for submission of undertaking.
	Evaluation by PEC	The firm has already submitted duly signed form 5
	Prevoius decision	The Board in its 293rd meeting deferred the case for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.
	Evaluation by PEC	The firm submitted cover letter wherein they have attached leaflet of some reference product, which does not clarify the reason behind the deferment of the case.
	Decision: Deferred for confirmation of manufacturing method (powder filling or lyophilization) and requisite facility.	
2783.	Name and address of manufacturer / Applicant	M/s Ray Pharma Pvt Ltd. S-58, S.I.T.E Karachi.
	Brand Name +Dosage Form + Strength	Quzin 25mg Tablet
	Composition	Each film coated Tablet Contains: Quetiapine (as fumarate)…25mg
	Diary No. Date of R& I & fee	Dy.No 39275 dated 29-11-2018 Rs.20,000/- Dated 29-11-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Quetiapine 25 mg film-coated tablets (MHRA Approved)
	Me-too status	Quitapin 25mg Tablet by Fynk Pharma
	GMP status	GMP Inspection conducted on 14-03-2018 concluded that firm is operating a good level of GMP compliance
	Remarks of the Evaluator[IX]	Firm has initially applied for uncoated tablet containing quetiapine without fumarate salt. Later the firm revised its formulation as per reference product and submitted PKR 5,000/- fee.
	Prevoius decision	The Board in its 293rd meeting deferred the case for submission of differential fee of Rs. 15,000/- for changing the salt form of API.
	Evaluation by PEC	The firm submitted Rs. 15000/- fee. The Board shall clarify the matter of fee, as there are no guidelines for fee in case of preapproval changes and in majority of the cases, the firms submit Rs. 5000/- fee for revision of salt form.
	Decision: Approved.	
2784.	Name and address of manufacturer / Applicant	M/s Ray Pharma Pvt Ltd. S-58, S.I.T.E Karachi.
	Brand Name +Dosage Form + Strength	Escape 10mg Tablet

	Composition	Each film coated Tablet Contains: Escitalopram (as oxalate)…10mg
	Diary No. Date of R& I & fee	Dy.No 39276 dated 29-11-2018 Rs.20,000/- Dated 29-11-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipralex 10 mg film-coated tablets (**MHRA** Approved)
	Me-too status	Lexopram Tablets 10 mg by Evolution pharma
	GMP status	GMP Inspection conducted on 14-03-2018 concluded that firm is operating a good level of GMP compliance
	Remarks of the Evaluator[IX]	• Firm has initially applied for uncoated tablet containing escitalopram without oxalate salt. Later the firm revised its formulation as per reference product and submitted PKR 5,000/- fee.
	Prevoius decision	The Board in its 293rd meeting deferred the case for submission of differential fee of Rs. 15,000/- for changing the salt form of API.
	Evaluation by PEC	The firm submitted Rs. 15000/- fee. The Board shall clarify the matter of fee, as there are no guidelines for fee in case of preapproval changes and in majority of the cases, the firms submit Rs. 5000/- fee for revision of salt form.
	Decision: Approved.	
2785.	Name and address of manufacturer / Applicant	M/s Ray Pharma Pvt Ltd. S-58, S.I.T.E Karachi.
	Brand Name +Dosage Form + Strength	Pentax CR 25mg Tablet
	Composition	Each enteric film coated controlled release Tablet Contains: Paroxetine as HCl…25mg
	Diary No. Date of R& I & fee	Dy.No 39274 dated 29-11-2018 Rs.20,000/- Dated 29-11-2018
	Pharmacological Group	SSRIs/ Anti- depressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paxil CR Tablet of M/s Apotex Technologies (**USFDA**Approved)
	Me-too status	Panox CR Tablet 25 mg of Regal pharma
	GMP status	GMP Inspection conducted on 14-03-2018 concluded that firm is operating a good level of GMP compliance
	Remarks of the Evaluator[IX]	The firm has initially applied for paroxetine hydrochloride 25mg tablets, later the firm has revised its formulation as per the reference product and submitted PKR 5,000/- fee.
	Prevoius decision	The Board in its 293rd meeting deferred the case for submission of differential fee of Rs. 15,000/- for changing the salt form of API.
	Evaluation by PEC	The firm submitted Rs. 15000/- fee. The Board shall clarify the matter of fee, as there are no guidelines for fee in case of preapproval changes and in majority of the cases, the firms submit Rs. 5000/- fee for revision of salt form.
	Decision: Approved.	
2786.	Name and address of manufacturer/ Applicant	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore
	Brand Name + Dosage Form +	Metsol 500mg/100ml Infusion

	Strength	
	Composition	Each 100ml Contains: Metronidazole…500mg
	Diary No. Date of R & I & fee	Dy. No. 30195; 07.09.2018 PKR. 20,000/-; 07.09.2018
	Pharmacological Group	Imidazole derivatives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	100ml; Rs. 78/-
	Approval status of product in Reference Regulatory Authorities	METROZINE metronidazole 500mg in 100mL injection vial. TGA approved. Metronidazole 500 mg / 100 ml Intravenous Infusion. MHRA approved
	Me-too status	Flagynase Infusion 500mg/100ml. Reg. No. 82588
	GMP status	The firm was inspected on 22.03.2019. Conformance of GMP Compliance. However, Suspension of production in Table Section: DTL test report TRA 01-19000153/DTL TRA-01-19000154 Regarding Sub Standard and Adulterated Byscard 2.5mg Tablets Batch 0359 and 0360.
	Remarks of the Evaluator	
	Prevoius decision	The Board in its 293rd meeting referred the case for to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	The firm was inspected on 22.03.2019. Conformance of GMP Compliance. However, Suspension of production in Table Section: DTL test report TRA 01-19000153/DTL TRA-01-19000154 Regarding Sub Standard & Adulterated Byscard 2.5mg Tablets Batch 0359 and 0360..
	Decision: Approved.	
2787.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Brand Name +Dosage Form + Strength	Rebip 20mg Tablets
	Composition	Each enteric coated tablet Contains: Rabeprazole Sodium…20mg
	Diary No. Date of R& I & fee	DyNo. 32573: 01.10.2018 PKR. 20,000/-; 28.09.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PARIET™ 20mg gastro-resistant tablet. MHRA approved
	Me-too status	Rabekan Tablet, 20mg enteric coated. Reg. No. 83829
	GMP status	The inspection report dated 12.05.2018 concluded that Overall the firm was operating under good level of cGMP.
	Remarks of the Evaluator	The reference product does not reveal hydrate form of API. The firm did not mention hydrate form. However, they have adjusted the weight of API as per equivalency factor in Master formula, The USP has mentioned xH2O for the hydrate form of API.
	Previous decision	The board in its 293rd meeting deferred the case for clarification of hydrated form of the API label claim as well as in master formula
	Evaluation by PEC	The firm revised the weight of API to 20mg without equivalency factor in Master formula.

	Decision: Deferred for revision of master formulation alongwith applicable fee.	
2788.	Name and address of manufacturer/ Applicant	M/s Shazal's Pharmaceuticals. Plot No.41/1-A, Phase-I, Industrial Estate, Hattar, By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name + Dosage Form + Strength	Silver Cef 1g IV Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium …1g
	Diary No. Date of R & I & fee	Dy. No. 36098; 31.10.2018 PKR. 50,000/-; 31.10.2018
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per policy of MoH
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 1 g (IV). US-FDA approved
	Me-too status	Martixon 1gm (Ceftriaxone sodium) I.V Dry powder Injection. Reg. No. 70663
	GMP status	Applicant: **The firm was inspected on 16.08.2018, wherein the Fid has pointed out a number of observations.** Manufacturer: The firm M/s Welmark Pharma was inspected on 04.09.2018 and 26.09.2018 with the following conclusion: As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator	• Undertaking at the end of Form 5 is missing. • The firm M/s Shazal pharma shall submit list of all approved sections. • The firm M/s Shazal pharma shall submit list of already approved product for contract manufacturing. • The firm M/s Shazal pharma shall submit list of applied product for contract manufacturing.
	Previous decision	The board in its 293rd meeting deferred the case for the following: Submission of list of approved products of applicant for contract manufacturing. Submission of list of approved sections of M/s Shazal Pharma.. List of applied products for contract manufacturing of M/s Shazal Pharma. Submission of undertaking of Form 5.
	Evaluation by PEC	• The firm submitted undertaking at the end of Form 5. • The firm M/s Shazal pharma submitted list of 04 approved sections. • The firm M/s Shazal pharma submitted that there is no product already approved for contract manufacturing. • The firm M/s Shazal pharma submitted list of 05 product applied for contract manufacturing
	Decision: Registration Board referred the case to QA & LT for updated status of GMP of M/s Shazal's Pharmaceuticals, Plot No.41/1-A, Phase-I, Industrial Estate, Hattar and capacity assessment of M/s Welmark.	
2789.	Name and address of manufacturer/	M/s Shazal's Pharmaceuticals. Plot No.41/1-A, Phase-I,

	Applicant	Industrial Estate, Hattar, By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name + Dosage Form + Strength	Silver Cef 500mg IV Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium …500mg
	Diary No. Date of R & I & fee	Dy. No. 36099; 31.10.2018 PKR. 50,000/-; 31.10.2018
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per policy of MoH
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 500mg (IV). US-FDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IV. Reg. No. 78097
	GMP status	As above
	Remarks of the Evaluator	• Undertaking at the end of Form 5 is missing. • The firm M/s Shazal pharma shall submit list of all approved sections. • The firm M/s Shazal pharma shall submit list of already approved product for contract manufacturing. • The firm M/s Shazal pharma shall submit list of applied product for contract manufacturing.
	Previous decision	The board in its 293rd meeting deferred the case for the following: Submission of list of approved products of applicant for contract manufacturing. Submission of list of approved sections of M/s Shazal Pharma. List of applied products for contract manufacturing of M/s Shazal Pharma. Submission of undertaking of Form 5.
	Evaluation by PEC	• The firm submitted undertaking at the end of Form 5. • The firm M/s Shazal pharma submitted list of 04 approved sections. • The firm M/s Shazal pharma submitted that there is no product already approved for contract manufacturing. • The firm M/s Shazal pharma submitted list of 05 product applied for contract manufacturing
	Decision: Registration Board referred the case to QA & LT for updated status of GMP of M/s Shazal's Pharmaceuticals, Plot No.41/1-A, Phase-I, Industrial Estate, Hattar and capacity assessment of M/s Welmark.	
2790.	Name and address of manufacturer/ Applicant	M/s Shazal's Pharmaceuticals. Plot No.41/1-A, Phase-I, Industrial Estate, Hattar, By M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name + Dosage Form + Strength	Silver Cef 250mg IV Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium …250mg
	Diary No. Date of R & I & fee	Dy. No. 36100; 31.10.2018 PKR. 50,000/-; 31.10.2018
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per policy of MoH
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg (IV). USFDA approved
	Me-too status	Unixone Injection (ceftriaxone Sodium) 250mg IM. Reg. No. 82556
	GMP status	As above
	Remarks of the Evaluator	• Undertaking at the end of Form 5 is missing. • The firm M/s Shazal pharma shall submit list of all approved sections. • The firm M/s Shazal pharma shall submit list of already approved product for contract manufacturing. • The firm M/s Shazal pharma shall submit list of applied product for contract manufacturing.
	Previous decision	The board in its 293rd meeting deferred the case for the following: Submission of list of approved products of applicant for contract manufacturing. Submission of list of approved sections of M/s Shazal Pharma.. List of applied products for contract manufacturing of M/s Shazal Pharma. Submission of undertaking of Form 5.
	Evaluation by PEC	• The firm submitted undertaking at the end of Form 5. • The firm M/s Shazal pharma submitted list of 04 approved sections. • The firm M/s Shazal pharma submitted that there is no product already approved for contract manufacturing. • The firm M/s Shazal pharma submitted list of 05 product applied for contract manufacturing
	Decision: Registration Board referred the case to QA & LT for updated status of GMP of M/s Shazal's Pharmaceuticals, Plot No.41/1-A, Phase-I, Industrial Estate, Hattar and capacity assessment of M/s Welmark.	
2791.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Citrok Syrup 500mg/5ml
	Composition	Each 5ml contain: Citicoline (as sodium)…….500mg
	Diary No. Date of R& I & fee	Dy No. 1688: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	30ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Somazine 100 mg / ml oral solution. **CIMA Spain** approved
	Me-too status	Citolin Syrup. Reg. No. 29540
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04

		samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no.S-66, 5200 Bottles was "Ordered not to dispose off" due to poor sanitation & hygiene conditions in the oral liquid filling area.
	Remarks of the Evaluator.	•
	Previous decision	The board in its 287th meeting deferred the case for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC	• The firm submitted inspection report dated 11.12.2019, wherein resumption of production has been recommended in oral liquid syrup section.
	Decision: Approved with innovator's specifications.	
2792.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	IPS Syrup
	Composition	Each 15 ml contain: Iron (III) protein succinylate eq. to elemental iron…….40mg
	Diary No. Date of R& I & fee	Dy No. 1682: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Iron trivalent, oral preparations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	120 ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Hemiplex Syrup. Reg. No. 057283
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no.S-66, 5200 Bottles was "Ordered not to dispose off" due to poor sanitation & hygiene conditions in the oral liquid filling area.
	Remarks of the Evaluator.	•
	Previous decision	The board in its 287th meeting deferred the case for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC	The firm submitted inspection report dated 11.12.2019, wherein resumption of production has been recommended in oral liquid syrup section.
	Decision: Approved with innovator's specifications.	
2793.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fero-M Syrup
	Composition	Each 5 ml contain: Iron (III) polysaccharide complex eq. to elemental iron…….100mg
	Diary No. Date of R& I & fee	Dy No. 1677: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Iron trivalent, oral preparations

	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Irosac Syrup. Reg. No. 82631
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no.S-66, 5200 Bottles was "Ordered not to dispose off" due to poor sanitation & hygiene conditions in the oral liquid filling area.
	Remarks of the Evaluator.	•
	Previous decision	The board in its 287th meeting deferred the case for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC	• The firm submitted inspection report dated 11.12.2019, wherein resumption of production has been recommended in oral liquid syrup section.
	Decision: Approved with innovator's specifications.	
2794.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Sypatite Syrup 120 ml
	Composition	Each 5 ml contain: Pizotifen (as malate)…….0.25mg
	Diary No. Date of R& I & fee	Dy No. 1676: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Other antimigraine preparations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	SANOMIGRAN **Elixir** 0.25mg/5ml. **MHRA** approved
	Me-too status	Aptigar Syrup (0.5mg/10ml). Reg. No. 54398
	GMP status	The firm was last inspected on 29.12.2015, wherein the renewal of DML was recommended
	Remarks of the Evaluator.	•
	Previous decision	The board in its 287th meeting deferred the case due to suspension of production by the firm.
	Evaluation by PEC	• The firm submitted inspection report dated 11.12.2019, wherein resumption of production has been recommended in oral liquid syrup section.
	Decision: Approved with innovator's specifications.	
2795.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Floutrone/Trimon Cream
	Composition	Each gram cream contains: Fluocinolone acetonide……0.1mg

		Hydroquinone…….40mg Tretinoin……0.5mg
	Diary No. Date of R& I & fee	Dy No. 1691: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	15g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRI-LUMA® (fluocinolone acetonide, hydroquinone, and tretinoin) cream, 0.01%, 4%, 0.05% for topical use by Galderma Labs LP. **US-FDA** approved
	Me-too status	Trimelasin Cream by Valor Pharmaceuticals. Reg. No. 31104
	GMP status	The firm was last inspected on 29.12.2015, wherein the renewal of DML was recommended
	Remarks of the Evaluator.	• The brand name shall be changed • The firm was asked to submit complete finished product specifications and testing methods. However, the firm did not submit the same.
	Previous decision	The board in its 287th meeting deferred the case due to suspension of production by the firm.
	Evaluation by PEC	• The firm submitted inspection report dated 11.12.2019, wherein resumption of production has been recommended in oral liquid syrup section.
	Decision: Approved with innovator's specifications.	
2796.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Hb-Ron Syrup 60 ml, 120 ml
	Composition	Each 5 ml contain: Iron (III) hydroxide polymaltose complex eq. to elemental iron…….50mg Folic acid…….0.35mg
	Diary No. Date of R& I & fee	Dy No. 1683: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Iron in combination with folic acid
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Poly-F Syrup. Reg. No. 64045
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no.S-66, 5200 Bottles was "Ordered not to dispose off" due to poor sanitation & hygiene conditions in the oral liquid filling area.
	Remarks of the Evaluator.	• The firm revised to the quantity of Folic acid from 0.50 mg to 0.35mg without submission of fee.

	Previous decision	The board in its 287th meeting deferred the case for: • Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. • Submission of fee for revision of formulation.
	Evaluation by PEC	• The firm submitted inspection report dated 11.12.2019, wherein resumption of production has been recommended in oral liquid syrup section. • The firm shall submit fee for revision of strength of API.
	Decision: Deferred for submission of fee for revision of strength of API.	
2797.	Name and address of manufacturer / Applicant	Moon Pharmaceuticals, Plot # 05, SS4, National Industrial Zone RCCI Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Citrok Syrup 500mg/5ml
	Composition	Each 5ml contain: Citicoline (as sodium)…….500mg
	Diary No. Date of R& I & fee	Dy No. 1688: 17.10.2016 PKR 20,000/-: 17.10.2016
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	30ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Somazine 100 mg / ml oral solution. **CIMA Spain** approved
	Me-too status	Citolin Syrup. Reg. No. 29540
	GMP status	The firm was inspected on 18.09.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Moon Pharma Islamabad has not made adequate arrangements for rectification of the observations from inspection dated 19-10-2017. The undersigned has taken 04 samples on prescribed Form-3. The batch of product Mondison 4mg/5ml (50ml) Syrup, Batch no.S-66, 5200 Bottles was "Ordered not to dispose off" due to poor sanitation & hygiene conditions in the oral liquid filling area.
	Remarks of the Evaluator.	•
	Previous decision	The board in its 287th meeting deferred the case for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC	The firm submitted inspection report dated 11.12.2019, wherein resumption of production has been recommended in oral liquid syrup section.
	Decision: Approved with innovator's specifications.	
2798.	Name and address of manufacturer / Applicant	Berlex Lab. International, 10 Km Nangshah Chowk Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Tramalex Plus Tablet
	Composition	Each film-coated tablet contains: Tramadol HCl……37.5 Paracetamol……..325
	Diary No. Date of R& I & fee	Dy No. 33096: 04.10.2018 PKR 20,000/-: 29.03.2017 (**Duplicate Dossier**)
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	2x5's; Rs. 100/-
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms **US-FDA** approved
	Me-too status	Tril-P Tablet by Linta Pharmaceuticals. Reg. No. 78181
	GMP status	The firm was inspected on 05.07.2018, wherein the panel recommended renewal of DML
	Remarks of the Evaluator.	• The firm was asked to revise the formulation to film-coated tablet along with correction in label claim, Master Formula and manufacturing outlines and submission of applicable fee. However, the firm only revised label claim in Form 5 and did not submit any fee.
	Previous decision	The Board in its 288th meeting deferred the case for submission of fee for revision of formulation.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee. • Revision of Master Formula and manufacturing outlines required.
	Previous decision	The Board in its 291st meeting deferred the case revision of Master Formula and manufacturing outlines for film-coated tablet.
	Evaluation by PEC	• The firm revised the master formula and manufacturing outlines, wherein blistering and packaing processes are missing.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of details of blistering and packaging process
	Evaluation by PEC	• The firm revised the manufacturing outlines, with blistering and packaing processes.
	Decision: Approved.	
2799.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	Ivamet 25/7.5 mg Film Coated Tablet
	Composition	Each Film Coated Tablet Contains: Metoprolol Tartrate…25mg Ivabradine as HCl …7.5mg
	Diary No. Date of R& I & fee	DyNo. 32773: 02.10.2018 PKR. 20,000/-; 28.09.2018
	Pharmacological Group	Beta blocking agents, other combinations
	Type of Form	Form 5
	Finished product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Implicor 25 mg / 7.5 mg film-coated tablets. Germany approved
	Me-too status	**Could not be confirmed**
	GMP status	The inspection report dated 02.07.2019 concluded that: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. **Moreover, firm should focus on above mentioned observations and comply with them on priority basis.**
	Remarks of the Evaluator	• Provide proof of approval of me-too product (name registration number and name of company) by DRAP.
	Previous decision	The Board in its 293rd meeting deferred the case for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC	The firm provided the following me-too:

		Implicor Reg. No. 97373 (Servier Pharmaceuticals), which could not be verified
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic/me-too status) along with registration number, brand name and name of the firm.	
2800.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Claripex 125mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Clarithromycin…….125mg
	Diary No. Date of R& I & fee	Dy No. 30583: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CLARITHROMYCIN 125 MG/5ML GRANULES FOR ORAL SUSPENSION. MHRA approved
	Me-too status	IB-CLAR Dry Suspension 125mg/5ml. Reg. No. 85051
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5. • The firm was asked to submit source of granules, GMP certificate thereof, and CoA and stability data of three batches of the granules (Zone IV-A). The firm referred to 288th meeting of the RB (page 320, case no 36), wherein clarithromycin dry suspension has been approved and no information has been mentioned about the source of granules.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of details regarding source of pellets, GMP certificate of manufacturer, stability studies of 03 batches conducted under the conditions of Zone IV-A and if pellets are imported then the fee Rs. 100,000/- should be submitted.
	Evaluation by PEC	The firm submitted COA and stability summary sheets of the granules. The source of granule is vision pharmaceutical Islamabad, which have been issued GMP ceritificate on the basis of inspection dated 11.02.2019.
	Decision: Approved.	
2801.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Claripex 250mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Dy No. 30584: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CLARITHROMYCIN 250 MG/5ML GRANULES FOR ORAL SUSPENSION. MHRA approved
	Me-too status	Clarimyth Dry Suspension 250mg/5ml. Reg. No. 85047
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 was not submitted. The firm submitted Form 5 on

		30.09.2019. Name of signatory is missing on Form 5. • The firm was asked to submit source of granules, GMP certificate thereof, and CoA and stability data of three batches of the granules (Zone IV-A). The firm referred to 288th meeting of the RB (page 118, case no 283), wherein clarithromycin dry suspension has been approved and no information has been mentioned about the source of granules.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of details regarding source of pellets, GMP certificate of manufacturer, stability studies of 03 batches conducted under the conditions of Zone IV-A and if pellets are imported then the fee Rs. 100,000/- should be submitted.
	Evaluation by PEC	The firm submitted COA and stability summary sheets of the granules. The source of granule is vision pharmaceutical Islamabad, which have been issued GMP ceritificate on the basis of inspection dated 11.02.2019.
	Decision: Approved.	
2802.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Droxipal 125mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefadroxil Monohydrate Eq. to Cefadroxil…125mg
	Diary No. Date of R& I & fee	Dy No. 30585: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Biodroxil 125 mg /5 ml - Pulver zur Herstellung einer Suspension zum Einnehmen (Biodroxil 125 mg / 5 ml - Powder for oral suspension). **AGES** approved
	Me-too status	Evacef Suspension 125mg. Reg. No. 11213
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5. • The firm has mentioned granulation process in the manufacturing outlines. Justification that the international reference product is the form of granule for suspension, was asked from the firm. The firm did not justify.
	Previous decision	The Board in its 293rd meeting deferred the case for clarification/submission of the manufacturing outline inline with the reference product.
	Evaluation by PEC	The firm submitted biodroxil as reference product and stated that the product mentioned that it is granule for suspension. The said product could not be verified.
	Decision: Deferred for submission of manufacturing outline in line with reference product.	
2803.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Droxipal 250mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefadroxil Monohydrate Eq. to Cefadroxil…250mg
	Diary No. Date of R& I & fee	Dy No. 30586: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	First-generation cephalosporins

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefadroxil 250 mg/5 ml **powder** for oral suspension. USFDA approved. Cefadroxil 250 mg/5 ml **granules** for oral suspension. MHRA approved
	Me-too status	Evacef Suspension 250mg. Reg. No. 11214
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	Form 5 has not been submitted.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of Form 5.
	Evaluation by PEC	The firm submitted Form 5. Undertaking at the end of form is missing.
	Decision: Deferred for submission of undertaking of Form-5.	
2804.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Droxipal 250mg Capsule
	Composition	Each capsule contains: Cefadroxil Monohydrate Eq. to Cefadroxil…250mg
	Diary No. Date of R& I & fee	Dy No. 30587: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Adrox -250 Capsule. Reg. No. 81218
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.
	Previous decision	The Board in its 293rd meeting deferred the case for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.
	Evaluation by PEC	The firm submitted reference of Duricef capsule of USFDA which has been discontinued
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting.	
2805.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lansopex 30mg Capsule
	Composition	Each Capsule Contains: Lansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 30582: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP (delayed release capsule)

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Vosta capsule 30mg. Reg. No. 81884
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.
	Previous decision	The Board in its 293rd meeting deferred the case for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting is required.
	Evaluation by PEC	The firm submitted the following reference: PREVACID (lansoprazole) delayed-release capsules, for oral use. USFDA approved. The firm has now revised the label claim to delayed release capsule.
	Decision: Deferred for submission of fee for revision of formulation.	
2806.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Lansopex 15mg Capsule
	Composition	Each Capsule Contains: Lansoprazole…15mg
	Diary No. Date of R& I & fee	Dy No. 30581: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP (delayed release capsule)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed. Available as enteric coated pellets
	Me-too status	Prozol 15mg Capsules. Reg. No. 24449
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.
	Previous decision	The Board in its 293rd meeting deferred the case for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting is required.
	Evaluation by PEC	The firm submitted the following reference: PREVACID (lansoprazole) delayed-release capsules, for oral use. USFDA approved. The firm has now revised the label claim to delayed release capsule.
	Decision: Deferred for submission of fee for revision of formulation.	
2807.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Famopal 20mg Tablet
	Composition	Each film-coated tablet contains: Famotidine…20mg
	Diary No. Date of R& I & fee	Dy No. 30579: 11.09.2018 PKR 20,000/-: 11.09.2018

	Pharmacological Group	H2-receptor antagonists
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AUSFAM famotidine 20mg and 40mg tablet, film-coated blister pack. TGA approved
	Me-too status	Welcid-20mg Tablet film-coated. Reg. No. 81681
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 has not been submitted. • You have mentioned methylene chloride in the coating composition. Justify its safety.
	Previous decision	The Board in its 293rd meeting deferred the case for the following: • Submission of form 5. • Use of banned excipient that is methylene chloride in coating.
	Evaluation by PEC	The firm submitted Form 5. Undertaking at the end of Form 5 is missing. The firm revised the coating composition.
	Decision: Deferred for submission of undertaking of Form-5.	
2808.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Famopal 40mg Tablet
	Composition	Each film-coated tablet contains: Famotidine…40mg
	Diary No. Date of R& I & fee	Dy No. 30580: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	H2-receptor antagonists
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AUSFAM famotidine 20mg and 40mg tablet, film-coated blister pack. TGA approved
	Me-too status	Famitol 40mg Tablet film-coated. Reg. No. 85770
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 has not been submitted. • You have mentioned methylene chloride in the coating composition. Justify its safety.
	Previous decision	The Board in its 293rd meeting deferred the case for the following: • Submission of form 5. • Use of banned excipient that is methylene chloride in coating.
	Evaluation by PEC	The firm submitted Form 5. Undertaking at the end of Form 5 is missing. The firm revised the coating composition.
	Decision: Deferred for submission of undertaking of Form-5.	
2809.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Propex 1g/100ml Infusion
	Composition	Each 100ml Contains: Acetaminophen…1g
	Diary No. Date of R& I & fee	Dy No. 30578: 11.09.2018

		PKR 20,000/-: 11.09.2018
	Pharmacological Group	Anilides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved.
	Me-too status	Provas Infusion 10mg/ml. No. 53223 (filled volume not specified)
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5.
	Previous decision	The Board in its 293rd meeting deferred the case for completion of Form 5.
	Evaluation by PEC	The firm submitted Form 5. Undertaking at the end of Form is missing.
	Decision: Deferred for submission of undertaking of Form-5.	
2810.	Name and address of manufacturer / Applicant	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ranitipal 50mg/2ml Injection
	Composition	Each 2ml Contains: Ranitidine as HCl…50mg
	Diary No. Date of R& I & fee	Dy No. 30577: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	H2 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2ml ampoule; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZANTAC® (ranitidine hydrochloride) Injection (2ml **vial**). USFDA approved
	Me-too status	Ranigen 50mg/2ml Injection. Reg. No. 24449 (does not show vial or ampule)
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Form 5 was not submitted. The firm submitted Form 5 on 30.09.2019. Name of signatory is missing on Form 5. • The reference product contains Ranitidine as HCl. Correction was asked along with adjustment of weight of API in master formula as per salt factor. The firm did not revise.
	Previous decision	The Board in its 293rd meeting deferred the case for submission of correct composition of applied product as per the reference product and revised master formula.
	Evaluation by PEC	The firm revised the label claim from Ranitidine HCl to Ranitidine as HCl and submitted revised master formula.
	Decision: Deferred for submission of fee for revision of formulation and decision of Registration Board in 293rd meeting regarding ranitidine products.	
2811.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot No. 122, Phase V, Block A, Industrial Estate Hatter, KPK
	Brand Name +Dosage Form + Strength	Rozin 1000mg Tablets
	Composition	Each extended release film coated tablet contains: Ranolazine…….1000mg
	Diary No. Date of R& I & fee	36054, 31-10-2018, 20,000/-, 29-10-2018
	Pharmacological Group	Anti-anginal

	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO As per SRO
	Approval status of product in Reference Regulatory Authorities.	RANEXA® (ranolazine) 1000mg extended-release tablets, film-coated. **USFDA** approved
	Me-too status	Ranzol-XR 1000mg Tablet. Reg. No. 61010
	GMP status	Panel inspection dated 18-01-2018 unanimously recommends the renewal of DML no. 000610 by way of formulation.
	Remarks of the Evaluator.	The firm revised the formulation to extended release film coated tablet with submission of Rs. 5000/-.
	Previous decision	The Board in its 293rd meeting deferred the case for the submission of differential fee of Rs. 15,000/- for revision of formulation.
	Evaluation by PEC	The firm submitted Rs. 15000/- differential fee; the matter of fee for such revision may be clarified.
	Decision: Approved.	
2812.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Getprazole 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Rabeprazole Sodium…20mg
	Diary No. Date of R& I & fee	Dy No. 25784: 24.07.2018 PKR 20,000/-: 24.07.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; Rs. 400/-
	Approval status of product in Reference Regulatory Authorities.	PARIET™ 20mg gastro-resistant tablet. MHRA approved
	Me-too status	Rabekan Tablet, 20mg enteric coated. Reg. No. 83829
	GMP status	The firm was inspected on 26.06.2018 with the following conclusion: "Based on the area inspected, the people met and the documents reviewed, the considering the findings of the inspection, including the observations listed in the inspection report, M/s Getz pharma, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today."
	Remarks of the Evaluator.	• Form has been signed by Sr. Manager Reulatory affairs. • The firm has mentioned methylene chloride (dichloromethane) in the manufacturing outlines. The firm did not clarify the same.
	Previous decision	The Board in its 292nd meeting deferred the case for the the justification of using methylene chloride as coating solvent since it has been declared as banned excipient.
	Evaluation by PEC	• The firm removed methylene chloride.
	Decision: Approved with innovator's specifications.	
2813.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Getprazole 10mg Tablet
	Composition	Each Enteric Coated Tablet Contains:

		Rabeprazole Sodium…10mg
	Diary No. Date of R& I & fee	Dy No. 25783: 24.07.2018 PKR 20,000/-: 24.07.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; Rs. 200/-
	Approval status of product in Reference Regulatory Authorities.	PARIET™ 10mg gastro-resistant tablet. MHRA approved
	Me-too status	Raprazole Tablet, 10mg enteric coated. Reg. No. 83279
	GMP status	The firm was inspected on 26.06.2018 with the following conclusion: "Based on the area inspected, the people met and the documents reviewed, the considering the findings of the inspection, including the observations listed in the inspection report, M/s Getz pharma, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today."
	Remarks of the Evaluator.	• Form has been signed by Sr. Manager Reulatory affairs. • The firm has mentioned methylene chloride (dichloromethane) in the manufacturing outlines. The firm did not clarify the same
	Previous decision	The Board in its 292nd meeting deferred the case for the the justification of using methylene chloride as coating solvent since it has been declared as banned excipient.
	Evaluation by PEC	• The firm removed methylene chloride.
	Decision: Approved with innovator's specifications.	
2814.	Name and address of manufacturer / Applicant	M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; contract manufacturing by: Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	SEC 40mg IV Injection
	Composition	Each vial contains: Omeprazole as sodium……40mg
	Diary No. Date of R& I & fee	Dy No. 9513: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial. **TGA** approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate. The firm M/s Honig Pharmaceuticals was inspected on 11.10.2018 and reported complying GMP.
	Remarks of the Evaluator.	• **The shelf-life of the product in TGA is 18 months.** • The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned. • The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing.

		• The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • Adjustment of weight of API as per salt factor is required in Master Formula. • The firm has mentioned the dosage form as injection. However, the composition and manufacturing outlines depict that the product is lyophilized powder for injection. • The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer. • The firm was asked to clarify the lyophilization process, but the firm did not reply.
	Previous decision	The Board in its 289th meeting deferred the case for the following: • Adjustment of weight of API as per salt factor is required in Master Formula. • Clarify whether the product is filled and lyophilized or only lyophilized powder is filled. • Clarify the dosage form.
	Evaluation by PEC	• The firm revised the master formula. • The firm submitted that lyophilized powder will be filled in the vials. • The dosage form is dry powder (lyophilized).
	Decision: Deferred for submission of fee for revision of master formula.	
2815.	Name and address of manufacturer / Applicant	M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; contract manufacturing by: Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Moxing 400mg/250ml IV Injection
	Composition	Each 250ml contains: Moxifloxacin as HCl……400mg
	Diary No. Date of R& I & fee	Dy No. 9512: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	(250ml) 1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. **TGA** approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	
	Remarks of the Evaluator.	• The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned. • The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing. • The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • The firm mentioned HDPE as primary packaging. Then changed to LDPE). The reference product is packed in Glass Type I clear bottle.

		• The firm was asked for adjustment of weight of API as per salt factor. The firm did not revised the same. • The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer.
	Previous decision	The Board in its 289th meeting deferred the case for clarification about the packaging.
	Evaluation by PEC	The firm submitted that they will use clear glass bottles of USP type I.
	Decision: Approved with innovator's specifications.	
2816.	Name and address of manufacturer / Applicant	M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; contract manufacturing by: Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Xamp 40mg IV Injection
	Composition	Each vial contains: Esomeprazole as sodium……40mg
	Diary No. Date of R& I & fee	Dy No. 9511: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for injection vial. **TGA** approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	
	Remarks of the Evaluator.	• The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned. • The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing. • The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • The firm has mentioned the dosage form as injection. However, the composition and manufacturing outlines depict that the product is lyophilized powder for injection. • The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer. • Adjustment of weight of API as per salt factor is required in Master Formula. • The firm has mentioned 33% potency of lyophilized powder, but did not clarify the other 67% composition. • The firm was asked to clarify the lyophilization process, but the firm did not reply.
	Previous decision	The Board in its 289th meeting deferred the case for the following: • Adjustment of weight of API as per salt factor is required in Master Formula. • Clarification whether the product is filled and lyophilized or only lyophilized powder is filled. • Clarification of the dosage form. • Clarification about the composition of the

		dosage form (powder).
	Evaluation by PEC	• The firm revised the master formula. • The firm submitted that lyophilized powder will be filled in the vials. • The dosage form is dry powder (lyophilized).
	Decision: Deferred for submission of fee for revision of master formula.	
2817.	Name and address of manufacturer / Applicant	Relizon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Pantozon Tablet 40mg
	Composition	Each delayed release tablet contains: Pantoprazole (as sodium sesquihydrate)……40mg
	Diary No. Date of R& I & fee	Dy No. 7145: 23.02.2018 PKR 20,000/-: 23.02.2018 PKR 20,000/-: 25.09.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROTONIX (pantoprazole sodium) delayed-release tablets 40mg, for oral use. USFDA approved
	Me-too status	PROTIUM GASTRO RESISTANT TABLETS 40mg. Reg. No. 21039
	GMP status	The firm was inspected on 05.12.2017, wherein the panel recommended the grant of DML.
	Remarks of the Evaluator.	• The brand, generic or strength has not been mentioned on the fee challan. The firm submitted undertaking • The firm revised the dosage form from capsule to delayed release tablet with submission of Rs. 20000/- fee. • Correction of pantoprazole to pantoprazole sodium sesquihydrate in Master formula along with adjustment of its weight as per salt factor. • The reference product has a sub-coating above which enteric coating is present. The submitted dossier does not depict the same.
	Previous decision	The Board in its 293rd meeting deferred the case for for clarification of composition of applied product regarding the sub-coating above which the enteric coating is present as per the composition of the reference product.
	Evaluation by PEC	The firm revised pantoprazole to pantoprazole sodium sesquihydrate in Master formula along with adjustment of its weight as per salt factor and revised the manufacturing outlines.
	Decision: Deferred for submission of fee for revision of master formula.	
2818.	Name and address of manufacturer / Applicant	Relizon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Pantozon Capsule 20mg
	Composition	Each capsule contains: Pantoprazole……20mg
	Diary No. Date of R& I & fee	Dy No. 7144: 23.02.2018 PKR 20,000/-: 23.02.2018 PKR 20,000/-: 25.09.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Panzium (pantoprazole base) capsules 20mg. 60482
	GMP status	The firm was inspected on 05.12.2017, wherein the panel recommended the grant of DML.
	Remarks of the Evaluator.	• The brand, generic or strength has not been mentioned on the fee challan. The firm submitted undertaking • The firm revised the dosage form from capsule to delayed release tablet with submission of Rs. 20000/- fee. • Correction of pantoprazole to pantoprazole sodium sesquihydrate in Master formula along with adjustment of its weight as per salt factor. • The reference product has a sub-coating above which enteric coating is present. The submitted dossier does not depict the same.
	Previous decision	The Board in its 293rd meeting deferred the case for for clarification of composition of applied product regarding the sub-coating above which the enteric coating is present as per the composition of the reference product.
	Evaluation by PEC	The firm revised pantoprazole to pantoprazole sodium sesquihydrate in Master formula along with adjustment of its weight as per salt factor and revised the manufacturing outlines.
	Decision: Deferred for submission of fee for revision of master formula.	

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

a. New Cases

2819.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+Strength	Veticam Plus Injectin
	Composition	Each ml contains: Meloxicam……..…..20 mg
	Diary No. Date of R & I & fee	Dy. No. 42888; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	50ml; Decontrolled
	Me-too status	Metrym Injection (50ml, 100ml). Reg. no. 044961
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	Terminal sterilization/ sterile filling process is missing in the manufacturing outlines.
	Decision: Deferred for clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.	
2820.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+Strength	Vetzmisole 15 % Oral powder
	Composition	Each Kg contains: Levamisole HCl ……..…..150 g
	Diary No. Date of R & I & fee	Dy. No. 42894; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Imidazothiazole derivatives

	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	100 gm,150 gm, 200gm, 250 gm, 500 gm, 1 Kg, 5 Kg, 25 Kg Decontrolled
	Me-too status	FIZISOL 15 WATER SOLUBLE POWDER. Reg. No. 081343
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
2821.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Vetzmisole 50 % Oral powder
	Composition	Each Kg contains: Levamisole HCl ……..500 gm
	Diary No. Date of R & I & fee	Dy. No. 42895; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Imidazothiazole derivatives
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	100 gm,150 gm, 200gm, 250 gm, 500 gm, 1 Kg, 5 Kg, 25 Kg Decontrolled
	Me-too status	Wormidec WS Powder. Reg. No. 079827
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
2822.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Vitaflox 20 % Injection
	Composition	Each ml contains: Enrofloxacin ……..…..…..200 mg
	Diary No. Date of R & I & fee	Dy. No. 42889; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Fluoroquinolone
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	100 ml Decontrolled
	Me-too status	Enflox 20 % Injection (50ml, 100ml). Reg. no. 048153
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.	
2823.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	V-Mox LA 15 % Injection
	Composition	Each ml contains: Amoxicillin as trihydrate…….…..150 mg
	Diary No. Date of R & I & fee	Dy. No. 42889; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Penicillins
	Types of Form	Form-5

	Finished Product Specification	In-house specifications. The product is available in USP as powder for injectable suspension.
	Pack Size & Demanded Price	10 ml Decontrolled
	Me-too status	Symox LA Injection (10ml, 50ml, 100ml). Reg. No. 058999
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Deferred for clarification whether product is long acting (as mentioned in brand name) or otherwise (as no long acting claim in brand name) and confirmation of section.	
2824.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Imivetz Injection
	Composition	Each ml contains: Imidocarb dipropaionate ……120 mg
	Diary No. Date of R & I & fee	Dy. No. 42891; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Antiprotozoal agent
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	10 ml Decontrolled
	Me-too status	Imedo Injection (50ml, 100ml). Reg. No. 052385
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	Terminal sterilization is missing in the manufacturing outlines. Provide me-too product (Name and registration number) with same strength and filled volume approved by DRAP.
	Decision: Deferred for following: • **Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2825.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Penmicin Injection
	Composition	Each ml contains: Procaine Penicillin G……..150000IU Benzathin PenicillinG……..100000IU Dihydrostreptomycin Sulfate…… 200 mg
	Diary No. Date of R & I & fee	Dy. No. 42892; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Antibacterials
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	20 ml Decontrolled
	Me-too status	Penmicin Injection (50ml). Reg. No. 084959 By same firm
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	Terminal sterilization is missing in the manufacturing outlines. Provide me-too product (Name and registration number) with same strength and filled volume approved by DRAP.

	Decision: Deferred for following: • **Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2826.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Vetz Mineral Oral Powder
	Composition	Each Kg contains: Ca(Calcium)..……...155 gm P (Phosphorous).…135 gm Mg(Magnesium)….. 55 gm Na (Sodium)……. 45 gm Fe (Iron)…….……1000mg Zn (Zinc) ……3000 mg Mn(Manganese)…2000 mg Cu (Copper)…… 600 mg Co (Cobalt) ……. 10 mg I (Iodine)……40 mg Se (Selenium)…….. 3 mg
	Diary No. Date of R & I & fee	Dy. No. 42893; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Minerals
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	100 gm,150 gm, 250 gm, 500 gm ,1 Kg, 5 Kg, 25 Kg Decontrolled
	Me-too status	L. S. Minerals Powder. Reg. no. 021306
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
2827.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Clormec injection
	Composition	Each ml contains: Ivermectin……. 10 mg Clorsulon…….100 mg
	Diary No. Date of R & I & fee	Dy. No. 42886; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Anthelmintics
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	10 ml Decontrolled
	Me-too status	ALMEC PLUS INJECTION. (10ml, 25ml, 50ml, 100ml, 500ml). Reg No. 049678
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
		The firm revised the strength of API (Ivermectin……. 20mg) to Ivermectin……. 10 mg in line with the me-too product along with submission of Rs 20000/- fee.
	Decision: Approved with USP specifications.	

2828.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Aminovetz injection 250ml
	Composition	Each ml contains Dextrose …….50 mg Calcium chloride …….0.15mg Potassium chloride……. 0.2mg Magnesium Sulfate…….. 0.2mg Sodium acetate trihydrate ……2.5mg L-Histidine HCl …..……..0.34mg DL-Methionine ……0.34mg DL-Tryptophan ……0.34mg L-Cysteine HCl ……0.34mg L-Threonine ……0.68mg DL-Isoleucine ……0.68mg L-Arginine HCl ……0.85mg DL-Phenylalanine …….1.02mg DL-Valine ……..1.7mg L-Lysin HCl ……..1.02mg L-Leucine …….1.36mg Monosodium glutamate ……1.36mg Vitamin B1 (Thiamin HCl) …….0.10mg Vitamin B2 (Riboflavin-5-Phosphate).. 0.04mg Vitamin B6 (Pyridoxine Hydrochloride)..0.1mg Vitamin B12 (Cyanocobalamin) …..0.05mcg Nicotinamide ……..1.5mg
	Diary No. Date of R & I & fee	Dy. No. 42896; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Amino Acid/ Electrolytes/ Vitamins
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	250 ml Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remark of Evaluator	The composition do not match with the provided me-too. Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2829.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Aminovetz injection 500ml
	Composition	Each ml contains Dextrose …….50 mg Calcium chloride …….0.15mg Potassium chloride……. 0.2mg Magnesium Sulfate…….. 0.2mg Sodium acetate trihydrate ……2.5mg L-Histidine HCl …..……..0.34mg DL-Methionine ……0.34mg DL-Tryptophan ……0.34mg L-Cysteine HCl ……0.34mg

		L-Threonine ……0.68mg DL-Isoleucine ……0.68mg L-Arginine HCl ……0.85mg DL-Phenylalanine ……1.02mg DL-Valine ……..1.7mg L-Lysin HCl ……..1.02mg L-Leucine ……1.36mg Monosodium glutamate ……1.36mg Vitamin B1 (Thiamin HCl) ……0.10mg Vitamin B2 (Riboflavin-5-Phosphate).. 0.04mg Vitamin B6 (Pyridoxine Hydrochloride)..0.1mg Vitamin B12 (Cyanocobalamin) …..0.05mcg Nicotinamide ……..1.5mg
	Diary No. Date of R & I & fee	Dy. No. 42892; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Amino Acid/ Electrolytes/ Vitamins
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	500 ml Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remark of Evaluator	The composition do not match with the provided me-too. Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2830.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Aceclovetz injection
	Composition	Each ml contains: Aceclofenac……. 25 mg
	Diary No. Date of R & I & fee	Dy. No. 42887; 17.12.2018 PKR. 20,000/-; 17.12.2018
	Pharmacological Group	Acetic acid derivatives and related substances
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	50 ml Decontrolled
	Me-too status	Aceclovetz Injection (20ml). Reg. No. 088160 By same firm
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remark of Evaluator	Provide me-too product (Name and registration number) with same strength and filled volume approved by DRAP. Terminal sterilization is missing in the manufacturing outlines.
	Decision: Deferred for following: • **Clarification of method of terminal sterilization/ sterile filling process in manufacturing outlines.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

2831.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Fosphovetz Injection 50ml
	Composition	Each ml contains: Butaphosphan……..…100 mg Cyanocobalamine….. 50 mcg Taurine ……..37.3 mg Nicotinamide…….. 23 mg DL-Methionine……18.7 mg
	Diary No. Date of R & I & fee	Dy. No. 43743; 24.12.2018 PKR. 20,000/-; 24.12.2018
	Pharmacological Group	Vitamins, amino acids and minerals
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	50 ml Decontrolled
	Me-too status	Fospho-AV Injection (50ml). Reg. No. 088084
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	The firm has mentioned filtration as process of sterilization.
	Decision: Approved with innovator's specificaitons.	
2832.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Fosphovetz Injection 100ml
	Composition	Each ml contains: Butaphosphan……..…100 mg Cyanocobalamine….. 50 mcg Taurine ……..37.3 mg Nicotinamide…….. 23 mg DL-Methionine……18.7 mg
	Diary No. Date of R & I & fee	Dy. No. 43744; 24.12.2018 PKR. 20,000/-; 24.12.2018
	Pharmacological Group	Vitamins, amino acids and minerals
	Types of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	100 ml Decontrolled
	Me-too status	Fospho-AV Injection (100ml). Reg. No. 099370
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	The firm has mentioned filtration as process of sterilization.
	Decision: Approved with innovator's specifications.	
2833.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Fosphovetz Injection
	Composition	Each ml contains: Butaphosphan……..…100 mg Cyanocobalamine….. 50 mcg Taurine ……..37.3 mg Nicotinamide…….. 23 mg DL-Methionine……18.7 mg
	Diary No. Date of R & I & fee	Dy. No. 43745; 24.12.2018 PKR. 20,000/-; 24.12.2018
	Pharmacological Group	Vitamins, amino acids and minerals
	Types of Form	Form-5

	Finished Product Specification	In-house specifications
	Pack Size & Demanded Price	250 ml Decontrolled
	Me-too status	Fospho-AV Injection (50ml). Reg. No. 088084
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	The firm has mentioned filtration as process of sterilization.
	Decision: Approved with innovator's specifications.	
2834.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Vetzphos Injection 100ml
	Composition	Each ml contains: Sodium Acid Phosphate……400 mg
	Diary No. Date of R & I & fee	Dy. No. 43741; 24.12.2018 PKR. 20,000/-; 24.12.2018
	Pharmacological Group	Phosphate deficiency (general tonic)
	Types of Form	Form-5
	Finished Product Specification	In-house specifications. Avaialable in USP as (Each mL contains: Monobasic sodium phosphate, monohydrate, 276 mg; dibasic sodium phosphate, anhydrous, 142 mg (equivalent to dibasic sodium phosphate, heptahydrate, 268 mg); Water for Injection q.s. In the 5 mL and 15 mL product, phosphoric acid and/or NaOH may have been added for pH adjustment.)
	Pack Size & Demanded Price	100 ml Decontrolled
	Me-too status	Alphos-40 Injection (10ml, 20ml, 50ml, 100ml). Reg. No. 046573
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	The firm has mentioned filtration as process of sterilization.
	Decision: Approved with innovator's specifications.	
2835.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +DosageForm+Strength	Vetzphos Injection
	Composition	Each ml contains: Sodium acid phosphate……400 mg
	Diary No. Date of R & I & fee	Dy. No. 43742; 24.12.2018 PKR. 20,000/-; 24.12.2018
	Pharmacological Group	Phosphate deficiency (general tonic)
	Types of Form	Form-5
	Finished Product Specification	In-house specifications. Avaialable in USP as (Each mL contains: Monobasic sodium phosphate, monohydrate, 276 mg; dibasic sodium phosphate, anhydrous, 142 mg (equivalent to dibasic sodium phosphate, heptahydrate, 268 mg); Water for Injection q.s. In the 5 mL and 15 mL product, phosphoric acid and/or NaOH may have been added for pH adjustment.)
	Pack Size & Demanded Price	250 ml Decontrolled
	Me-too status	Alphos-40 Injection (10ml, 20ml, 50ml, 100ml). R.No. 046573
	GMP status	The firm was inspected on 26 & 27-7-2019 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of Evaluator	The firm has mentioned filtration as process of sterilization.
	Decision: Deferred for justification and evidence of applied pack size.	

2836.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name +Dosage Form + Strength	Biowan S Oral Powder 1000gm
	Composition	Each 1000gm contains: Doxycycline HCL…200gm Tylosin Tartrate…100gm Colistin Sulphate…50MIU Bromhexine HCL…5gm Streptomycin sulphate…20gm
	Diary No. Date of R & I & fee	Dy. No. 7972; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antibiotics + mucolytics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g; 1000g, 5000g; Decontrolled
	Me-too status	RIZ WAN-S WATER SOLUBLE POWDER. Reg. No. 78296 (colistin suphate 0.5MIU/g)
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• The firm revised the strength of colistin sulphate in line with the me-too product without submission of applicable fee.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Submission of fee for revision of formulation.**	
2837.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bio Doxine Oral Powder
	Composition	Each 100gm contains: Doxycycline Hyclate…50gm
	Diary No. Date of R & I & fee	Dy. No. 7961; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g; 1000g, 5000g; Decontrolled
	Me-too status	DOXYPOL POWDER. Reg. no. 95641
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• The firm revised Doxycycline as Hyclate to Doxycycline Hyclate.
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2838.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Big Dox Oral Powder
	Composition	Each gm contains: Doxycycline Hyclate…918.23mg (eq to Doxycycline base 800mg)
	Diary No. Date of R & I & fee	Dy. No. 7963; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Tetracyclines

	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g; 1000g, 5000g; Decontrolled
	Me-too status	"DOXYRAL 80% WATER SOLUBLE POWDER FOR ORAL ROUTE (each gram contains: Doxycycline Hyclate…923.32mg (eq to Doxycycline 800mg). The hyclate factor is 1.154
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• Revise the strength of API in line with the me-too product along with submission of applicable fee.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Revision of formulation alongwith applicable fee.**	
2839.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bromo Oxime Oral Liquid
	Composition	Each 100ml contains: Bromohexine HCL…5g
	Diary No. Date of R & I & fee	Dy. No. 7982; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Mucolytics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	BROMBAK SOLUTION (50mg/ml). Reg. No. 49786
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2840.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Toltroxime Oral Liquid
	Composition	Each 100ml contains: Toltrazuril…2.5g
	Diary No. Date of R & I & fee	Dy. No. 7981; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Treatment for coccidiosis
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	COXIRIL SOLUTION (25mg/ml). Reg. No. 34581
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• Provide proof of approval of me-too product (name and registration number) approved by DRAP.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status)**	

	alongwith registration number, brand name and name of firm.	
2841.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Toltra Prim Oral Liquid
	Composition	Each 100ml contains: Toltrazuril…2.5g Trimethoprin…5g
	Diary No. Date of R & I & fee	Dy. No. 7980; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Treatment for coccidiosis and antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	Truecox Oral (Each ml contains: Toltrazuril…25mg, Trimethoprin…5mg).
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	Provide proof of approval of me-too product (name and registration number) approved by DRAP. Otherwise revise the strength of API in line with the above emtnioned product along woth submission of applicable fee.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2842.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bioambrox Oral Liquid
	Composition	Each 100ml contains: Ambroxol HCL…2gm
	Diary No. Date of R & I & fee	Dy. No. 7973; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Mucolytics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• Provide proof of approval of me-too product (name and registration number) approved by DRAP.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2843.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bio Enro Oral Liquid

	Composition	Each 100ml contains: Enrofloxacin…10g
	Diary No. Date of R & I & fee	Dy. No. 7974; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	KARIFLOX 10% ORAL SOLUTION. Reg. No. 81715
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2844.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Speclin 100 Oral Liquid
	Composition	Each 150gm contains: Lincomycin HCL…33.3 Spectinomycin HCL…66.7gm
	Diary No. Date of R & I & fee	Dy. No. 7968; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	Decontrolled
	Me-too status	LINCO-S 100 W/S POWDER. Reg. No. 62169
	GMP status	
	Remarks of the Evaluator	• Submit latest GMP inspection report. • You have applied for liquid pack size. Justify. • Revise Lincomycin HCL to Lincomycin as HCl and Spectinomycin HCl to Spectinomycin as HCl. Also, adjust their weight in master formula as per salt factor.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Revision of formulation as per me-too reference** • **Confirmation of pack size**	
2845.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Noflor Oral Powder
	Composition	Each gm contains: Neomycin suplhate…150mg Florfenicol…100mg Oxytetracycline…300mg
	Diary No. Date of R & I & fee	Dy. No. 7969; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g, 1000g, 5000g; Decontrolled
	Me-too status	E-COL WATER SOLUBLE POWDER. Reg. No. 81733

	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years	
2846.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Neotetra Oral Powder
	Composition	Each 450gm contains: Neomycin suplhate…10gm Oxytetracycline…10gm
	Diary No. Date of R & I & fee	Dy. No. 7970; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	Decontrolled
	Me-too status	NEXYBAK WATER SOLUBLE POWDER. Reg. No. 63840
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years	
2847.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Biostin Oral Powder
	Composition	Each 100gm contains: Colistin Sulphate…500,000IU
	Diary No. Date of R & I & fee	Dy. No. 7971; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• Provide proof of approval of me-too product (name and registration number) approved by DRAP.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2848.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bio Renal Oral Powder
	Composition	Each 100gm contains: Hexamethylenetetramine…95.5gm Riboflavin…1gm Calcium pentothenate…0.5gm Nicotinamide…2.5gm
	Diary No. Date of R & I & fee	Dy. No. 7962; 22.02.2019

		PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Calcium supplement with multivitamins and bactericidal
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g, 1000g, 5000g; Decontrolled
	Me-too status	RINOSEL POWDER. Reg. No. 49621
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2849.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Biomanta Oral Powder
	Composition	Each 100gm contains: Amantadine HCL…10gm
	Diary No. Date of R & I & fee	Dy. No. 7966; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g, 1000g, 5000g; Decontrolled
	Me-too status	AMANTABAK 10% POWDER. Reg. no. 75697
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2850.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Specto Plus Oral Powder
	Composition	Each 100gm contains: Lincomycin HCL…5gm Spectinomycin HCL…7.5gm Spiramycin Adipate…2.5gm Bromohexime HCL…0.5gm
	Diary No. Date of R & I & fee	Dy. No. 7967; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antibiotics and mucolytics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g, 1000g, 5000g; Decontrolled
	Me-too status	SPECLINX ORAL POWDER, Reg. No. 80714
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2851.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bio Bromflox Oral Liquid
	Composition	Each ml contains: Enrofloxacin…200mg

		Bromohexine HCL…10mg
	Diary No. Date of R & I & fee	Dy. No. 7975; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antibiotics and mucolytics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	Bromoflox Oral Solution. Reg. No. 73905
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• The firm revised the master formula /composition according to the provided label claim.
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2852.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bioampro 98 Oral Powder
	Composition	Each 1000gm contains: Amprolium HCL…980gm
	Diary No. Date of R & I & fee	Dy. No. 7965; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Treatment for coccidiosis
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g, 1000g, 5000g; Decontrolled
	Me-too status	AMPRO-98 ORAL POWDER. 83241
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2853.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Tilco Oral Liquid
	Composition	Each 100ml contains: Tilmicosin phosphate…25g
	Diary No. Date of R & I & fee	Dy. No. 7979; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	MYCOTIL LIQUID. Reg. No. 49663
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• The firm revised Tilmicosin as phosphate to Tilmicosin phosphate.
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2854.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Mento Plus Oral Liquid

	Composition	Each litre contains: Aminophyline…150gm Bromohexine HCL…10.5gm Guaiphenesin…100gm Menthol…10gm Camphor…10gm
	Diary No. Date of R & I & fee	Dy. No. 7978; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Bronchodilator + mucolytics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator	• Submit latest GMP inspection report. • Provide proof of approval of me-too product (name and registration number) approved by DRAP.
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2855.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Mento Care Oral Liquid
	Composition	Each 100ml contains: Aminophyline HCL…8gm Bromohexine HCL…5gm Guaiphenesin…10gm Menthol…10gm
	Diary No. Date of R & I & fee	Dy. No. 7977; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Bronchodilator + mucolytics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator	• Submit latest GMP inspection report. • Provide proof of approval of me-too product (name and registration number) approved by DRAP.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2856.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Ceflor 30 Oral Liquid
	Composition	Each 100ml contains: Florfenicol…30g
	Diary No. Date of R & I & fee	Dy. No. 7976; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5

	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	• Provide proof of approval of me-too product (name and registration number) approved by DRAP.
	Decision: Deferred for following: • **Updated status of GMP since submitted inspection report is not within the period of three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2857.	Name and address of manufacturer/ Applicant	M/s Bio-Oxime Pharmaceuticals Plot.no.31,32 Millat Garment City, Dry Port Road, Faisalabad
	Brand Name + Dosage Form + Strength	Ampoxie Oral Powder
	Composition	Each kg contains: Amprolium HCL…500g
	Diary No. Date of R & I & fee	Dy. No. 7964; 22.02.2019 PKR. 20,000/-; 22.02.2019
	Pharmacological Group	Treatment for coccidiosis
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	500g, 1000g, 5000g; Decontrolled
	Me-too status	BIO-AMP 50% POWDER. Reg. No. 23410
	GMP status	The firm was inspected on 05.04.2016, wherein the firm was considered GMP compliant.
	Remarks of the Evaluator	
	Decision: Deferred for updated status of GMP since submitted inspection report is not within the period of three years.	
2858.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Acetol Powder
	Composition	Each 100gm contains: Paracetamol…2gm Vitamin C…20gm Potassium chloride…4gm Calcium Carbonate…4.5gm Magnesium sulphate…3.5gm
	Diary No. Date of R & I & fee	Dy. No. 6772; 15.02.2019 PKR. 20,000/-; 15.02.2019
	Pharmacological Group	Antipyretic + vitamin C + minerals
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	SPIN-C POWDER. Reg. No. 78239
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2859.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Neogence 72 Powder

	Composition	Each 1000gm contains: Neomycin sulphate…720gm
	Diary No. Date of R & I & fee	Dy. No. 6773; 15.02.2019 PKR. 20,000/-; 15.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	N-72 WATER SOLUBLE POWDER. Reg. No. 78297
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2860.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Spira L Powder 75mg/25mg
	Composition	Each gm contains: Spiramycin Adipate…75mg Lincomycin HCL…25mg
	Diary No. Date of R & I & fee	Dy. No. 9214; 15.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	SPECTO ORAL POWDER. Reg. No. 80134
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2861.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Erythrim S Powder
	Composition	Each 1000gm contains: Erythromycin Thiocyanate CPV…100gm Trimethoprim…20gm Sulphadiazine…100gm
	Diary No. Date of R & I & fee	Dy. No. 9226; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	ERYSUL-T ORAL POWDER. Reg. No. 80135
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2862.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Neoxycol Powder

	Composition	Each 1000gm contains: Oxytetracycline HCL…250GM Neomycin Sulphate…250gm Colistin Sulphate…300MIU
	Diary No. Date of R & I & fee	Dy. No. 9227; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	COLICYCLINE-N ORAL POWDER. Reg. No. 89829
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2863.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Eledox T Powder
	Composition	Each 1000gm contains: Doxycycline HCL…400gm Tylosin tartrate…200gm Colistin sulphate…500MIU Bromhexine HCl…10gm
	Diary No. Date of R & I & fee	Dy. No. 9225; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotic + mucolytic
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	FIT RESPI WATER SOLUBLE POWDER. Reg. No. 78268
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2864.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Fosfin TS Powder
	Composition	Each kg contains: Fosfomycin calcium…200gm Tylosine tartrate…100gm Fructose…180gm Sodium phosphate…150gm Magnesium sulphate…100gm
	Diary No. Date of R & I & fee	Dy. No. 9221; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antiobiotics + carbohydrate + rehydration salts
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	FOSFO-20 ORAL POWDER. Reg. No. 88861
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied &

		working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2865.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	E colis 48 Powder
	Composition	Each gm contains: Colistin sulphate…4,800,000 IU
	Diary No. Date of R & I & fee	Dy. No. 9216; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 250g, 500g, 1kg; Decontrolled
	Me-too status	COLIVETO-4800 SOLUBLE POWDER. Reg. No. 23476
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2866.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Flori c Liquid
	Composition	Each 100ml contains: Florfenicol…23gm Colistin sulphate…50MIU
	Diary No. Date of R & I & fee	Dy. No. 9217; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100ml, 500ml, 1 L; Decontrolled
	Me-too status	MAXIFLOR-PLUS LIQUID. Reg. No. 75617
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2867.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Elistine Powder
	Composition	Each gm contains: Lincomycin HCL…100mg Colistin Sulphate…800,000IU
	Diary No. Date of R & I & fee	Dy. No. 9218; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	VETY LINCOCO POWDER. Reg. No. 46665
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied &

		working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2868.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Elepro 60 Powder
	Composition	Each gm contains: Amprolium HCL…600mg
	Diary No. Date of R & I & fee	Dy. No. 9219; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Treatment for intestinal coccidiosis
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	AMPROCIDIA WATER SOLUBLE POWDER. Reg. No. 28568
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with USP specifications.	
2869.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Tiagence Powder
	Composition	Each 1000gm contains: Tiamulin as hydorgen fumarate…100gm Chlortetacycline as HCl …300gm
	Diary No. Date of R & I & fee	Dy. No. 9220; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	SB TIACLOR ORAL POWDER. Reg. NO. 48223
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2870.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Enro Ts Liquid
	Composition	Each ml contains: Enrofloxacin…75mg Sulphamethoxy Pyridazine…75mg Sulphamethazine…50mg Trimethoprim…25mg
	Diary No. Date of R & I & fee	Dy. No. 9229; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100ml, 500ml, 1L; Decontrolled
	Me-too status	CINA T.S ORAL SUSPENSION. Reg. NO. 31456 (enroflodicaine

		has been mentioned instead of enrofloxacin).
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	• The firm mentioned Sulphamethoxy Pyridazine in the label claim and Sulphamethoxy Pyridazine as sodium in the master formula and manufacturing outlines. Upon justification the firm revised the master formula.
	Decision: Deferred for clarification of composition of applied formulation since ratio of trimethoprim and sulphamethazine should be 1:5.	
2871.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Bro M Powder
	Composition	Each gm contains: Bromhexine HCl…20mg Menthol…4mg
	Diary No. Date of R & I & fee	Dy. No. 9230; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Expectorants
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	TUSNIL 2% POWDER. Reg. No. 75627
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2872.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Chlorotech Powder
	Composition	Each 100gm contains: Chlortetracycline HCl…..20gm
	Diary No. Date of R & I & fee	Dy. No. 9214; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	W.S. CTC 20% POWDER. Reg. No. 41268
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
2873.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Doc Powder
	Composition	Each 100gm contains: Doxycycline HCL…20gm Colistin sulphate…40,000,000IU Carrier q.s.…100gm
	Diary No. Date of R & I & fee	Dy. No. 9222; 28.02.2019

		PKR. 20,000/-; 28.02.2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	DOXYCOL DS ORAL POWDER. Reg. no. 31482
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	• The firm has mentioned the carrier in the label claim. Upon clarification the firm submitted they have applied as per label of me-too product available in the market.
	Decision: Deferred for clarification of carrier in the applied formulation.	
2874.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	E Linco Powder
	Composition	Lincomycin HCl…4.4%
	Diary No. Date of R & I & fee	Dy. No. 9215; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Lincosamide
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	LINCOS-P POWDER. Reg. No. 49667
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	• The firm was asked to clarify Lincomycin HCl…4.4%. The firm submitted they have applied as per label of me-too product available in the market.
	Decision: Deferred for correction in the label claim of applied formulation.	
2875.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Elecox Powder
	Composition	Each 100gm contains: Amprolium HCL…30gm Sulphaquinoxalin sodium…20gm Vitamin K3…600mg
	Diary No. Date of R & I & fee	Dy. No. 9223; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Treatment of coccidiosis + vitamin K
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg; Decontrolled
	Me-too status	DYECOX WATER SOLUBLE POWDER. Reg. No. 74064
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	• The firm was asked to revise the strength of APIs in line with the me-too product along with submission of applicable fee. The firm submitted they have applied as per laebl of me-too product available in the market.
	Decision: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

2876.	Name and address of manufacturer/ Applicant	M/s Elegance Pharmaceuticals. Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name + Dosage Form + Strength	Norfim S Liquid
	Composition	Each 100ml contains: Norfloxacin…10gm Sulphamethoxypyridazine sodium…15gm Trimethoprim…30gm
	Diary No. Date of R & I & fee	Dy. No.9224; 28.02.2019 PKR. 20,000/-; 28.02.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100ml, 500ml, 1 L; Decontrolled
	Me-too status	NORTRIM-S ORAL LIQUID. Reg. No. 75779
	GMP status	The firm was inspected on 29.11.2018 and 04.05.2019 with the following conclusion: The observation mostly been complied & working good level of GMP as of today.
	Remarks of the Evaluator	• Revise the strength of APIs in line with the me-too product along with submission of applicable fee.
	Decision: Deferred for revision of formulation as per me-too reference.	

b. Deferred Cases

2877.	Name and address of Applicant	M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan
	Detail of Drug Sale License	Address: 11G, Shah Rukh e Alam Colony, District Multan Godown: House No. 24/C, Loha Market, Vehari Road, Near Metro Station, People Colony Multan License No. 04-361-0171-0926D vaild till: **26.08.2019**
	Name and address of Manufacturer	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name and address of marketing authorization holder	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No.23255: 05.07.2018
	Fee including differential fee	PKR 100,000/-: 05.07.2018
	Brand Name +Dosage Form + Strength	Asi-Amoxcol Powder
	Composition	Each 1000g Contains: Amoxicillin Trihydrate…200 g Colistin Sulphate…1000 MIU
	Pharmacological Group	Antibiotics
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1 kg; Rs. 9625/-
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Could not be confirmed
	Detail of certificate attached	• Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 24.07.2018. Only brand name has been mentioned without label claim. • Legalized copy of GMP certificate issued by Department of

		Animal Health of Vietnam for five years from 23.1.2017. • Letter of authorization is provided.
	Remarks of the Evaluator.	• First page of Form 5A was from manufacturer not importer and had not been signed. The firm submitted revised first page of Form 5. • The firm was asked to submit certificate of analysis. The firm did not submit the same. • The firm has provided stability summary sheets, wherein description, loss on drying and assay have been performed as per Zone IV-A. However, USp general chapter has mentioned description, identification, assay and impurities for universal tests. Furthermore, USP has mentionedadditional tests for powder as: "Oral powders should indicate: "For Oral Use Only". Tests that are considered specific to the type of powders include: Minimum Fill (755) and volatile content ((731) and (921)). Minimum Fill (755) has specifications that apply to oral powders. On the basis of the nature of the article and scientific criteria, additional tests may apply, including pH in an aqueous solution, powder fineness, microbial limits, and others.
	Previous decision	The Board in its 291st meeting deferred the case for: • Submission of testing method and certificate of analysis. • Submission of Original legalized and valid FSC with label claim of the product.
	Evaluation by PEC	• The firm changed the address in form 5 from "M/s Schiwo Pakistan. Office No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad, Multan, Punjab" to "M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan. • The firm submitted the testing method and CoA. • The firm submitted Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 26.09.2019
	Previous decision	The Board in its 293rd meeting deferred the case for or changing the address of applicant in Form 5A.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2878.	Name and address of Applicant	M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan
	Detail of Drug Sale License	Address: 11G, Shah Rukh e Alam Colony, District Multan Godown: House No. 24/C, Loha Market, Vehari Road, Near Metro Station, People Colony Multan License No. 04-361-0171-0926D vaild till: **26.08.2019**
	Name and address of Manufacturer	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name and address of marketing authorization holder	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form 5A

	Diary No. Date of R& I	Dy No.23258: 05.07.2018
	Fee including differential fee	PKR 100,000/-: 05.07.2018
	Brand Name +Dosage Form + Strength	Asi-Tydox Plus Powder
	Composition	Each 1000g Contains: Tylosin Tartrate…100g Doxycycline Hyclate…200g
	Pharmacological Group	Antibiotics
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1 kg; Rs. 10500/-
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TYLODOX 100/200 W.S. POWDER. Reg No. 43595
	Detail of certificate attached	• Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 30.07.2018. Only brand name has been mentioned without label claim. • Legalized copy of GMP certificate issued by Department of Animal Health of Vietnam for five years from 23.1.2017. • Letter of authorization is provided.
	Remarks of the Evaluator.	• First page of Form 5A was from manufacturer not importer and had not been signed. The firm submitted revised first page of Form 5. • The firm was asked to submit certificate of analysis. The firm did not submit the same. • Only brand name has been mentioned without label claim. • The firm has provided stability summary sheets, wherein description, identification, loss on drying and assay have been performed as per Zone IV-A. However, USP general chapter has mentioned description, identification, assay and impurities for universdal tests. Furthermore, USP has mentionedadditional tests for powder as: "Oral powders should indicate: "For Oral Use Only". Tests that are considered specific to the type of powders include: Minimum Fill (755) and volatile content ((731) and (921)). Minimum Fill (755) has specifications that apply to oral powders. On the basis of the nature of the article and scientific criteria, additional tests may apply, including pH in an aqueous solution, powder fineness, microbial limits, and others.
	Previous decision	The Board in its 291st meeting deferred the case for: • Submission of testing method and certificate of analysis. • Submission of Original legalized and valid FSC with label claim of the product.
	Evaluation by PEC	• The firm changed the address in form 5 from "M/s Schiwo Pakistan. Office No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad, Multan, Punjab" to "M/s Schiwo Pakistan, 11G, Shah Rukh e Alam Colony, Multan. • The firm submitted the testing method and CoA. • The firm submitted Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 26.09.2019.
	Previous decision	The Board in its 293rd meeting deferred the case for or changing the address of applicant in Form 5A.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee.

	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
2879.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B. Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Neosan-72 (Oral w/s powder)
	Composition	Each 1000 gm contains: Neomycin sulphate…..……720g
	Diary No. Date of R& I & fee	Dy No. 17237: 10.05.2018 PKR 20,000/-: 09.05.2018
	Pharmacological Group	Other aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 25kg; Decontrolled
	Me-too status	MYCIN 72 ORAL POWDER. Reg. No. 81309
	GMP status	The firm was inspected on 04.07.2017, wherein FAIR level of GMP compliance was reported.
	Previous decision	The Board in its 292nd meeting deferred the case for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	Me-too status confirmed
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2880.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Procapen GP Injection
	Composition	Each ml contains: Penicillin G procaine ……..300 mg
	Diary No. Date of R&I & Fee	Dy. No. 21200: 18-10-2019, Rs. 20,000/-: 18-10.2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Nawapen-30 (10ml, 50ml, 100ml). Reg. 053996 (procaine penicillin)
	GMP status	New Section Veterinary Liquid Injection Penicillin
	Remarks of the Evaluator	• Finished product is available as Procaine penicillin G injectable suspension in BP. The firm revised procaine penicillin to Penicillin G procaine without submission of fee.
	Previous decision	• The Board in its 294th meeting deferred the case for submission of fee for revision of salt form.
	Evaluation by PEC	• The frim submitted Rs. 5000/- fee.
	Decision: Approved with innovator's specifications.	
2881.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Streptocaine Injection
	Composition	Each ml contains: Penicillin G procaine……..200 mg Dihydrostreptomycin Sulphate……...160 mg
	Diary No. Date of R&I & Fee	Dy. No. 21201: 18-10-2019, Rs. 20,000/-: 18-10.2019

	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Neo Strep-Pen Injection (10ml, 50ml, 100ml). Reg. 053997 (Penicillin procaine, streptomycin Sulphate)
	GMP status	New Section Veterinary Liquid Injection Penicillin
	Remarks of the Evaluator	• Finished product is available as Procaine penicillin G, dihydrostreptomycin Sulphate injectable suspension in BP. The firm revised procaine penicillin to Penicillin G procaine without submission of fee.
	Previous decision	• The Board in its 294th meeting deferred the case for submission of fee for revision of salt form.
	Evaluation by PEC	• The frim submitted Rs. 5000/- fee.
	Decision: Approved with innovator's specifications.	
2882.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Streptocaine Injection
	Composition	Each ml contains: Penicillin G procaine……..200 mg dihydrostreptomycin Sulphate……...160 mg
	Diary No. Date of R&I & Fee	Dy. No. 21202: 18-10-2019, Rs. 20,000/-: 18-10.2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Neo Strep-Pen Injection (10ml, 50ml, 100ml). Reg. 053997 (Penicillin procaine, streptomycin Sulphate)
	GMP status	New Section Veterinary Liquid Injection Penicillin
	Remarks of the Evaluator	• Finished product is available as Procaine penicillin G, dihydrostreptomycin Sulphate injectable suspension in BP. The firm revised procaine penicillin to Penicillin G procaine without and streptomycin Sulphate to Dihydrostreptomycin Sulphate without submission of fee..
	Previous decision	• The Board in its 294th meeting deferred the case for submission of fee for revision of salt form.
	Evaluation by PEC	• The frim submitted Rs. 5000/- fee.
	Decision: Approved with innovator's specifications.	
2883.	Name and address of manufacturer / Applicant	Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	Tri-Pen LA Injection
	Composition	Each ml contains: Benzathine Pencillin G…..…….100,000 IU Procaine Penicillin G……..150,000 IU Dihydrostreptomycin sulphate……..200 mg
	Diary No. Date of R&I & Fee	Dy. No. 21204: 18-10-2019, Rs. 20,000/-: 18-10.2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	BPS-LA Injection (50ml). Reg. 080951
	GMP status	New Section Veterinary Liquid Injection Penicillin
	Remarks of the Evaluator	• Revise "Dihydrostreptomycin sulphate" to "Dihydrostreptomycin as sulphate" in the label

		claim only and adjust the weight of Dihydrostreptomycin sulphate in Master formula as per salt factor.
	Previous decision	The Board in its 294th meeting deferred the case revision of formulation including the salt form as per the DRAP approved generic product along with submission of revised master formulation and requisite fee.
	Evaluation by PEC	The frim submitted Rs. 5000/- fee. However, they did not revise "Dihydrostreptomycin sulphate" to "Dihydrostreptomycin as sulphate" in the label claim. In previous cases, the Board did not demand fee for revision of API in terms of salt equivalency.
	Decision: Deferred for revision of formulation as per me-too reference.	

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

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

e. Export facilitation

The following cases have been referred by Assistant Director (PR-I/EFD) Vide Letter No. 1-6/2019-PR.I (EFD): 27.12.2019, wherein the firm M/s Bio labs has achieved benchmark of USD 516077. The following 12 products are placed in the agenda.

2884.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bio-Tim 45 Powder
	Composition	Each gram contains: Tiamulin hydrogen fumarate…450mg
	Diary No. D of R & I & Fee	Dy. No 1166: 09-01-2019 Rs. 20,000/-: 04-01-2019
	Pharmacological group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	Dynamutillin WSP 45 % Soluble PDR. Reg. No 14532
	GMP Status	Last inspection report: 05 & 06-12-2017 concludes fair level of GMP compliance.
	Remarks of Evaluator	Form 5 has been signed by the quality control manager.
	Decision: Approved.	
2885.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Super TD Powder 20/25g
	Composition	Each 100 gram contains: Tylosin Tartrate…20g Doxycycline hyclate…25g
	Diary No. D of R & I & Fee	Dy.No 1160: 09-01-2019 Rs. 20,000/-: 04-01-2019
	Pharmacological group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	RAPID-TD WATER SOLUBLE POWDER (20%/25%). Reg. No. 75660
	GMP Status	As above
	Remarks of Evaluator	• Form 5 has been signed by the quality control manager. • The firm had mentioned "Each gram contains: Tylosin Tartrate…20g, Doxycycline hyclate…25g in the label claim and Tylosin Tartrate…200g, Doxycycline

		HCl…250g per kg in master formula. Upon clarification, the firm revised the label claim to "Each 100 gram contains: Tylosin Tartrate…20g, Doxycycline hyclate…25g" without submission of fee. • Revision of Doxycycline HCl to Doxycycline hyclate in master formula is required.
	Decision: Deferred for revision of formulation alongwith applicable fee.	
2886.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Super Dox 80 Powder
	Composition	Each 1000gram contains: Doxycycline as hyclate…800g
	Diary No. D of R & I & Fee	Dy.No 1161: 09-01-2019 Rs. 20,000/-: 04-01-2019
	Pharmacological group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	Could not be confirmed
	GMP Status	As above
	Remarks of Evaluator	• Form 5 has been signed by the quality control manager. • Provide proof of me-too product (name and registration number) having same strength and salt form already approved by DRAP.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2887.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bio-Cosul 50 WSP
	Composition	Each Gram Powder Contains: Colistin sulphate…50 MIU
	Diary No. D of R & I & Fee	Dy. No 5561: 08-05-2019 Rs. 20,000/-: 08-05-2019
	Pharmacological group	cationic polypeptide antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	Could not be confirmed
	GMP Status	As above
	Remarks of Evaluator	• Form 5 has been signed by the quality control manager. • Provide proof of me-too product (name and registration number) having same strength and salt form already approved by DRAP.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2888.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bio-Flor 25% Oral Solution
	Composition	Each 100ml Contains: Florfenicol…25g
	Diary No. D of R & I & Fee	Dy. No 7662: 30-05-2019 Rs. 20,000/-: 29-05-2019
	Pharmacological group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	NOBIFLOR 25% LIQUID. Reg. No. 63639

	GMP Status	As above
	Remarks of Evaluator	Form 5 has been signed by the quality control manager.
	Decision: Approved.	
2889.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bio-Flor 30% Oral Solution
	Composition	Each 100ml Contains: Florfenicol…30gm
	Diary No. D of R & I & Fee	Dy. No 8157: 12-06-2019 Rs. 20,000/-: 11-06-2019
	Pharmacological group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	Could not be confirmed
	GMP Status	As above
	Remarks of Evaluator	• Form 5 has been signed by the quality control manager. • The firm has submitted reference as "I-Florcol oral solution" of international pharma lab Lahore (along with label print), which could not be verified. • Provide proof of me-too product (name and registration number) having same strength and salt form already approved by DRAP.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2890.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bio-Cosul 60 WSP
	Composition	Each 1kg Powder Contains: Colistin Sulphate…60 MIU
	Diary No. D of R & I & Fee	Dy.No 8156: 12-06-2019 Rs. 20,000/-: 11-06-2019
	Pharmacological group	cationic polypeptide antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specificationss
	Pack Size & demanded price	As per SRO
	Me-too status	Could not be confirmed
	GMP Status	As above
	Remarks of Evaluator	• Form 5 has been signed by the quality control manager. • Provide proof of me-too product (name and registration number) having same strength and salt form already approved by DRAP.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
2891.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bio-Doxytil Plus WSP
	Composition	Each 100gm Powder Contains: Doxycycline Hyclate…40% Tylosin Tartrate…20%
	Diary No. D of R & I & Fee	Dy. No 11469: 10-07-2019 Rs. 20,000/-: 08-07-2019
	Pharmacological group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	"DOXITYL WATER SOLUBLE POWDER. Reg. No. 59115, wherein doxycycline has been mentioned instead of doxycycline HCl.

	GMP Status	As above
	Remarks of Evaluator	Form 5 has been signed by the quality control manager. In the me-too product, doxycycline has been mentioned instead of doxycycline HCl.
	Decision: Approved.	
2892.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Bio-Mycin 11% Premix Powder
	Composition	Each 100g Powder Contains: Lincomycin as HCl…11g
	Diary No. D of R & I & Fee	Dy. No 13086: 24-07-2019 Rs. 20,000/-: 23-07-2019
	Pharmacological group	Lincosamide
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	LINCORFARM 100 POWDER (11%). Reg. No. 20149
	GMP Status	As above
	Remarks of Evaluator	Form 5 has been signed by the quality control manager.
	Decision: Approved.	
2893.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Biohexin Oral Liquid
	Composition	Each ml Contains: Bromhexine Hcl…10mg
	Diary No. D of R & I & Fee	Dy. No 13081: 24-07-2019 Rs. 20,000/-: 23-07-2019
	Pharmacological group	Mucolytic agent
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	BROMO-10 LIQUID. Reg. No. 59102
	GMP Status	As above
	Remarks of Evaluator	Form 5 has been signed by the quality control manager.
	Decision: Approved.	
2894.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Biohexin 5% Solution
	Composition	Each ml contains: Bromhexine HCl….. 50mg
	Diary No. D of R & I & Fee	Dy. No 16630: 03-09-2019 Rs. 20,000/-: 02-09-2019
	Pharmacological group	Mucolytic agent
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	BROMBAK SOLUTION 5%. Reg. NO. 49786
	GMP Status	As above
	Remarks of Evaluator	Form 5 has been signed by the quality control manager.
	Decision: Approved.	
2895.	Name and address of Manufacturer/ Applicant	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Biogistic 40% WSP
	Composition	Each gram powder contains: Lincomycin Hcl…… 400mg
	Diary No. D of R & I & Fee	Dy. No 24574: 21-11-2019 Rs. 20,000/-: 21-11-2019
	Pharmacological group	Lincosamides
	Type of Form	Form 5

	Finished product Specifications	Innovator's specifications
	Pack Size & demanded price	As per SRO
	Me-too status	LINCOSEL-40 ORAL POWDER (lincomycin as HCl). Reg. No. 89826
	GMP Status	As above
	Remarks of Evaluator	• Form 5 has been signed by the quality control manager. • Upon asking for me-too status, the firm provided LINCOSEL-40 ORAL POWDER (lincomycin as HCl). Reg. No. 89826, wherein each gram powder contains: Lincomycin as HCl……. 400mg. • Revision of Lincomycin HCl to Lincomycin as HCl is required in the label claim along with adjustment of its weight as per salt factor in amster formula.
	Decision: Deferred for revision of label claim alongwith adjustment of weight in master formula.	

Evaluator PEC-XIII

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

a. **New cases**

2896.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	T- Dine Tablet 600mg
	Composition	Each Film Coated Tablet Contains: Telbivudine…….600mg
	Diary No. Date of R & I & fee	Dy.No 6728 dated 15-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Nucleoside and nucleotide reverse transcriptase
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	28's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Sebivo Tablets of M/s Novartis Pharma 047523
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
2897.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Sefron Tablet 8mg
	Composition	Each Film Coated Tablet Contains: Ondansetron as HCl Dihydrate ……...8mg
	Diary No. Date of R & I & fee	Dy.No 6725 dated 15-02-2019 Rs.20,000/- Dated 14-02-2019
	Pharmacological Group	Serotonin antagonist
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 12 As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ondan 8mg Tablet of M/s Medley Pharmaceuticals Islamabad 080551
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The applied formulation is available in BP.
	Decision: Approved with BP specifications.	

2898.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Trex Tablet 2.5mg
	Composition	Each Tablet Contains: Methotrexate as Sodium……...……2.5mg
	Diary No. Date of R & I & fee	Dy.No 7846 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100's & 3x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Methotrexate tablet 2.5mg of M/s Pak China International, Karachi 066007
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications and workers protection.	
2899.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Everol 0.75mg Tablet
	Composition	Each Tablet Contains: Everolimus……...……..…0.75mg
	Diary No. Date of R & I & fee	Dy.No.7841 dated 22-02-2019 Rs.20,000/- Dated 21-02-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Certican 0.75mg of M/s Novartis Pharma 044830
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications and worker's protection.	
2900.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Sirox 500mg Tablet
	Composition	Each dispersible tablet contains: Deferasirox…….500mg
	Diary No. Date of R & I & fee	Dy.No 7848 dated 22-02-2019 Rs.20,000/- 21-02-2018
	Pharmacological Group	Immunosupressant / iron chelating agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Oderox -500 Dispersible Tablets of M/s Aj Mirza Pharma 078116
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	

2901.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Droxy 500mg Capsule
	Composition	Each Capsule Contains: Hydroxyurea…..500mg
	Diary No. Date of R & I & fee	Dy.No 7851 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti- neoplastic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 x10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Uro- Z 500mg Capsule Z. Jans Pharmaceuticals 026792
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The applied formulation is available in BP.
	Decision: Deferred for evidence of approval of required manufacturing facility of "Capsule (Oncology) section" from Central Licensing Board.	
2902.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Mycomo Tablet 500mg
	Composition	Each Film Coated Tablet Contains: Mycophenolate Mofetil…...500mg
	Diary No. Date of R & I & fee	Dy.No 7842 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Immunosuppressive agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	50 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Mycophenol 500 mg Tablets of M/s Wellborne Pharmachem and Biologicals 077412
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
2903.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Capsit 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Capecitabine……500mg
	Diary No. Date of R & I & fee	Dy.No 7843 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti- neoplastic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 120 12x 10 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Xeloda Tablets of M/s S.Ejazuddin & Co Karachi 027375
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.

	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Deferred for evidence of approval of required manufacturing facility of "Tablet (Oncology) section" from Central Licensing Board.	
2904.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Lenom 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Leflunomide…….……20mg
	Diary No. Date of R & I & fee	Dy.No 7850 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti- neoplastic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30's As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lefluno Tablet of M/s Caraway Pharma 050063
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Deferred for the applied pharmacological group as the applied formulation does not fall in the L01 class of anti- neoplastic drugs.	
2905.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ripe 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone ……..…1mg
	Diary No. Date of R & I & fee	Dy.No 7845 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x10's, 3x 6's, 1x20's, 1x30's & 5x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Risperidone-Sandoz 1mg Tablet of M/s Novartis Pharma, Karachi 048831
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
2906.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ripe 2mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone …2mg
	Diary No. Date of R & I & fee	Dy.No 7847 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x10's, 3x 6's, 1x20's, 1x30's & 5x 10's & As per SRO
	Approval status of product in Reference	MHRA Approved

	Regulatory Authorities.	
	Me-too status	Risperidone-Sandoz 2mg Tablet of M/s Novartis Pharma, Karachi 048832
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
2907.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ripe 3mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone ……3mg
	Diary No. Date of R & I & fee	Dy.No 7849 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x10's, 3x 6's, 1x20's, 1x30's & 5x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Peridal Tablets 3mg Global Pharmaceuticals, Industrial Area, Islamabad 023863
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
2908.	Name and address of manufacturer/ Applicant	M/s CKD Pharmaceuticals Pakistan Private Limited, Plot No. 50/28, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ripe 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone ……4mg
	Diary No. Date of R & I & fee	Dy.No 7844 dated 22-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti-psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x10's, 3x 6's, 1x20's, 1x30's & 5x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Peridal Tablets 4mg Global Pharmaceuticals, Industrial Area, Islamabad 023864
	GMP status	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
2909.	Name and address of manufacturer/ Applicant	M/s Axis Pharmaceuticals, Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad
	Brand Name + Dosage Form + Strength	Posnid Suspension 50mg/5ml
	Composition	Each 5ml contains: Mefenamic Acid……...……50mg
	Diary No. Date of R & I & fee	Dy.No 8810 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	NSAIDs

	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Rexafen Suspension of M/s SJ & G Fazul Ellahie (Pvt) Ltd, Karachi 020566
	GMP status	Last GMP inspection was conducted on 19-09-2018 & 03-10-2018 and the report concludes fair level of GMP compliance and the panel recommends grant of cGMP certificate.
	Remarks of the Evaluator	• General oral liquid section is available in the firm as mentioned in the submitted GMP inspection report. • The applied formulation is non- pharmacopoeial.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2910.	Name and address of manufacturer/ Applicant	M/s Axis Pharmaceuticals, Value Addition City, 3-B, 1.5km, Khurrianwala- Sahianwala Road, Faisalabad.
	Brand Name + Dosage Form + Strength	Metrozid Suspension 200mg/5ml
	Composition	Each 5ml contains: Metronidazole as benzoate……..200mg
	Diary No. Date of R & I & fee	Dy.No 8809 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Diagyl Suspension 5ml of M/s Swiss Pharma 020229
	GMP status	Last GMP inspection was conducted on 19-09-2018 & 03-10-2018 and the report concludes fair level of GMP compliance and the panel recommends grant of cGMP certificate.
	Remarks of the Evaluator	• General oral liquid section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications.	
2911.	Name and address of manufacturer/ Applicant	M/s Axis Pharmaceuticals, Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad
	Brand Name + Dosage Form + Strength	Bandil Suspension 100mg/5ml
	Composition	Each 5ml contains: Albendazole……..……100mg
	Diary No. Date of R & I & fee	Dy.No 8808 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nenzole Suspension of M/s Nenza pharmaceutical Peshawar 025891
	GMP status	Last GMP inspection was conducted on 19-09-2018 & 03-10-2018 and the report concludes fair level of GMP compliance and the panel recommends grant of cGMP certificate.

	Remarks of the Evaluator	• General oral liquid section is available in the firm as mentioned in the submitted GMP inspection report. • International availability could not be confirmed. • The official monograph for the applied formulation is available in USP.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
2912.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, 125-P, Gulberg-II, Lahore.
	Brand Name + Dosage Form + Strength	Dermalar 0.01% Solution
	Composition	Fluocinolone Acetonide…0.01% w/v
	Diary No. Date of R & I & fee	Dy.No 5106 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 05-07-2018 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator	Manufacturing facility needs to be confirmed. Composition is not applied completely. Me- too could not be confirmed.
	Decision: Deferred due to the following reasons: **i. Confirmation of required manufacturing facility / section from Licensing Division.** **ii. Composition is not applied completely.** **iii. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
2913.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, 125-P, Gulberg-II, Lahore.
	Brand Name + Dosage Form + Strength	Clindacin 1% Lotion
	Composition	Each 5ml contains: Clindamycin as phosphate……1% w/w
	Diary No. Date of R & I & fee	Dy.No 5107 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30ml As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Acsolve 1% Lotion of M/s Atco Labarotories Karachi 067528
	GMP status	Last GMP inspection was conducted on 05-07-2018 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator	Manufacturing facility needs to be confirmed.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
2914.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, 125-P, Gulberg-II, Lahore.
	Brand Name + Dosage Form + Strength	Clindacin 1% Gel
	Composition	Each 5ml contains: Clindamycin as Phosphate……1% w/w
	Diary No. Date of R & I & fee	Dy. No. 5105 dated 06-02-2019 Rs.20,000/- 06-02-2019

	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Clingard- Gel by M/s Hoover Pharmaceuticals (Reg#064533)
	GMP status	Last GMP inspection was conducted on 05-07-2018 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator	Manufacturing facility needs to be confirmed.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
2915.	Name and address of manufacturer/ Applicant	M/s Himont Pharmaceuticals Pvt Ltd, 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Tracamol P Tablets 37.5mg/325mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl……..…37.5mg Paracetamol…….……325mg
	Diary No. Date of R & I & fee	Dy.No 7272 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Analgesic opioid
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	Tonoflex of M/s Sami
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 04-10-2018 and 05-10-2018.
	Remarks of the Evaluator	Tablet section is available in the firm as mentioned in the submitted GMP certificate. The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
2916.	Name and address of manufacturer/ Applicant	M/s Himont Pharmaceuticals Pvt Ltd, 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Tracamol Tablets 50mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl……50mg
	Diary No. Date of R & I & fee	Dy.No 7268 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Analgesic opioid
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	Tramed- Tablets of M/s Platinum Pharma 024457
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 04-10-2018 and 05-10-2018.
	Remarks of the Evaluator	Tablet section is available in the firm as mentioned in the submitted GMP certificate. The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	

2917.	Name and address of manufacturer/ Applicant	M/s Himont Pharmaceuticals Pvt Ltd, 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Tracamol Injection 50mg/ml I/V
	Composition	Each amp contains: Tramadol HCl……..…….50mg
	Diary No. Date of R & I & fee	Dy.No 7271 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	Merlon Injection of M/s Ali Gohar Pharma 024502
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 04-10-2018 and 05-10-2018.
	Remarks of the Evaluator	Liquid injectable general section is available in the firm as mentioned in the submitted GMP certificate. The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
2918.	Name and address of manufacturer/ Applicant	M/s Himont Pharmaceuticals Pvt Ltd, 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Tracamol Capsule 50mg
	Composition	Each Capsule Contains: Tramadol HCl……50mg
	Diary No. Date of R & I & fee	Dy.No 7270 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	Tramal of M/s Searle
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 04-10-2018 and 05-10-2018.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications.	
2919.	Name and address of manufacturer/ Applicant	M/s Himont Pharmaceuticals Pvt Ltd, 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Tracamol SR Tablets 100mg
	Composition	Each Film Coated Tablet Contains: Tramadol HCl……..…100mg
	Diary No. Date of R & I & fee	Dy.No 7269 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved as modified- release tablet
	Me-too status	Tramed- SR Tablets of M/s Platinum Pharma 024458
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 04-10-2018 and 05-10-2018.

	Remarks of the Evaluator	Tablet section is available in the firm as mentioned in the submitted GMP certificate. TGA; Australia Approved as modified- release tablet. Me- too is also of SR Tablets.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
2920.	Name and address of manufacturer/ Applicant	M/s Himont Pharmaceuticals Pvt Ltd, 17-km, Ferozepur Road, Lahore, Pakistan
	Brand Name + Dosage Form + Strength	Spasmogin Tablet 40mg
	Composition	Each Film Coated Tablet Contains: Otilonium Bromide……40mg
	Diary No. Date of R & I & fee	Dy.No 7273 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Anti- cholinergic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10 As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Italy
	Me-too status	Spasmomen of M/s Pharmatec
	GMP status	GMP certificate has been granted to the firm on the basis of evaluation done on 04-10-2018 and 05-10-2018.
	Remarks of the Evaluator	Tablet section is available in the firm as mentioned in the submitted GMP certificate. The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
2921.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Astaprine 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Azathioprine…….50mg
	Diary No. Date of R & I & fee	Dy.No 9010 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Immuno- supressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Azathioprine Pharmachemie of M/s S.M.Yahya & Co / Turner, Grahms Ltd 011448
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	
	Decision: Approved.	
2922.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Acycloster 200mg Tablet
	Composition	Each uncoated tablet contains: Acyclovir……..…200mg
	Diary No. Date of R & I & fee	Dy.No.9007 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti- Viral
	Type of Form	Form- 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Elovir Tablets of M/s Siza International (Pvt) Ltd, Main Ferozepur Road, Lahore 024041
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	
	Decision: Approved.	
2923.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Astozole 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Anastrozole……1mg
	Diary No. Date of R & I & fee	Dy.No 9006 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti- neoplastic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Anastrozole Of M/s Sandoz 1mg Film Coated Tablets Novartis Pharma (Pakistan) Ltd, Karachi 066179
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications with protective measures for workers.	
2924.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan.
	Brand Name + Dosage Form + Strength	Famtovit 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Famciclovir……..250mg
	Diary No. Date of R & I & fee	Dy.No 9008 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti- Viral
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Famcivir 250mg Tablets of M/s Amson Vaccine & Pharma (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad. 050189
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	
	Decision: Approved.	
2925.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan .
	Brand Name + Dosage Form + Strength	Valganter 450mg Tablet
	Composition	Each Film Coated Tablet Contains: Valganciclovir HCl ……450mg
	Diary No. Date of R & I & fee	Dy.No 9009 dated 28-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti- viral
	Type of Form	Form- 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Valcyte Tablets 450mg Of M/s Roche Pakistan 052253
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	
	Decision: Approved.	
2926.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Defestre 250mg Tablet
	Composition	Each dispersible contains: Deferasirox…….....250mg
	Diary No. Date of R & I & fee	Dy.No 9213 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Iron chelating agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Obsarox of OBS
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	The applied formulation is non- pharmacopoeial while firm has applied USP specification.
	Decision: Approved with innovator's specifications.	
2927.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Astomm 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Mycophenolate Mofetil…...500mg
	Diary No. Date of R & I & fee	Dy.No 9211 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Immune suppressive agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	100 As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Mycophenol 500 mg Tablets of M/s Wellborne Pharmachem and Biologicals 077412
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	
	Decision: Approved.	
2928.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Tacrolister 0.5mg Capsule
	Composition	Each Capsule Contains: Tacrolimus as Monohydrate…….0.5mg
	Diary No. Date of R & I & fee	Dy.No 9212 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Immune- suppressive agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved

	Regulatory Authorities.	
	Me-too status	Tacrosan 0.5mg Capsule of M/s Novartis Pharma 078163
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Deferred for confirmation whether application is for soft gel or hard gel capsule and confirmation of relevant manufacturing facility.	
2929.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Eslimus 2mg Capsule
	Composition	Each Capsule Contains: Everolimus……...0.5mg
	Diary No. Date of R & I & fee	Dy.No.9210 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- neoplastic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	• Both dosage forms are mentioned in the dossier. (Tablet and Capsule). Form- 5 is of capsule while fee challan is of tablet. While applied formulation is of Valganciclovir HCl. • International availability could not be confirmed. • Me- too could not be confirmed. • Available in USFDA and MHRA as tablets while capsules are applied.
	Decision: Deferred for the following: • **Both dosage forms are mentioned in the dossier. (Tablet and Capsule). Form- 5 is of capsule while fee challan is of tablet. While applied formulation is of Valganciclovir HCl.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Available in USFDA and MHRA as tablets while capsules are applied.**	
2930.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Gancivir 250mg Capsule
	Composition	Each Capsule Contains: Ganciclovir……..250mg
	Diary No. Date of R & I & fee	Dy.No 9011 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- viral
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM; France
	Me-too status	Ganvir of Mission Pharma 047549
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	The applied formulation is non- pharmacopoeial while USP specification is applied by the firm.
	Decision: Approved with innovator's specifications.	

2931.	Name and address of manufacturer/ Applicant	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name + Dosage Form + Strength	Letazole 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole……..…2.5mg
	Diary No. Date of R & I & fee	Dy.No.9005 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Aromatase Inhibitor
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Letrozole Tablets 2.5mg of M/s Hakimsons Overseas Trading 072582
	GMP status	17-01-2018 and satisfactory
	Remarks of the Evaluator	
	Decision: **Approved with worker's protection measures.**	
2932.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd, Hakimsons House, A/ 56, S.I.T.E Manghopir Road, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Avazet Tablets 10/10mg
	Composition	Each Film Coated Tablet Contains: Ezetimibe……..10mg Atorvastatin as Atorvastatin calcium…….....10mg
	Diary No. Date of R & I & fee	Dy.No 8832 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10 As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM; France
	Me-too status	Atozet 10/10 Tablet of M/s Hilton Pharma (Pvt.)Limited 055148
	GMP status	Last GMP inspection was conducted on 17-01-2020 and the report concludes **poor** level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
2933.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd, Hakimsons House, A/ 56, S.I.T.E Manghopir Road, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Avazet Tablets 10/40mg
	Composition	Each Film Coated Tablet Contains: Ezetimibe……..10mg Atorvastatin as atorvastatin calcium…….40mg
	Diary No. Date of R & I & fee	Dy.No 8831 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10& As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM; France
	Me-too status	Atozet 10/40 Tablet of M/s Hilton Pharma (Pvt.)Limited 061217
	GMP status	Last GMP inspection was conducted on 17-01-2020 and the

		report concludes **poor** level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
2934.	Name and address of manufacturer/ Applicant	M/s Helix Pharma Pvt Ltd, Hakimsons House, A/ 56, S.I.T.E Manghopir Road, Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Serten Tablets 30mg
	Composition	Each Tablet Contains: Phentermine as HCl…….30mg
	Diary No. Date of R & I & fee	Dy.No 8833 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- obesity
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Azura of Wilshire
	GMP status	Last GMP inspection was conducted on 17-01-2020 and the report concludes **poor** level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
2935.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Canaglif 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin as hemihydrate……..100mg
	Diary No. Date of R & I & fee	Dy.No.9028 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2936.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Dapaglif M XR 10/1000mg Tablet
	Composition	Each extended release film coated tablet contains: Dapagliflozin as Propanediol Monohydrate..10mg Metformin HCl……1000mg
	Diary No. Date of R & I & fee	Dy.No 9027 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2937.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Emapaglif M 5/1000mg tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…….5mg Metformin HCl……..1000mg
	Diary No. Date of R & I & fee	Dy.No 9024 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2938.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Emapaglif M 12.5/1000mg tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…1000mg
	Diary No. Date of R & I & fee	Dy.No 9023 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2939.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.

	Brand Name + Dosage Form + Strength	Canaglif M 150/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin as hemihydrate……..150mg Metformin HCl……..1000mg
	Diary No. Date of R & I & fee	Dy.No.9031 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as extended- release tablet
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	• USFDA Approved as extended- release tablet. • Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Deferred for the following reasons: **i. The formulation is applied as film-coated tablet while it is approved in reference regulatory authority as extended- release tablet.** **ii. Submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.**	
2940.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Canaglif- M 150/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin as hemihydrate……..…150mg Metformin HCl……500mg
	Diary No. Date of R & I & fee	Dy.No 9032 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as extended- release tablet
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	• USFDA Approved as extended- release tablet. • Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Deferred for the following reasons: **i. The formulation is applied as film-coated tablet while it is approved in reference regulatory authority as extended- release tablet.** **ii. Submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.**	
2941.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Lesinext 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Lesinurad……200mg
	Diary No. Date of R & I & fee	Dy.No 9036 dated 28-02-2019 Rs.20,000/- 28-02-2019
	Pharmacological Group	Anti- gout
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	International availability could not be confirmed. Me- too status could not be confirmed.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
2942.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Prucalo 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Prucalopride as succinate……1mg
	Diary No. Date of R & I & fee	Dy.No 9034 dated 28-02-2019 Rs.20,000/- 28-02-2019
	Pharmacological Group	Drugs for constipation
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Me- too status could not be confirmed
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
2943.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Canaglif M 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin as hemihydrate……..…50mg Metformin HCl……..1000mg
	Diary No. Date of R & I & fee	Dy.No 9030 dated 28-02-2019 Rs.20,000/- 28-02-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as extended- release tablet
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	• USFDA Approved as extended- release tablet. • Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Deferred for the following reasons: **1. The formulation is applied as film-coated tablet while it is approved in reference regulatory authority as extended- release tablet.** **2. Submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.**	

2944.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Prucalo 2mg Tablet
	Composition	Each Film Coated Tablet Contains: Prucalopride as succinate……2mg
	Diary No. Date of R & I & fee	Dy.No 9035 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Drugs for constipation
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Me- too status could not be confirmed
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
2945.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Canaglif M 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin as hemihydrate……50mg Metformin HCl……500mg
	Diary No. Date of R & I & fee	Dy.No 9033 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as extended- release tablet
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	• USFDA Approved as extended- release tablet. • Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Deferred for the following reasons: **i. The formulation is applied as film-coated tablet while it is approved in reference regulatory authority as extended- release tablet.** **ii. Submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.**	
2946.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Canaglif 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin as hemihydrate……300mg
	Diary No. Date of R & I & fee	Dy.No 9029 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 As per SRO
	Approval status of product in Reference	USFDA Approved

	Regulatory Authorities.	
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2947.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Empaglif M 5/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…….……..5mg Metformin HCl……...…500mg
	Diary No. Date of R & I & fee	Dy.No 9021 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2948.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Dapaglif M Xr 10/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate.10mg Metformin HCl……500mg
	Diary No. Date of R & I & fee	Dy.No 9026 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2949.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Dapaglif M XR 5/1000mg Tablet

	Composition	Each Film Coated extended release Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg Metformin HCl……..……..1000mg
	Diary No. Date of R & I & fee	Dy.No 9025 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2950.	Name and address of manufacturer/ Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Pamacet 500/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Acetaminophen……..500mg Pamabron.……25mg
	Diary No. Date of R & I & fee	Dy.No 7574 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antipyretic/ Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	25 100 As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Women's Tylol Caplets. M/s Don Valley Pharmaceuticals (Pvt.) Ltd. Lahore. 062787
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	Stability data is required for this applied molecule along with submission of differential fees.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2951.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Zoltrip OD Tablet 2.5mg
	Composition	Each orodispersible tablet contains: Zolmitriptan……..…2.5mg
	Diary No. Date of R & I & fee	Dy.No 3961 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	3's, 10's & As per SRO/ DRAP policy
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Xoming 2.5mg Tablet by Nabiqasim Reg. No. 081782
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
2952.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Zoltrip Tablet 5mg
	Composition	Each orodispersible tablet contains: Zolmitriptan…5mg
	Diary No. Date of R & I & fee	Dy.No 3962 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	3's, 10's & As per SRO/ DRAP policy
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Triptan Tablets 5mg by M/s Efroze (Reg#042345)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
2953.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Zilium Tablets 10mg
	Composition	Each Tablet Contains: Domperidone Maleate eq to Domperidone…10mg
	Diary No. Date of R & I & fee	Dy.No 3949 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Propulsive
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Almedon-V Tablets 10mg by M/s Alina Combine Pakistan (Pvt) Ltd (Reg#023886)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	

2954.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Diabex Tablets 500mg
	Composition	Each Film Coated Tablet Contains: Metformin HCL…500mg
	Diary No. Date of R & I & fee	Dy.No 3952 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Glucodal 500mg Tab LC & PW Lahore 012598
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2955.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Diabex Tablets 850mg
	Composition	Each Film Coated Tablet Contains: Metformin HCl…….850mg
	Diary No. Date of R & I & fee	Dy.No 3953 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Orabat 850mg Tab Saitex Karachi 011860
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2956.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Neopride Tablets 25mg
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R & I & fee	Dy.No 3957 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form- 5

	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved
	Me-too status	Scipride tablet 25mg M/s Getz Pharma 057902
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
2957.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Valpret Tablets 500mg
	Composition	Each delayed release tablet contains: Divalproex Sodium eq to Valproic acid…500mg
	Diary No. Date of R & I & fee	Dy.No 3947 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	20's, 30's, 50's, 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Epinil tablet of M/s Platinum Pharmaceuticals, (Reg.# 024464
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
2958.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Neopride Tablets 50mg
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R & I & fee	Dy.No 3958 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form- 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Levopraid 50 mg tablets (Approved by AIFA of Italy)
	Me-too status	Nauvomit Tablets of M/s Saaaf Pharmaceutical. (Reg.# 068312)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can

		only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
2959.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Aeronix Tablets 10mg
	Composition	Each Film Coated Tablet Contains: Zafirlukast…10mg
	Diary No. Date of R & I & fee	Dy.No 3959 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	14's, 28's & as per SRO/ DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Accolate 10mg film-coated tablets of M/s Astra Zeneca Pharmaceuticals (USFDA Approved)
	Me-too status	Zilesta 10mg tablet of M/s Genix Pharma 055978
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	The product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Approved.	
2960.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Cingest 1mg Tablet
	Composition	Each Tablet Contains: Cinitapride(as acid tartrate) …1mg
	Diary No. Date of R & I & fee	Dy.No 3945 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Propulsives
	Type of Form	Form- 5
	Finished product Specification	innovator's specification
	Pack size & Demanded Price	10 20 50 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg Tablet of Spain approved
	Me-too status	Sitip 1mg Tablet by M/s Sami Pharma. Karachi (Reg. No. 076174)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
2961.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Doxfil Tablets 400mg
	Composition	Each Tablet Contains:

		Doxofylline…400mg
	Diary No. Date of R & I & fee	Dy.No 3950 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Other Systemic Drugs for Obstructive Airway Diseases (Xanthines)
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxofillina ABC 400mg Tablet By M/s ABC Farmaceutici S.P.A (Italian Medicine Agency Approved)
	Me-too status	Profylline Tablet 400mg by M/s Kaizen (Reg# 073744)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
2962.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Valpret Tablets 250mg
	Composition	Each delayed release tablet contains: Divalproex Sodium eq to Valproic acid…250mg
	Diary No. Date of R & I & fee	Dy.No 3946 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anticonvulsants & Anti-epileptics
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	20's, 30's, 50's, 100's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Divalproex Sodium delayed-release tablet (USFDA Approved)
	Me-too status	Epival tablet 250mg of M/s Abbott Laboratories (Reg. # 007160)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
2963.	Name and address of manufacturer/ Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name + Dosage Form + Strength	Aeronix Tablets 20mg
	Composition	Each Film Coated Tablet Contains: Zafirlukast….....20mg
	Diary No. Date of R & I & fee	Dy.No 3960 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Leukotriene Receptor Antagonists
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	14's, 28's & as per SRO
	Approval status of product in Reference	Accolate (10mg, 20mg) Film Coated Tablets by M/s Par

	Regulatory Authorities.	Pharms INc, USFDA Approved
	Me-too status	Zilesta 20mg tablet of M/s Genix Pharma Reg No. 055979
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator	The product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Approved.	
2964.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Paracital 5mg Tablet
	Composition	Each film- coated Tablet Contains: Escitalopram as Oxalate……..5mg
	Diary No. Date of R & I & fee	Dy.No 9018 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 14 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Zavesca 5mg Tablets Getz Pharma, Karachi 045278
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2965.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Paracital 20mg Tablet
	Composition	Each film- coated Tablet Contains: Escitalopram as Oxalate……20mg
	Diary No. Date of R & I & fee	Dy.No 9017 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 14 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Escital Tablet Helix Pharma (Pvt.) Ltd; 061635
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division:

		1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2966.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Paranol 10mg Tablet
	Composition	Each film- coated Tablet Contains: Propranolol HCl……10mg
	Diary No. Date of R & I & fee	Dy.No 9020 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	5X 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Blokonol 10mg Tab of M/s Lisko Karachi 011685
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2967.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Paranol 40mg Tablet
	Composition	Each film- coated Tablet Contains: Propranolol HCl……40mg
	Diary No. Date of R & I & fee	Dy.No 9019 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	5x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Propranolol -40mg Tablets Drugpharm (Pvt) Ltd, 28-KM, Sheikhupura Road, Lahore. 064952
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General)

		The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2968.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Lowlip 5mg Tablet
	Composition	Each film- coated Tablet Contains: Rosuvastatin as Calcium…….5mg
	Diary No. Date of R & I & fee	Dy.No 9014 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10, 20, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Rosuvax 5mg Tablets Asian Continental Karachi 067539
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	Non- pharmacopoeial.
	Decision: Approved.	
2969.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Lowlip 10mg Tablet
	Composition	Each film- coated Tablet Contains: Rosuvastatin as Calcium……10mg
	Diary No. Date of R & I & fee	Dy.No 9013 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Rosuvax 10mg Tablets of M/s Asian Continental Karachi 067540
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in

		Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	Non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
2970.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Lowlip 20mg Tablet
	Composition	Each film- coated Tablet Contains: Rosuvastatin as Calcium……20mg
	Diary No. Date of R & I & fee	Dy.No 9012 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Rosuvax 10mg Tablets Asian Continental Karachi 067540
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	Non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
2971.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Linzol 400mg Tablet
	Composition	Each film- coated Tablet Contains: Linezolid……..400mg
	Diary No. Date of R & I & fee	Dy.No 9015 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	12's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA but not for safety reasons
	Me-too status	Barizold Tablet 400mg Barrett Hodgson Kar. 076342
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to

		start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	Non pharmacopoeial
	Decision: Approved with innovator's specifications.	
2972.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Linzol 600mg Tablet
	Composition	Each film- coated Tablet Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy.No 9016 dated 28-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	12's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Barizold Tablet 600mg Barrett Hodgson Kar. 076341
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	Non pharmacopoeial
	Decision: Approved with innovator's specifications.	
2973.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bromount tablets 3mg
	Composition	Each Tablet Contains: Bromazepam…3mg
	Diary No. Date of R & I & fee	Dy.No 9235 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Psychotropic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lexotan 3mg, tablets by M/s Roche Products Pty Limited, TGA Australia Approved.
	Me-too status	Bromazepam 3 mg Tablets Heal Pharmaceuticals, Peshawar 079393
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export

		purpose.
	Remarks of the Evaluator	Availability of Psychotropic tablet section in the firm needs to be verified.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division	
2974.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Lacop Tablets 100mg
	Composition	Each film- coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R & I & fee	Dy.No 9232 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10 14 As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Lacosbar 100mg Tablet Barrett Hodgson Kar 083223
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2975.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Epicure oral Solution 100mg/ml
	Composition	Each oral solution contains: Levetiracetam…100mg
	Diary No. Date of R & I & fee	Dy.No 9233 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tamlev 100mg/ml oral Solution Medisure LabKar. Karachi 081613
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel

		further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	Firm has syrup section a mentioned in the submitted GMP inspection report.
	Decision: Approved.	
2976.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Trina SR Tablets 2.6mg
	Composition	Each sustained release tablet contains: Glyceryl Trinitrate…2.6mg
	Diary No. Date of R & I & fee	Dy.No 9234 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- anginal/ Vasodilator used in cardiac diseases
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Slotac S.Rtablet of M/s Werrick, Islamabad 025167
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	International reference could not be confirmed. The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications.	
2977.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Desloc Tablet 5mg
	Composition	Each film coated Tablet Contains: Desloratadine…….5mg
	Diary No. Date of R & I & fee	Dy.No 9239 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10s As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Deslort 5mg Tablet Panacea Pharmaceuticals, Rawat, Islamabad. 056332
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to

		start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2978.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Lacop Tablets 50mg
	Composition	Each film- coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R & I & fee	Dy.No 9231 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10 14 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Lacosbar 50mg Tablet Barrett Hodgson Kar 083224
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2979.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Vilmet Tablet 50/500mg
	Composition	Each film- coated tablet contains: Vildagliptin…50mg Metformin HCl…500mg
	Diary No. Date of R & I & fee	Dy.No 9236 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	14 30 As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	Galvus Met 50/500mg tablet of M/s Novartis Pharma (Reg. # 078106)
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to

		start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2980.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Trian SR Tablet 6.4mg
	Composition	Each sustained release tablet contains: Glyceryl Trinitrate…6.4mg
	Diary No. Date of R & I & fee	Dy.No 9237 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- anginal
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Slotec 6.4mg Tablet (025168) M/s Werrick Pharmaceutical Pakistan (Pvt.) Limited.
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	
	Decision: Approved.	
2981.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Desloc Syrup 0.5mg/ml
	Composition	Each syrup contains: Desloratadine…0.5mg
	Diary No. Date of R & I & fee	Dy.No 9238 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aerius For Children Syrup Desloratadine 2.5mg/5ml oralliquid bottle by M/s Bayer Australia Ltd (TGA Approved)
	Me-too status	Desora 0.5mg/ml syrup by M/s Continental Pharma.(Reg.#055192)
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to

		start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	No USP or BP monograph is available for applied formulation. Firm has syrup section as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovator's specifications.	
2982.	Name and address of manufacturer/ Applicant	M/s Paramount Pharmaceuticals, Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Cetol Tablet 325mg/ 37.5mg
	Composition	Each film-coated Tablet Contains: Paracetamol…325mg Tramadol HCL…37.5mg
	Diary No. Date of R & I & fee	Dy.No 9240 dated 28-02-2019 Rs.20,000/- 28-02-2019
	Pharmacological Group	Opiate Analogue
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tramacet 37.5mg/ 325mg film-coated tablet of M/s Grunenthal Limited (MHRA Approved)
	Me-too status	Tonoflex-P of M/s Sami Pharmaceuticals (Reg. # 067163)
	GMP status	Last GMP inspection conducted on 08-02-2019 and report concludes that following two sections need regularization from Licensing Division: 1- Cream/Ointment 2- Tablet (General) The firm has applied for the regularization of same in Licensing Division. The panel is of the opinion that the firm may be allowed to start manufacturing in the light of GMP guidelines. The panel further recommended granting the GMP certificate for export purpose.
	Remarks of the Evaluator	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
2983.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name +Dosage Form + Strength	Wengrontablet 25mg
	Composition	Each extended- release film- coated tablet contains: Mirabegron……..25mg
	Diary No. Date of R& I & fee	Dy.No.41373; 07-12-2018; Rs.20,000 (07-12-2018)
	Pharmacological Group	Beta-3 adrenergic agonist
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• Evidence of me- too or submission of differential fee and stability studies data as per the requirements of 278th meeting of Registration Board.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	

2984.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31 & 32 Punjab Small Industrial Estate, Taxila, Pakistan.
	Brand Name +Dosage Form + Strength	Wengron tablet 50mg
	Composition	Each extended- release film- coated tablet contains: Mirabegron……..50mg
	Diary No. Date of R& I & fee	Dy.No.41374; 07-12-2018; Rs.20,000 (07-12-2018)
	Pharmacological Group	Beta-3 adrenergic agonist
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• Evidence of me- too or submission of differential fee and stability studies data as per the requirements of 278th meeting of Registration Board.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
2985.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Painext- K tablet 50mg
	Composition	Each film- coated tablet contains: Diclofenac potassium……...……...50mg
	Diary No. Date of R& I & fee	Dy.No.41048; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Flexura 50mg tablet of M/s Fassgen Pharma (Reg. # 060922)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2986.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ibunext tablet 200mg
	Composition	Each film- coated tablet contains: Ibuprofen……200mg
	Diary No. Date of R& I & fee	Dy.No.41043; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's,100's& As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Pacifen 200mg tab of M/s Pakistan Pharmaceutical And Chemical Laboratories (Reg. # 013326)

	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2987.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ibunexttablet 400mg
	Composition	Each film- coated tablet contains: Ibuprofen……400mg
	Diary No. Date of R& I & fee	Dy.No.41044; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's, 100's& As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Pyrofen 400mg tablet of M/s SharexRaheemyar Khan (Reg. # 010565)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2988.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Atenotablet 50mg
	Composition	Each tablet contains: Atenolol……..……..50mg
	Diary No. Date of R& I & fee	Dy.No.41049; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	Beta- blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's& As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Vascol- 50 Tablets Indus Pharma (Pvt.) Ltd, Karachi (Reg. # 020324)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2989.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Atelol 100mg Tablet
	Composition	Each tablet contains: Atenolol……..……100mg
	Diary No. Date of R& I & fee	Dy.No.41053; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	Beta- blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's& As per SRO

	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Vascol- 100 tablets of M/s Indus Pharma (Pvt.) Ltd, Karachi (Reg. # 020323)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2990.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Donexttablet 5mg
	Composition	Each tablet contains: Glibenclamide……5mg
	Diary No. Date of R& I & fee	Dy.No.41343; 07-12-2018; Rs.20,000 (07-12-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's& As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Glibenclamide 5mg tablet of M/s Dosaco Lahore (Reg. # 008806)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2991.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Clopinext tablet 75mg
	Composition	Each film- coated tablet contains: Clopidogrel as bisulfate……..……75mg
	Diary No. Date of R& I & fee	Dy.No.41352; 07-12-2018; Rs.20,000 (07-12-2018)
	Pharmacological Group	Anti- thrombotic agent (Platelet aggregation inhibitor)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's& As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Clopid tablet of M/s Mass Pharma (Pvt.) Ltd, 17 Km Ferozpur Road, Lahore. (Reg. # 041680)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2992.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Clopinext tablet 300mg
	Composition	Each film- coated tablet contains: Clopidogrel as bisulfate…….300mg
	Diary No. Date of R& I & fee	Dy.No 41354; 07-12-2018; Rs.20,000 (07-12-2018)

	Pharmacological Group	Anti- thrombotic agent (Platelet aggregation inhibitor)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's& As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Plavix tablet of M/sSanofi Karachi(Reg. # 075977)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
2993.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, KotLakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Varine tablet 0.5mg
	Composition	Each film- coated tablet contains: Varenicline as tartrate ……..……..0.5mg
	Diary No. Date of R& I & fee	Dy.No.40370; 05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Drugs used in addictive disorders (Nicotine dependence)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 15's, 20's, 25's, 60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Chantix 0.5mg tablet of M/sParke Davis & Company Limited, Karachi (Reg. # 045697)
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial. • General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved with innovator's specifications.	
2994.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, KotLakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Varine tablet 1mg
	Composition	Each film- coated tablet contains: Varenicline as tartrate ……..……..1mg
	Diary No. Date of R& I & fee	Dy.No.40371; 05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Drugs used in addictive disorders (Nicotine dependence)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 56's, 60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Chantix 1mg tablet of M/s Parke Davis & Company Limited, Karachi (Reg. # 045698)
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial. • General tablet section is available in the firm as mentioned in the submitted section approval letter.

	Decision: Approved with innovator's specifications.	
2995.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt. Ltd, Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Curoxaban tablet 15mg
	Composition	Each film- coated tablet contains: Rivaroxaban……15mg
	Diary No. Date of R& I & fee	Dy.No.44503; 31-12-2018; Rs.20,000 (31-12-2018)
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rivaro15mg tablet of M/s Highnoon Laboratories (Reg. # 085872)
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial. • General tablet section is available in the firm as mentioned DML.
	Decision: Approved with innovator's specifications.	
2996.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd, Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Curoxaban tablet 20mg
	Composition	Each film- coated tablet contains: Rivaroxaban……....20mg
	Diary No. Date of R& I & fee	Dy.No.44483; 31-12-2018; Rs.20,000 (31-12-2018)
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rivaro 20mg tablet of M/s HighnoonLaboratories (Reg. # 085873)
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial. • General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovator's specifications.	
2997.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd, Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Fescol capsule 20mg
	Composition	Each capsule contains: Fluvastatin as sodium……..……20mg
	Diary No. Date of R& I & fee	Dy.No.44504; 31-12-2018; Rs.20,000 (31-12-2018)
	Pharmacological Group	Indole heptanoic acid derivative
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Farmastin capsules of M/s FarmaceuticsInt Karachi (Reg. # 045142)
	GMP status	Last GMP inspection was conducted on 31-01-2018 and

		the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in USP. • General capsule section is available as mentioned in the submitted DML.
	Decision: Approved with USP specifications.	
2998.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Fescol capsule 40mg
	Composition	Each capsule contains: Fluvastatin as sodium……..……40mg
	Diary No. Date of R& I & fee	Dy.No.44505; 31-12-2018; Rs.20,000 (31-12-2018)
	Pharmacological Group	Indoleheptanoic acid derivative
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Free-flo capsules 40mg of M/s Werrick Pharma (Reg. # 041840)
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in USP. • General capsule section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with USP specifications.	
2999.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cucerein capsule 50mg
	Composition	Each capsule contains: Diacerein……..50mg
	Diary No. Date of R& I & fee	Dy.No.44487; 31-12-2018; Rs.20,000 (31-12-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved
	Me-too status	Dycer-50 capsule of M/s Bloom Pharma (Reg. # 071665)
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	General capsule section is available in the firm as mentioned in the submitted DML. The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3000.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt. Ltd, Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Biselect tablet 2.5mg
	Composition	Each film- coated tablet contains: Bisoprolol Fumarate…..……....2.5mg
	Diary No. Date of R& I & fee	Dy.No.44484; 31-12-2018; Rs.20,000 (31-12-2018)
	Pharmacological Group	Beta- blocking agent

	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Bisfat tablets 2.5mg Dyson Research Laboratories (Pvt.) Ltd, 28-km, Ferozepur Road, Lahore. (Reg. # 077054)
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in USP. • General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with USP specifications.	
3001.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Ibunext suspension 100mg/5ml
	Composition	Each 5ml suspension contains: Ibuprofen……100mg
	Diary No. Date of R& I & fee	Dy.No.41054; 06-12-2018; Rs.20,000(06-12-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Bruprofen 100mg/5ml Suspension of M/s Klifton Pharma, Jamshoro Karachi (Reg. # 058342)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Oral liquid general section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
3002.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Olexit capsule 3mg/25mg
	Composition	Each capsule contains: Olanzapine……..…3mg Fluoxetine as HCl…….25mg
	Diary No. Date of R& I & fee	Dy.No.39855; 04-12-2018; Rs.20,000 (03-12-2018)
	Pharmacological Group	SSRIs / Antipsychotic
	Type of Form	Form -5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10's, 14's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Olanzo- F 3/25 mg capsules of M/s Regal Pharmaceuticals (Reg. # 081973)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General capsule section is available in the firm as mentioned in the submitted DML.

	Decision: Approved.	
3003.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Olexit capsules 6mg/25mg
	Composition	Each capsule contains: Olanzapine……..……...…6mg Fluoxetine as HCl……..……...…25mg
	Diary No. Date of R& I & fee	Dy.No.39856; 04-12-2018; Rs.20,000 (03-12-2018)
	Pharmacological Group	SSRIs / Antipsychotic
	Type of Form	Form – 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10's, 14's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Olanzo-F 6/25 mg capsules of M/s Regal Pharmaceuticals(Reg. # 081974)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General capsule section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
3004.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Olexit capsule 12mg/25mg
	Composition	Each capsule contains: Olanzapine……...……12mg Fluoxetine as HCl……..……..25mg
	Diary No. Date of R& I & fee	Dy.No.39857; 04-12-2018; Rs.20,000 (03-12-2018)
	Pharmacological Group	SSRIs / Antipsychotic
	Type of Form	Form- 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10's, 14's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Olanzo- F 12/25 mg capsules of M/s Regal Pharmaceuticals (Reg. # 081975)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General capsule section is available in the firm as mentioned in the submitted DML.
	Decision: Approved.	
3005.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Dyris capsule 50mg
	Composition	Each capsule contains: Diacerein……..……50mg
	Diary No. Date of R& I & fee	Dy.No.39857; 04-12-2018; Rs.20,000 (03-12-2018)
	Pharmacological Group	Anti- inflammatory/ Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved
	Me-too status	Dycer- 50 capsule of M/s Bloom Pharmaceuticals (Pvt.)

		Ltd, Industrial Estate, Hattar (Reg. # 071665)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• General capsule section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3006.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Famerol tablet 450mg/35mg
	Composition	Each tablet contains: Paracetamol……..…450mg Orphenadrine citrate…….…..…35mg
	Diary No. Date of R& I & fee	Dy.No.43348; 16-12-2018; Rs.20,000 (16-12-2018)
	Pharmacological Group	Muscle relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 100 & as per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	P- Orph tablet of M/s Swiss, Karachi (Reg. # 070661)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Generaltablet section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3007.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Migley tablet 20mg
	Composition	Each film- coated tablet contains: Eletriptan as HBr…….….20mg
	Diary No. Date of R& I & fee	Dy.No.43349; 16-12-2018; Rs.20,000 (16-12-2018)
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Elle tablets 20mg of M/s Wilshire Laboratories, Lahore (Reg. # 052828)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes that the firm was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3008.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Migley tablet 40mg
	Composition	Each film- coated tablet contains: Eletriptan as HBr……...40mg
	Diary No. Date of R& I & fee	Dy.No.43350 dated 16-12-2018 Rs.20,000/- Dated 16-

		12-2018
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Elle tablets 40mg of M/s Wilshire Laboratories, Lahore (Reg. # 044603)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes that the firm was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• General tablet section is available in the firm as mentioned in the submitted DML. • The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3009.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd, 28 km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Vasofax tablets 180mg
	Composition	Each film- coated tablet contains: Fexofenadine HCl……...180mg
	Diary No. Date of R& I & fee	Dy.No.39866 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Afex 180mg tablet of M/s Shaheen Pharma (Reg. # 064319)
	GMP status	Last GMP inspection was conducted on 11-01-2019 and the report concludes satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further upgradations.
	Remarks of the Evaluator [XIII]	The applied formulation is available in BP.
	Decision: Approved with BP specifications.	
3010.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals, Plot # 22, 23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Biohep 3g Sachet
	Composition	Each sachet contains: L- Ornithine L- Aspartate…….3g
	Diary No. Date of R& I & fee	Dy.No.44471 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	cholagogue and used in hepatic encephalopathy
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Hepa-Merz Sachet containing Ornithine Aspartate (granules for solution) AGES(Austria) Approved
	Me-too status	HepaMerzGranmabs of M/s Brookes Karachi (Reg. # 012143)
	GMP status	Last GMP inspection was conducted on 11-02-2019 and the report concludes that the panel recommends the issuance of GMP certificate to M/s Vision Pharma

		Islamabad as the firm is found at a good level of GMP as of today.
	Remarks of the Evaluator [XIII]	General sachet (powder) section is available in the firm as mentioned in the submitted GMP certificate. The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3011.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Zoltrip OD Tablet 2.5mg
	Composition	Each orodispersible tablet contains: Zolmitriptan…2.5mg
	Diary No. Date of R& I & fee	Dy.No 3961 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	3's, 10's & As per SRO/ DRAP policy
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Xoming 2.5mg Tablet by Nabiqasim Reg. No. 081782
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3012.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Zoltrip Tablet 5mg
	Composition	Each orodispersible tablet contains: Zolmitriptan…5mg
	Diary No. Date of R& I & fee	Dy.No 3962 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	3's, 10's & As per SRO/ DRAP policy
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Triptan Tablets 5mg by M/s Efroze (Reg#042345)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3013.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Zilium Tablets 10mg

	Composition	Each Tablet Contains: Domperidone Maleate eq to Domperidone…10mg
	Diary No. Date of R& I & fee	Dy.No 3949 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Propulsive
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Almedon-V Tablets 10mg by M/s Alina Combine Pakistan (Pvt) Ltd (Reg#023886)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3014.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Diabex Tablets 500mg
	Composition	Each Film Coated Tablet Contains: Metformin HCL…500mg
	Diary No. Date of R& I & fee	Dy.No 3952 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	GLUCODAL 500MG TAB LC&PW Lahore 012598
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	General tablet section is avaailable in the firm as mentioned in the submitted DML.
	Decision: Approved.	
3015.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Diabex Tablets 850mg
	Composition	Each Film Coated Tablet Contains: Metformin HCL…850mg
	Diary No. Date of R& I & fee	Dy.No 3953 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Biguanides
	Type of Form	Form- 5
	Finished product Specification	USP

	Pack size & Demanded Price	10's, 20's, 30's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Orabat 850mg Tab Saitex Karachi 011860
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	General tablet section is avaailable in the firm as mentioned in the submitted DML.
	Decision: Approved.	
3016.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Neopride Tablets 25mg
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Dy.No 3957 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form- 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved
	Me-too status	Scipride tablet 25mg M/s Getz Pharma 057902
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3017.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Valpret Tablets 500mg
	Composition	Each delayed release tablet contains: Divalproex Sodium eq to Valproic acid…500mg
	Diary No. Date of R& I & fee	Dy.No 3947 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	20's, 30's, 50's, 100's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Epinil tablet of M/s Platinum Pharmaceuticals, (Reg.# 024464
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes:

		Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3018.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Neopride Tablets 50mg
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R& I & fee	Dy.No 3958 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form- 5
	Finished product Specification	Innovator's specification.
	Pack size & Demanded Price	20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Levopraid 50 mg tablets (Approved by AIFA of Italy)
	Me-too status	Nauvomit Tablets of M/s Saaaf Pharmaceutical. (Reg.# 068312)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3019.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Aeronix Tablets 10mg
	Composition	Each Film Coated Tablet Contains: Zafirlukast…10mg
	Diary No. Date of R& I & fee	Dy.No 3959 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	14's, 28's & as per SRO/ DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Accolate 10mg film-coated tablets of M/s Astra Zeneca Pharmaceuticals (USFDA Approved)
	Me-too status	Zilesta 10mg tablet of M/s Genix Pharma 055978
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.

	Remarks of the Evaluator [XIII]	The product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Approved.	
3020.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Cingest 1mg Tablet
	Composition	Each Tablet Contains: Cinitapride (as acid tartrate) …1mg
	Diary No. Date of R& I & fee	Dy.No 3945 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Propulsives
	Type of Form	Form- 5
	Finished product Specification	innovator's specification
	Pack size & Demanded Price	10 20 50 & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg Tablet of Spain approved
	Me-too status	Sitip 1mg Tablet by M/s Sami Pharma, Karachi (Reg. No. 076174)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3021.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Doxfil Tablets 400mg
	Composition	Each Tablet Contains: Doxofylline…400mg
	Diary No. Date of R& I & fee	Dy.No 3950 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Other Systemic Drugs for Obstructive Airway Diseases (Xanthines)
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	DOXOFILLINA ABC 400mg tablet by M/s ABC FARMACEUTICI S.p.A (Italian Medicine Agency approved)
	Me-too status	Profylline Tablet 400mg by M/s Kaizen (Reg# 073744)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	

3022.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Valpret Tablets 250mg
	Composition	Each delayed release tablet contains: Divalproex Sodium eq to Valproic acid…250mg
	Diary No. Date of R& I & fee	Dy.No 3946 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Anticonvulsants & Anti-epileptics
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	20's, 30's, 50's, 100's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Divalproex Sodium delayed-release tablet (USFDA Approved)
	Me-too status	Epival tablet 250mg of M/s Abbott Laboratories (Reg. # 007160)
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3023.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals pvt Ltd, Plot no 25 & 26, Street S- 3., RCCI Industrial Estate Rawat.
	Brand Name +Dosage Form + Strength	Aeronix Tablets 20mg
	Composition	Each Film Coated Tablet Contains: Zafirlukast….....20mg
	Diary No. Date of R& I & fee	Dy.No 3960 dated 29-01-2019 Rs.20,000/- Dated 25-01-2019
	Pharmacological Group	Leukotriene Receptor Antagonists
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Accolate (10mg, 20mg) Film Coated Tablets by M/s Par Pharms INc, USFDA Approved
	Me-too status	Zilesta 20mg tablet of M/s Genix Pharma Reg No. 055979
	GMP status	Last GMP inspection was conducted on 25-10-2018 and the report concludes: Recommendations: As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator [XIII]	The product is not present in available pharmacopoeia (USP, BP, IP, JP).
	Decision: Approved.	

3024.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Vildamin 50/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg

		Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy.No 7044 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Vildabar PLUS Tablet Barrett Hodgson Karachi. 085998
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Non pharmacopoeial
	Decision: Approved with innovators' specifications.	
3025.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Vildamin 50/850 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy.No 7043 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Vildabar PLUS Tablet Barrett Hodgson Karachi. 085997
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Non pharmacopoeial
	Decision: Approved with innovators' specifications.	
3026.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Vildamin 50/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No 7042 dated 19-02-2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 21 28 As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Vildabar PLUS Tablet Barrett Hodgson Karachi. 085996
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Non pharmacopoeial
	Decision: Approved with innovators' specifications.	
3027.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Amnil Tablet 100mg
	Composition	Each Tablet Contains: Amisulpride…100mg

	Diary No. Date of R& I & fee	Dy.No 8880 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	20 30 40 As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Solium-100 Tablets Genome Pharmaceuticals (Pvt,) Ltd. 16/1-Phase IV Industrial Estate, Hattar. 074533
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	BP
	Decision: Approved with BP specifications.	
3028.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Vita 3 250mg
	Composition	Each Tablet Contains: Nicotinic Acid (Niacin)…250mg
	Diary No. Date of R& I & fee	Dy.No 8250 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Peripheral vasodilator/ Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60 90 120 As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	NICOSUR 250MG TAB ZAFA KARACHI 011956
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Reference could not be confirmed BP
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
3029.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Vita 3 500mg
	Composition	Each Tablet Contains: Nicotinic Acid…500mg
	Diary No. Date of R& I & fee	Dy.No 8249 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Peripheral vasodilator/ Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	NICOSUR 500MG TAB ZAFA KARACHI 011957
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Reference could not be confirmed BP
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
3030.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Terbin Tablet 250mg
	Composition	Each Tablet Contains: Terbinafine as HCL…250mg

	Diary No. Date of R& I & fee	Dy.No 8253 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 14 20 28 As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Lamisil Sandoz 250mg Tab Sandoz Karachi 013209
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Present in BP
	Decision: Approved with BP specifications.	
3031.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Sitafor 50mg/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate…50mg Metformin HCL…1000mg
	Diary No. Date of R& I & fee	Dy.No 8251 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Sita Plus 50/1000 Tablet PharmEvo (Pvt.)Ltd, ,Karachi 055486
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Non pharmacopoeial
	Decision: Approved with innovators' specifications.	
3032.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Bivodil 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Nebivolol as HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 8248 dated 25-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved as uncoated tablet
	Me-too status	Nebivol Tablet Tabros Pharma (Pvt) Ltd , Karachi 061532
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	MHRA Approved as uncoated tablet No pharmacopoeial.
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee.	
3033.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Rifamin 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Rifaximin …200mg

	Diary No. Date of R& I & fee	Dy.No 8879 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rifaxa 200mg Tablets Ferozesons Labs, P.O Ferozesons Amangarh Nowshera. 068205
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Non pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3034.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd, 21 Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Rifamin 550mg Tablet
	Composition	Each Film Coated Tablet Contains: Rifaximin ……550mg
	Diary No. Date of R& I & fee	Dy.No 8881 dated 27-02-2019 Rs.20,000/- Dated 27-02-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 21 28 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rifaxa 500mg Tablets Ferozesons Labs, Amangarh Nowshera. 071661
	GMP status	Last GMP inspection was conducted on 13-09-2019 and the report concludes renewal of DML
	Remarks of the Evaluator [XIII]	Non pharmacopoeial.
	Decision: Approved with innovators' specifications.	

3035.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad.
	Brand Name +Dosage Form + Strength	Rivar 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…10mg
	Diary No. Date of R& I & fee	Dy.No 7547 dated 21-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rivar 10mg Tablet Hilton Pharma Kar. 081476
	GMP status	Last GMP isnepction was conducted on 26-07-2018 and the report concludes that the firm is operating at good level of GMP compliance. The panel unanimously recommends the grant of renewal of DML by way of formulation of M/s Hicon Pharma Peshawar for following sections: i- Tablet Section (Gen) ii- Tablet section (Gen Antibiotic) iii- Liquid Syrup section (Gen)
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	

3036.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad.
	Brand Name +Dosage Form + Strength	Rivar 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
	Diary No. Date of R& I & fee	Dy.No 7548 dated 21-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rivaro Tablet Highnoon Laboratories Ltd 085872
	GMP status	Last GMP isnepction was conducted on 26-07-2018 and the report concludes that the firm is operating at good level of GMP compliance**. T**he panel unanimously recommends the grant of renewal of DML by way of formulation of M/s Hicon Pharma Peshawar for following sections: i- Tablet Section (Gen) ii- Tablet section (Gen Antibiotic) iii- Liquid Syrup section (Gen)
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3037.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad.
	Brand Name +Dosage Form + Strength	Rivar 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…20mg
	Diary No. Date of R& I & fee	Dy.No 7549 dated 21-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rivaro Tablet Highnoon Laboratories Ltd 085873
	GMP status	Last GMP isnepction was conducted on 26-07-2018 and the report concludes that the firm is operating at good level of GMP compliance**. T**he panel unanimously recommends the grant of renewal of DML by way of formulation of M/s Hicon Pharma Peshawar for following sections: i- Tablet Section (Gen) ii- Tablet section (Gen Antibiotic) iii- Liquid Syrup section (Gen)
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3038.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad.
	Brand Name +Dosage Form + Strength	Itocon OD Tablets 150mg
	Composition	Each Film Coated Tablet Contains: Itopride HCl…150mg
	Diary No. Date of R& I & fee	Dy.No 7546 dated 21-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Propulsive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Itop S.R 150mg Tablet Nexus Pharma, Karachi 070883
	GMP status	Last GMP isnepction was conducted on 26-07-2018 and the report concludes that the firm is operating at good level of GMP compliance**. T**he panel unanimously recommends the grant of renewal of DML by way of formulation of M/s Hicon Pharma Peshawar for following sections: i- Tablet Section (Gen) ii- Tablet section (Gen Antibiotic) iii- Liquid Syrup section (Gen)
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
3039.	Name and address of manufacturer / Applicant	M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad.
	Brand Name +Dosage Form + Strength	Ston Nil Suspension 250mg
	Composition	Each 5ml contains: Ursodeoxycholic Acid…250mg
	Diary No. Date of R& I & fee	Dy.No 7550 dated 21-02-2019 Rs.20,000/- Dated 20-02-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Ursodol Suspension OBS Pakistan Pvt Ltd 085632
	GMP status	Last GMP isnepction was conducted on 26-07-2018 and the report concludes that the firm is operating at good level of GMP compliance**. T**he panel unanimously recommends the grant of renewal of DML by way of formulation of M/s Hicon Pharma Peshawar for following sections: i- Tablet Section (Gen) ii- Tablet section (Gen Antibiotic) iii- Liquid Syrup section (Gen)
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications.	
3040.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Kalgab Capsule 50mg
	Composition	Each Capsule Contains: Pregabalin……50mg
	Diary No. Date of R& I & fee	Dy.No 9246 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 14 100 As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Pregaba 50 mg capsule of Winilton Pharmaceutics 077586
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and

		general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator [XIII]	Non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3041.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Kaldin D Syrup
	Composition	Each 5ml contains: Desloratadine…2.5mg
	Diary No. Date of R& I & fee	Dy.No 9242 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30ml, 60ml, 90ml, 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	D- Jardin 0.5mg/ml Syrup of High-Q, Karachi 073610
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator [XIII]	Gen liquid section GMP report Non pharmacopoeioal.
	Decision: Approved with innovator's specifications.	
3042.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Terlap Cream 0.01g (1%)
	Composition	Each gram contains: Terbinafine HCl…0.01g (1% w/w)
	Diary No. Date of R& I & fee	Dy.No 9243 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Lamisil Cream 1% GSK OTC (Pvt) Ltd., Petaro Road, Jamshoro 084005
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator [XIII]	Present in JP.
	Decision: Approved with JP specifications.	
3043.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Kalzox Capsule 100mg
	Composition	Each Capsule Contains: Itraconazole…...100mg
	Diary No. Date of R& I & fee	Dy.No 9247 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti-fungal
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	MHRA Approved

	Regulatory Authorities	
	Me-too status	Rolac 100mg Capsules Sami Pharma 024491
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator [XIII]	Non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3044.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt Ltd, 5-Km, Manga Road, Raiwind, Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Kalgab Capsule 100mg
	Composition	Each Capsule Contains: Pregabalin……..100mg
	Diary No. Date of R& I & fee	Dy.No 9251 dated 28-02-2019 Rs.20,000/- Dated 28-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 14 100 As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Pregalax Capsule Magns Pharmaceuticals, Faisalabad 084137
	GMP status	Last GMP inspection was conducted on 30-03-2018 and the report concludes renewal of DML for general tablet and general capsule section and grant of additional psychotropic tablet section.
	Remarks of the Evaluator [XIII]	Non pharmacopoeial
	Decision: Approved with innovator's specifications.	
3045.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rixa 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban……..…10mg
	Diary No. Date of R& I & fee	Dy.No 5841 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anti- coagulant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Xarelto 10mg Tablet Bayer Pakistan (Pvt) Ltd Karachi 059057
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Non- pharmacopoeial
	Decision: Approved with innovator's specifications.	
3046.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rixa 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…20mg
	Diary No. Date of R& I & fee	Dy.No 5846 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Anti- coagulant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved

	Me-too status	Xarelto of M/s Bayer 072550
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3047.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Solicept 5mg Tablet
	Composition	Each film coated release tablet contains: Solifenacin succinate…5mg
	Diary No. Date of R& I & fee	Dy.No 5842 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10's, 2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Solifen Tablet Getz Pharma Karachi 061202
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3048.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Solicept 10mg Tablet
	Composition	Each film coated release tablet contains: Solifenacin succinate…10mg
	Diary No. Date of R& I & fee	Dy.No 5843 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10's, 2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Solifen Tablet Getz Pharma Karachi 061203
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovator's specifications.	
3049.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Brifin 200mg Tablet
	Composition	Each sugar coated tablet contains: Ibuprofen…200mg
	Diary No. Date of R& I & fee	Dy.No 5153 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 50 100 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Pacifen 200mg Tab Pakistan Pharmaceutical And Chemical Laboratories 013326
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	BP

	Decision: Approved with BP specifications.	
3050.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Brifin 400mg Tablet
	Composition	Each sugar coated tablet contains: Ibuprofen……400mg
	Diary No. Date of R& I & fee	Dy.No 5154 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 50 100 & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Pacifen 200mg Tab Pakistan Pharmaceutical And Chemical Laboratories 013325
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Present in BP
	Decision: Approved with BP specifications.	
3051.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Nim 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Nimesulide…100mg
	Diary No. Date of R& I & fee	Dy.No 7767 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 20 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in France as uncoated tablet
	Me-too status	Nimex Tablets Medizan Labs (Pvt) Ltd, Islamabad. 042571
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Approved in France as uncoated tablet Non- pharmacopoeial.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.	
3052.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mirago CR 25mg Tablet
	Composition	Each film coated controlled release tablet contains: Mirabegron…25mg
	Diary No. Date of R& I & fee	Dy.No 5844 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Beta- 3 adrenergic agonists
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Me- too could not be verified. The applied molecule is on stability.

		Non- pharmacopoeial.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3053.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mirago CR 50mg Tablet
	Composition	Each film coated controlled release tablet contains: Mirabegron…50mg
	Diary No. Date of R& I & fee	Dy.No 5845 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Beta- 3 adrenergic agonists
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Me- too could not be verified The applied molecule is on stability. Non- pharmacopoeial.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3054.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mdip 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Amlodipine Besylate……5mg
	Diary No. Date of R& I & fee	Dy.No 7759 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Ca Channel blockers
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 14's & as per sro
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA and MHRA as uncoated
	Me-too status	Amlocard 5 Tablets Pharmatec Pakistan (Pvt) Ltd, Karachi 020555
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Approved in USFDA and MHRA as uncoated
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.	
3055.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Mdip 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Amlodipine Besylate…10mg
	Diary No. Date of R& I & fee	Dy.No 7760 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Ca Channel blockers
	Type of Form	Form- 5
	Finished product Specification	Usp
	Pack size & Demanded Price	10's, 14's, 20's & as per sro
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA and MHRA as uncoated

	Me-too status	Amlocard 10 Tablets Pharmatec Pakistan (Pvt) Ltd, Karachi 020556
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Approved in USFDA and MHRA as uncoated
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.	
3056.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Doxasin 2mg Tablet
	Composition	Each Tablet Contains: Doxazosin Mesylate eq to Doxazosin…2mg
	Diary No. Date of R& I & fee	Dy.No 5158 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Alpha adreno receptor blocking drugs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 20 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	CARDURA 2MG TAB PFIZER KARACHI 011743
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3057.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Doxasin 4mg Tablet
	Composition	Each uncoated Tablet Contains: Doxazosin Mesylate eq to Doxazosin…4mg
	Diary No. Date of R& I & fee	Dy.No 5157 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Alpha adreno receptor blocking drugs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 20 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	CARDURA 4MG TAB PFIZER KARACHI 012444
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3058.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Aricin 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Erythromycin …250mg
	Diary No. Date of R& I & fee	Dy.No 5160 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Erythromycin Tablets Healers Pharmaceuticals, Peshawar. 070356
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the

		report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3059.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Aricin 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Erythromycin …500mg
	Diary No. Date of R& I & fee	Dy.No 5161 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Erythrotab 500mg Tab Lc&Pw Lahore 012505
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3060.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Epitop 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Topiramate……50mg
	Diary No. Date of R& I & fee	Dy.No 7770 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Topirama Tablets 50mg Platinum Pharma 030206
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3061.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Pioxi 20mg Capsule
	Composition	Each hard gelatin capsule contains: Piroxicam……...20mg
	Diary No. Date of R& I & fee	Dy.No 5156 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Anti- inflammatory/ Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 20 100 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Piroxigen Capsule Genera Pharma Islamabad 040829
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	

3062.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Bisveda 6.25mg Tablets
	Composition	Each Film Coated Tablet Contains: Carvedilol…6.25mg
	Diary No. Date of R& I & fee	Dy.No 7761 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 20 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Carveda Ferozsons Laboratories Ltd. Lahore 032569
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3063.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Bisveda 12.5mg Tablets
	Composition	Each Film Coated Tablet Contains: Carvedilol…12.5mg
	Diary No. Date of R& I & fee	Dy.No 7762 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 20 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Carveda Ferozsons Laboratories Ltd. Lahore 056263
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3064.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Ond 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron HCl Dihydrate eq to Ondansetron……...8mg
	Diary No. Date of R& I & fee	Dy.No 7768 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti- emetic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Ondan 8mg Tablet Medley Pharmaceuticals Islamabad 080551
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	BP
	Decision: Approved with BP specifications.	

3065.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Lamitore 50mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…50mg
	Diary No. Date of R& I & fee	Dy.No 7764 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti convulsant/ anti emetic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Lamotec Tablets 50 mg Rotex Medica Pakistan Islamabad 070154
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3066.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Ben 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Albendazole…….200mg
	Diary No. Date of R& I & fee	Dy.No 7758 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	2's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Alebendizit 200mg Tab Cyrus Lahore 013181
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3067.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Piratam 800mg Tablet
	Composition	Each Film Coated Tablet Contains: Piracetam……800mg
	Diary No. Date of R& I & fee	Dy.No 7769 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Gaba analogue
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10 30 100 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Piratril Tablets Webros Pharmaceuticals, RCCI Industrial Estate, Rawat 034705
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Non pharmacopoeial
	Decision: Approved with innovator's specifications.	
3068.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.

	Brand Name +Dosage Form + Strength	Anticold 60mg/400mg Tablet
	Composition	Each Film Coated Tablet Contains: Ibuprofen……..…400mg Pseudoephedrine HCl……....60mg
	Diary No. Date of R& I & fee	Dy.No 5159 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	NSAIDs / Sympathomimetic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	20 30 100 & as per SRO
	Approval status of product in Reference Regulatory Authorities	Lasynac Max Strength 400mg/ 60mg film-coated tablets (Approved by MHRA of UK)
	Me-too status	Arinac Forte Tablet of M/s Knoll Pharma (Reg. # 064206)
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3069.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	T- Dol 50mg Capsule
	Composition	Each hard gelatin capsule contains: Tramadol HCl……...50mg
	Diary No. Date of R& I & fee	Dy.No 5840 dated 11-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Could not be confirmed in the applied dosage form.
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Pellets data is needed and applied as hard caps while they are prolonged-release capsules. Me- too status could not be confirmed in the applied dosage form.
	Decision: Deferred for following reasons: • **Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
3070.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	ISO-V Cream 10mg
	Composition	Each gram contains: Isoconazole as Nitrate…10mg
	Diary No. Date of R& I & fee	Dy.No 7771 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Corticosteroid, Antifungal (Imidazole derivative)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Travogen cream (Italy)
	Me-too status	Gynocare Cream by Bloom Hattar (Reg. #026863)
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.

	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3071.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tacrim Ointment 0.03%
	Composition	Each tube contains: Tacrolimus…0.03g
	Diary No. Date of R& I & fee	Dy.No 7766 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Immunosupressive agent
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Tacroderm Ointment 0.03% of M/s Caraway (Reg. # 069932)
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• The formulation should be applied as: Each gram contains: Tacrolimus as Monohydrate……...…0.3mg (0.03%) • Fee for revision of strength is required.
	Decision: Deferred for correction of formulation alongwith fee.	
3072.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Benzic 4% Cream
	Composition	Each gram contains: Benzoyl Peroxide…40mg
	Diary No. Date of R& I & fee	Dy.No 7772 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	BREVOXYL CREAMBENZOYL PEROXIDE BP 4.00% W/W STIEFEL LABS LAHORE 019464
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	General semi solid section GMP report BP
	Decision: Approved with BP specifications.	
3073.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Livederm Cream 10mg/1mg
	Composition	Each gram contains: Isoconazole as Nitrate…10mg Diflucortolone Valerate…1mg
	Diary No. Date of R& I & fee	Dy.No 7765 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Travocort 0.1 + 1% w/w Cream by M/s Bayer Limited (HPRA Ireland Approved)
	Me-too status	Travocort 0.1 + 1% w/w Cream by M/s Bayer Healthcare (Reg#005830)

	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Non- pharmacopoeial
	Decision: Approved with innovators' specifications.	
3074.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Clid V-2% Cream
	Composition	Each gram contains: Clindamycin as Phosphate…20mg
	Diary No. Date of R& I & fee	Dy.No 7763 dated 21-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Clindanor 2 % Cream M/S Nortech Pharmaceuticals, Industrial Traingle, Kahuta Road, Islamabad 077982
	GMP status	Last GMP inspection was conducted on 10-07-2019 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	Present in USP
	Decision: Approved with USP specifications.	
3075.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A- 248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Dexib Tablet 300mg
	Composition	Each film coated tablet contains: Dexibuprofen ……..300mg
	Diary No. Date of R& I & fee	Dy.No.40348; 05-12-2018; Rs.20,000(05-12-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Seractil 300mg tablets (Austria Approved)
	Me-too status	Vanit Tablet 300mg Getz Pharma 061486
	GMP status	Last GMP inspection was conducted on 15-03-3018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3076.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A- 248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Dexib Tablet 400mg
	Composition	Each film coated tablet contains: Dexibuprofen ……..400mg
	Diary No. Date of R& I & fee	Dy.No.40349; 05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Seractil 400mg tablets (Austria Approved)
	Me-too status	Vanit Tablet 300mg Getz Pharma 061487
	GMP status	Last GMP inspection was conducted on 15-03-3018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	

3077.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Vesocare Tablet 5mg
	Composition	Each film coated tablet contains: Solifenacin Succinate ……..……5mg
	Diary No. Date of R& I & fee	Dy.No.40346; 05-12-2018; Rs.20,000(05-12-2018)
	Pharmacological Group	Muscarinic receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Fenaso 5mg Tablet of M/S Highnoon Laboratories 069314
	GMP status	15-03-3018 During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3078.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd. Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Nosaid Tablet250mg
	Composition	Each film coated tablet contains: Naproxen ……..…….250mg
	Diary No. Date of R& I & fee	Dy.No.40975; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA as uncoated
	Me-too status	Flexin 250mg Tablets of M/S Abbott Laboratories, Pakistan 011358
	GMP status	15-03-3018 During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remarks of the Evaluator [XIII]	• Approved in MHRA as uncoated • Firm has revised the applied dosage form as uncoated tablet and paid Rs. 5000/- under deposit slip No. 1996129 dated 04-05-2020
	Decision: Approved.	
3079.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A- 259 H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name +Dosage Form + Strength	Nosaid Tablet 500mg
	Composition	Each film coated tablet contains: Naproxen ……..….500mg
	Diary No. Date of R& I & fee	Dy.No.40976; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	NSAID
	Type of Form	Form- 5
	Finished product Specification	USP Specs
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved in MHRA as uncoated
	Me-too status	Flexin 500mg Tablets of M/S Abbott Laboratories, Pakistan 011359
	GMP status	Last GMP inspection was conducted on 03-01-2019 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator [xiii]	• Approved in MHRA as uncoated • Firm has revised the applied dosage form as uncoated tablet and paid Rs. 5000/- under deposit slip No. 1996128 dated 04-05-2020
	Decision: Approved.	
3080.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A- 259 H.I.T.E. Lasbela Balochistan, Pakistan
	Brand Name +Dosage Form + Strength	Nosaid Tablet 550mg
	Composition	Each film coated tablet contains: Naproxen ……...550mg
	Diary No. Date of R& I & fee	Dy.No.40977; 06-12-2018; Rs.20,000 (06-12-2018)
	Pharmacological Group	NSAID
	Type of Form	Form- 5
	Finished product Specification	USP Specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA as uncoated
	Me-too status	SYNFLEX 550MG TAB of SAITEX, Karachi 010197
	GMP status	Last GMP inspection was conducted on 03-01-2019 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator [xiii]	• Approved in TGA as uncoated. • Firm has revised form as uncoated tablet and paid Rs. 5000/- under deposit slip No. 1996127 dated 04-05-2020.
	Decision: Approved.	
3081.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Ximin Tablet 200mg
	Composition	Each film coated tablet contains: Rifaximin ……..…..… 200mg
	Diary No. Date of R& I & fee	Dy.No.39862; 04-12-2018; Rs.20,000(04-12-2018)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nimixa 200mg Tablet of M/s Getz Pharma Pakistan 070734
	GMP status	15-03-3018 During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remarks of the Evaluator [xiii]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3082.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Vastab- Ez Tablet 10mg/ 10mg
	Composition	Each film coated tablet contains: Ezetimibe …….. 10mg

		Atorvastatin (as calcium trihydrate)……. 10mg
	Diary No. Date of R& I & fee	Dy.No.41986; 07-12-2018; Rs.20,000(07-12-2018)
	Pharmacological Group	Cholesterol absorption inhibitors/ HMG- CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	Atorax-E Tablets Dyson Research Laboratories 078838
	GMP status	Last GMP inspection was conducted on 15-03-3018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3083.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Vastab- Ez Tablet 10mg/ 20mg
	Composition	Each film coated tablet contains: Ezetimibe …….. 10mg Atorvastatin (as calcium trihydrate)……. 20mg
	Diary No. Date of R& I & fee	Dy.No.41987; 07-12-2018; Rs.20,000(07-12-2018)
	Pharmacological Group	Cholesterol absorption inhibitors/ HMG-CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved
	Me-too status	Lipiget EZ 20mg+10mg Tablet Getz Pharma 073714
	GMP status	Last GMP inspection was conducted on 03-01-2019 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3084.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd., Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Vastab- ez Tablet
	Composition	Each film coated tablet contains: Ezetimibe …….. 10mg Atorvastatin (as calcium trihydrate)……. 40mg
	Diary No. Date of R& I & fee	Dy.No.41988; 07-12-2018; Rs.20,000(07-12-2018)
	Pharmacological Group	Cholesterol absorption inhibitors/ HMG-CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Lipiget EZ 40mg+ 10mg Tablet Getz Pharma 073715
	GMP status	Last GMP inspection was conducted on 03-01-2019 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	

3085.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Ximin Tablet 550mg
	Composition	Each film coated tablet contains: Rifaximin …… 550mg
	Diary No. Date of R& I & fee	Dy.No.39863; 04-12-2018; Rs.20,000 (04-12-2018)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nimixa 550mg Tablet of M/s Getz Pharma Pakistan 070733
	GMP status	15-03-3018 During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3086.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Clindagel Plus Gel 1% / 5%
	Composition	Each gram tube contains: Clindamycin Phosphate eq. to Clindamycin… 10mg Anhydrous Benzoyl Peroxide eq.to Hydrous Benzoyl Peroxide ……..….. 50mg
	Diary No. Date of R& I & fee	Dy.No.41985; 07-12-2018; Rs.20,000 (07-12-2018)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	10g Tube & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Benclin Gel of M/s Elko Org. (Pvt), Ltd. 061908
	GMP status	Last GMP inspection was conducted on 03-01-2019 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovators' specifications.	
3087.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd. Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Ortho Plus Tablet
	Composition	Each film coated tablet contains: Diclofenac Sodium …… 75mg. Misoprostol …….. 200mcg
	Diary No. Date of R& I & fee	Dy.No.41984; 07-12-2018; Rs.20,000 (07-12-2018)
	Pharmacological Group	NSAID
	Type of Form	Form- 5
	Finished product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as delayed release tablet
	Me-too status	Cytopan-75 Tablets Getz Pharma 024014
	GMP status	15-03-3018 During the comprehensive visit and detail

		inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remarks of the Evaluator [XIII]	in USP as delayed release tablet Severe Boxed warning in USFDA USFDA Approved as delayed release tablet Firm has revised the applied dosage form as delayed release tablet and paid Rs. 5000/- under deposit slip No. 1996124 dated 04-05-2020. Manufacturing facility of tablet in tablet requires confirmation.
	Decision: Deferred for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.	
3088.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd. Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Ortho Plus Tablet 50mg/ 200mcg
	Composition	Each film coated tablet contains: Diclofenac Sodium …… 50mg. Misoprostol …….. 200mcg
	Diary No. Date of R& I & fee	Dy.No.41983; 07-12-2018; Rs.20,000 (07-12-2018)
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as delayed release tablet
	Me-too status	Erwin 50mg Tablets Sami Pharma 024492
	GMP status	
	Remarks of the Evaluator [XIII]	in USP as delayed release tablet Severe Boxed warning in USFDA USFDA Approved as delayed release tablet Firm has revised the applied dosage form as delayed release tablet and paid Rs. 5000/- under deposit slip No. 1996125 dated 04-05-2020. Manufacturing facility of tablet in tablet requires confirmation.
	Decision: Deferred for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.	
3089.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt) Ltd Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan.
	Brand Name +Dosage Form + Strength	Vesocare Tablet 10mg
	Composition	Each film coated tablet contains: Solifenacin Succinate ……..……10mg
	Diary No. Date of R& I & fee	Dy.No.40347; 05-12-2018; Rs.20,000(05-12-2018)
	Pharmacological Group	Muscarinic Receptor Antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA

	Me-too status	Fenaso 10mg Tablet of M/s Highnoon Laboratories 069313
	GMP status	15-03-3018 During the comprehensive visit and detail inspection almost all respective documents from QA, QC, Production were reviewed and retrieval of the same was noted good. Based on the people met and documents reviewed overall GMP of the firm rated as GOOD.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3090.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis tablet 20mg
	Composition	Each tablet contains: Telmisartan……....20mg
	Diary No. Date of R& I & fee	Dy.No.40523; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Cresar 20mg Tablet Tabros Pharma (Pvt) Ltd 055900
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3091.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis tablet 40mg
	Composition	Each tablet contains: Telmisartan……..40mg
	Diary No. Date of R& I & fee	Dy.No.40524; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Cresar 40mg Tablet Tabros Pharma (Pvt) Ltd 055901
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3092.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis tablet 80mg
	Composition	Each film- coated tablet contains: Telmisartan……..80mg

	Diary No. Date of R& I & fee	Dy.No.40525; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as uncoated
	Me-too status	Cresar 80mg Tablet Tabros Pharma (Pvt) Ltd 055902
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	Manufacturing outline is not submitted and master formulation reveals uncoated while on Form- 5 it is mentioned as film- coated USFDA Approved as uncoated
	Decision: Deferred for submission of manufacturing outline and in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.	
3093.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis- A tablet 40mg/ 5mg
	Composition	Each tablet contains: Telmisartan …. ……..40mg Amlodipine as Besylate …….. 5mg
	Diary No. Date of R& I & fee	Dy.No.40526; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as bi- layered
	Me-too status	Telmis-A 5mg + 40mg Tablet Genix Pharma (Pvt.) Ltd 067150
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	USP Manufacturing facility of bi- layered machine needs to be confirmed.
	Decision: Deferred for following reasons: **i. Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bi-layered tablet, while the applied drug is uncoated tablet.** **ii. Confirmation of required manufacturing equipment i.e. tablet bi-layered machine by area FID.**	
3094.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis- A tablet 40mg/ 10mg
	Composition	Each tablet contains: Telmisartan …. 40mg Amlodipine as Besylate ……. 10mg
	Diary No. Date of R& I & fee	Dy.No.40529; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5

	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved as bi- layered
	Me-too status	Telmis-A 10mg + 40mg Tablet Genix Pharma (Pvt.) Ltd 067152
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	USP Manufacturing facility of bi- layered machine needs to be confirmed.
	Decision: Deferred for following reasons: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bi-layered tablet, while the applied drug is uncoated tablet.** • **Confirmation of required manufacturing equipment i.e. tablet bi-layered machine by area FID.**	
3095.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis- A tablet 80mg/ 5mg
	Composition	Each tablet contains: Telmisartan …. 80mg Amlodipine as Besylate ……. 5mg
	Diary No. Date of R& I & fee	Dy.No.40527; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved as bi- layered
	Me-too status	Telmis- A Tablet 5mg + 80mg Genix Pharma (Pvt.) Ltd 067151
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	USP Manufacturing facility of bi- layered machine needs to be confirmed.
	Decision: Deferred for following reasons: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bi-layered tablet, while the applied drug is uncoated tablet.** • **Confirmation of required manufacturing equipment i.e. tablet bi-layered machine by area FID.**	
3096.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis- A tablet 80mg/ 10mg
	Composition	Each tablet contains: Telmisartan ……... 80mg Amlodipine as Besylate ……. 10mg
	Diary No. Date of R& I & fee	Dy.No.40528; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5

	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved as bi- layered
	Me-too status	Telmis- A Tablet 10mg + 80mg Genix Pharma (Pvt.) Ltd 067470
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	USP Manufacturing facility of bi- layered machine needs to be confirmed.
	Decision: Deferred for following reasons: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bi-layered tablet, while the applied drug is uncoated tablet.** • **Confirmation of required manufacturing equipment i.e. tablet bi-layered machine by area FID.**	
3097.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis- H tablet 40mg/ 12.5mg
	Composition	Each tablet contains: Telmisartan …. 40mg hydrochlorothiazide ……. 12.5mg
	Diary No. Date of R& I & fee	Dy.No.40530; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved as bi- layered
	Me-too status	Co Telmas 40mg Tablets Global Pharma 056285
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	USP Manufacturing facility of bi- layered machine needs to be confirmed.
	Decision: Deferred for following reasons: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bi-layered tablet, while the applied drug is uncoated tablet.** • **Confirmation of required manufacturing equipment i.e. tablet bi-layered machine by area FID.**	
3098.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Telmis- H tablet 80mg/ 12.5mg
	Composition	Each tablet contains: Telmisartan …. 80mg hydrochlorothiazide ……. 12.5mg
	Diary No. Date of R& I & fee	Dy.No.40531; 06-12-2018; Rs.20,000(03-12-2018)
	Pharmacological Group	Angiotensin -II receptor Blocker
	Type of Form	Form- 5

	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA; Australia Approved as bi- layered
	Me-too status	Co Telmas 80mg Tablets Global Pharma 056286
	GMP status	16-01-2019 Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	USP Manufacturing facility of bi- layered machine needs to be confirmed.
	Decision: Deferred for following reasons: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bi-layered tablet, while the applied drug is uncoated tablet.** • **Confirmation of required manufacturing equipment i.e. tablet bi-layered machine by area FID.**	
3099.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Kifen tablet 1mg
	Composition	Each Tablet Contains: Ketotifen Hydrogen Fumarate Eq. to Ketotifen…1mg
	Diary No. Date of R& I & fee	Dy.No 39703 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Anti- histamine/ Anti- asthmatic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZADITEN Tablets 1mg by Alfasigma S.p.A. MHRA approved
	Me-too status	KETOFEN 1MG TAB CYRUS 013179
	GMP status	30-01-2018 Based on the above observations their overall GMP compliance is rated as Good.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3100.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Typen 1mg Tablets
	Composition	Each tablet contains: Cinitapride Hydrogen Tartrate Eq. to Cinitapride…1mg
	Diary No. Date of R& I & fee	Dy. No.39704 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Drugs for functional GIT disorders
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in Spain
	Me-too status	Cinita Tablets 1mg Novamed Pharmaceuticals, 064845
	GMP status	30-01-2018 Based on the above observations their overall GMP compliance is rated as Good.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	

3101.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Drov 40mg Tablets
	Composition	Each Tablet Contains: Drotaverine HCL…40mg
	Diary No. Date of R& I & fee	Dy.No 41272 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Drugs for functional GIT disorders
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in three EMA states as un-coated tablets in Hungary, Romania & Solvakia
	Me-too status	Paspa Tablets of M/s Pliva Pharma 026881
	GMP status	30-01-2018 Based on the above observations their overall GMP compliance is rated as Good.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3102.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Drov 80mg Tablets
	Composition	Each Tablet Contains: Drotaverine HCL…80mg
	Diary No. Date of R& I & fee	Dy.No 39703 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Drugs for functional GIT disorders
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in three EMA states as un-coated tablets in Hungary, Romania & Solvakia
	Me-too status	Paspa Forte Tablet Pliva, 073622
	GMP status	30-01-2018 Based on the above observations their overall GMP compliance is rated as Good.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3103.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Loxpa 60mg Tablet
	Composition	Each Tablet Contains: Loxoprofen Sodium hydrate……..60mg
	Diary No. Date of R& I & fee	Dy. No. 39707 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Loxonin Tablets 60 mg by M/s Daiichi Sankyo Co., Ltd. (PMDA Approved)
	Me-too status	Loxfen Tablets 60mg by M/s Medisure (Reg#031269)
	GMP status	30-01-2018 Based on the above observations their overall GMP compliance is rated as Good.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	

3104.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt Ltd, Plot No. A-39, S.I.T.E II, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Emlate 500mg Tablets
	Composition	Each Tablet Contains: Ethamsylate…500mg
	Diary No. Date of R& I & fee	Dy.No 39703 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Haemostatic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM France Approved
	Me-too status	Cytoplex Tablet AGP, Karachi 061420
	GMP status	30-01-2018 Based on the above observations their overall GMP compliance is rated as Good.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3105.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Olinex 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Olanzapine……..5mg
	Diary No. Date of R& I & fee	Dy.No.41757 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Olanzapine-Sandoz 5mg Tablets Novartis Pharma 048411
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications.	
3106.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Olinex 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Olanzapine…….....10mg
	Diary No. Date of R& I & fee	Dy.No.41758 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Olanzapine-Sandoz 10mg Tablets Novartis Pharma 048412
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications.	

3107.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Met- Gyl 400mg Tablets
	Composition	Each Film Coated Tablet Contains: Metronidazole…….400mg
	Diary No. Date of R& I & fee	Dy.No 41755 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Metrodex Tablets 400 mg Caraway Pharma 068531
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3108.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Alcotil 75mg Tablets
	Composition	Each Film Coated Tablet Contains: Clopidogrel as bisulfate…….75mg
	Diary No. Date of R& I & fee	Dy.No 41756 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- thrombotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Clopigen 75mg Tablets Cherwel Pharma 054542
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3109.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Asfin 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Dy.No 42008 dated 07-12-2018 Rs.10,000/- Dated 03-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Aceclocare 100mg Tablet Titlis Pharma, 082676
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3110.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Float 20mg Capsules
	Composition	Each hard gelatin capsule contains: Fluoxetine HCL…20MG

	Diary No. Date of R& I & fee	Dy.No 41752 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	SSRI
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Fluxine 20mg Capsules Don Valley Pharma 020295
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3111.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Doxic 100mg Capsules
	Composition	Each hard gelatin capsule contains: Doxycycline as Hyclate……100mg
	Diary No. Date of R& I & fee	Dy.No 41753 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Jawamycin 100mg Cap Irza 012479
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3112.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Isolin Gel 0.05%
	Composition	Each gram of gel contains: Isotretinoin …0.5mg
	Diary No. Date of R& I & fee	Dy.No 41751 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Retinoids for treatment of Acne
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Isotrex Gel By Stiefel Labs (MHRA Approved)
	Me-too status	Isotretinor 0.05% Gel Nortech Pharma 077987
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3113.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Isolin E Gel 0.05% / 2.0%
	Composition	Each gram of gel contains: Isotretinoin ……0.5mg Erythromycin……20mg
	Diary No. Date of R& I & fee	Dy.No 41754 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Retinoids for treatment of Acne

	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Tretocin Gel of Derma Techno 071260
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovators' specifications.	
3114.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Presol 0.1% Cream
	Composition	Each gram contains: Methylprednisolone Aceponate…1mg
	Diary No. Date of R& I & fee	Dy.No 42011 dated 06-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Topical Corticosteroids
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved
	Me-too status	Zema 1mg Cream Ciba Pharma081508
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3115.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Presol 0.1% Ointment
	Composition	Each gram contains: Methylprednisolone Aceponate…1mg
	Diary No. Date of R& I & fee	Dy.No. 42010 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Topical Corticosteroids
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved
	Me-too status	Advocort Fatty Ointment 0.1% Atco Lab. 074970
	GMP status	10-07-2019 acceptable
	Remarks of the Evaluator [XIII]	non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3116.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Mycozole 150mg Capsule
	Composition	Each Capsule Contains: Fluconazole…150mg
	Diary No. Date of R& I & fee	Dy.No 43946 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	BP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	DIFLUCAN 150MG CAP PFIZER KARACHI 011828
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3117.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Moxit 400mg Capsule
	Composition	Each Capsule Contains: Moxifloxacin as HCl…400mg
	Diary No. Date of R& I & fee	Dy.No 43947 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	me- too reference The applied formulation is non- pharmacopoeial.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
3118.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi.
	Brand Name +Dosage Form + Strength	Levoride 25mg Tablet
	Composition	Each enteric coated tablet contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Dy.No 43951 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Italy as uncoated tablet
	Me-too status	Levosal 25mg Tablets Medisearch Pharmacal 074396
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial. Approved in Italy as uncoated tablet
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is enteric- coated tablet.	
3119.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi.

	Brand Name +Dosage Form + Strength	Levoride 50mg Tablet
	Composition	Each enteric coated tablet contains: Levosulpiride……..50mg
	Diary No. Date of R& I & fee	Dy.No 43952 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Italy as uncoated tablet
	Me-too status	Prid Tablet Zanctok, Hyderabad 070421
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial. Approved in Italy as uncoated tablet
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is enteric- coated tablet.	
3120.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Nextor 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as Calcium trihydrate …10mg
	Diary No. Date of R& I & fee	Dy.No 41042 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	lipid lowering agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Atorvascot Tablets Scotmann Pharma 029902
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3121.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Nextor 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin Calcium trihydrate …20mg
	Diary No. Date of R& I & fee	Dy.No 41041 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	lipid lowering agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Atorvascot Tablets Scotmann Pharma 029903
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3122.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name+Dosage Form+ Strength	Nextor 40mg Tablet

	Composition	Each Film Coated Tablet Contains: Atorvastatin Calcium trihydrate …40mg
	Diary No. Date of R& I & fee	Dy.No 41040 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	lipid lowering agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Atorvastin Tablets Orta Lab Lahore 041809
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3123.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Nextor 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin Calcium trihydrate …80mg
	Diary No. Date of R& I & fee	Dy.No 41039 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	lipid lowering agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Lipirex Tablets 80mg. Highnoon Laboratories, Lahore. 044769
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3124.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Painext K 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…25mg
	Diary No. Date of R& I & fee	Dy.No 41047 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Could not be confirmed in the applied strength as 50, 70 and 100mg are available
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	Me- too Could not be confirmed in the applied strength as 50, 70 and 100mg are available.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
3125.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore

	Brand Name +Dosage Form + Strength	Raninext 150mg Tablet
	Composition	Each Tablet Contains: Ranitidine as Hydrochloride……150mg
	Diary No. Date of R& I & fee	Dy.No 41346 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- allergic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10, 20, 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved as film- coated
	Me-too status	RANITIDE 150MG TAB SIZA Lahore 011747
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	on fee challan brand name is raninext but composition is glimepiride and metformin while in form- 5 and master formulation applied composition is Ranitidine MHRA Approved as film- coated while is applied as uncoated.
	Decision: Deferred on the following reasons: **i. Justification that on fee- challan brand name is Raninext but composition is of glimepiride and metformin. While in Form- 5 and master formulation applied composition is Ranitidine.** **ii. Clarification of manufacturing outline as in reference regulatory authorities the approved drug is film-coated tablet, while the applied drug is uncoated tablet.** **iii. Decision of 293rd Registration Board meeting regarding Ranitidine containing products**	
3126.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Raninext 300mg Tablet
	Composition	Each Tablet Contains: Ranitidine as Hydrochloride…300mg
	Diary No. Date of R& I & fee	Dy.No 41347 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- allergic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10, 20, 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved as film- coated
	Me-too status	RANITIDE 150MG TAB SIZA Lahore 011747
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	on fee challan brand name is raninext but composition is glimepiride and metformin while in from- 5 and master formulation applied composition is Ranitidine MHRA Approved as film- coated while is applied as uncoated.
	Decision: Deferred on the following reasons: • **Justification that on fee- challan brand name is Raninext but composition is of glimepiride and metformin. While in Form- 5 and master formulation applied composition is Ranitidine.** • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is film-coated tablet, while the applied drug is uncoated tablet.** • **Decision of 293rd Registration Board meeting regarding Ranitidine containing products**	

3127.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Empaglif 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin……10mg
	Diary No. Date of R& I & fee	Dy.No.41051 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	14 28 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	the applied formulation is non- pharmacopoeial. me- too status could not be confirmed. Stability data is required for the applied formulation.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3128.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Empaglif 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin……25mg
	Diary No. Date of R& I & fee	Dy.No.41051 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	14 28 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	the applied formulation is non- pharmacopoeial. me- too status could not be confirmed. Stability data is required for the applied formulation.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3129.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Dapaglif 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Diary No. Date of R& I & fee	Dy.No 41345dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved

	Me-too status	Could not be confirmed
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	the applied formulation is non- pharmacopoeial. me- too status could not be confirmed. Stability data is required for the applied formulation.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3130.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Dapaglif 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Dy.No 41348 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14 28 30 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	the applied formulation is non- pharmacopoeial. me- too status could not be confirmed. Stability data is required for the applied formulation.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3131.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Lincot 500mg Tablet
	Composition	Each Tablet Contains: Citicoline…500mg
	Diary No. Date of R& I & fee	Dy.No 41344 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	psycho stimulant and nootropic
	Type of Form	Form-5
	Finished product Specification	manufacturesr
	Pack size & Demanded Price	10 20 30 & As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Cercolin Tablets. M/s Schazoo Laboratories, 46 Grand Trunk Road, Lahore. 048984
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	the applied formulation is non- pharmacopoeial. reference
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
3132.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Telday H 40/12.5mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg Hydrochlorithiazide…12.5mg

	Diary No. Date of R& I & fee	Dy.No 41045 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor blocker and diuretics
	Type of Form	Form- 5
	Finished product Specification	manufacturesr
	Pack size & Demanded Price	10 20 & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as bilayered
	Me-too status	Co Telmas 40mg Tablets Global Pharma 056285
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	USFDA Approved as bilayered The official monograph for the applied fromualiton is available in USP bilayered tablet machine machine
	Decision: Deferred on the following reasons: • **Confirmation of required manufacturing equipment i.e. tablet bi- layered machine by area FID.** • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bi- layered tablet, while the applied drug is uncoated tablet.**	
3133.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Telday H 80/12.5mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg Hydrochlorithiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 41046 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor blocker and diuretics
	Type of Form	Form- 5
	Finished product Specification	manufacturesr
	Pack size & Demanded Price	10 20 & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as bilayered
	Me-too status	Co Telmas 80mg Tablets Global Pharma 056286
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	USFDA Approved as bilayered The official monograph for the applied fromualiton is available in USP bilayered tablet machine machine
	Decision: Deferred on the following reasons: • **Confirmation of required manufacturing equipment i.e. tablet bi- layered machine by area FID.** • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is bi- layered tablet, while the applied drug is uncoated tablet.**	
3134.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Rostin Tablet 5mg
	Composition	Each film- coated tablet Contains: Rosuvastatin as calcium salt ……..5mg
	Diary No. Date of R& I & fee	Dy.No 40892 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rovista 5mg Tablets Getz Pharma, Karachi 044043
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3135.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Rostin Tablet 10mg
	Composition	Each film- coated tablet Contains: Rosuvastatin as calcium salt ……10mg
	Diary No. Date of R& I & fee	Dy.No.40894 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Rovista 10mg Tablets Getz Pharma, Karachi 044044
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3136.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Rostin Tablet 20mg
	Composition	Each film- coated tablet Contains: Rosuvastatin as calcium salt ……20mg
	Diary No. Date of R& I & fee	Dy.No.40893 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Rovista 20mg Tablets Getz Pharma, Karachi 044045
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	

3137.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Roxa Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…10mg
	Diary No. Date of R& I & fee	Dy.No 41315 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Rivar 10mg Tablet Hilton Pharma Kar. 081476
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3138.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Roxa Tablet 15mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…15mg
	Diary No. Date of R& I & fee	Dy.No 41314 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Rivaro Tablet 15mg Highnoon Laboratories Ltd, Multan Road, 085872
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3139.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Roxa Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…20mg
	Diary No. Date of R& I & fee	Dy.No 41313 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rivaro Tablet 20mg Highnoon Laboratories Ltd, Multan Road, 085873
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [xiii]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3140.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Trimax 10/160/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate…10mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee	Dy.No.41036 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Exforge- HCT 10/160/25mg film- coated tablets of M/s Novartis Pharma (Reg. # 069551)
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [xiii]	ON FORM- 5 APPLIED COMPOSITION IS IN THE STRENGTH OF 20/ 160/ 25 while on fee-challan and master formulation the applied strength is 10/160/25mg Diary number is same as that of 5/160/12.5 strength. The official monograph for the applied formulation is available in USP.
	Decision: Deferred for the justification that on Form- 5, applied composition is in the strength of 20/ 160/ 25 while on fee-challan and master formulation the applied strength is 10/160/25mg.	
3141.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Trimax 10/160/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate…10mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 41034 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved

	Me-too status	Exforge- HCT 10/160/12.5mg film- coated tablets of M/s Novartis Pharma (Reg. # 069550)
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3142.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Trimax 5/160/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amodipine as besilate…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy.No 41036 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Exforge-HCT 5/160/12.5mg film- coated tablets of M/s Novartis Pharma(Reg. # 069548)
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	Diary Number Is Same As That Of 10/160/25 Strength. On Form- 5 Applied Composition Is In The Strength Of 20/ 160/ 12.5 While On Fee-Challan And Master Formulation The Applied Strength Is 5/160/12.5mg. The Official Monograph For The Applied Formulation Is Available In Usp.
	Decision: Deferred for the justification that on Form- 5, applied composition is in the strength of 20/ 160/ 12.5 while on fee-challan and master formulation the applied strength is 5/160/12.5mg.	
3143.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Trimax 5/160/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate…5mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee	Dy.No 41033 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Exforge- HCT 5/160/25mg film- coated tablets of M/s Novartis Pharma (Reg. # 069549)
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP. ON FORM- 5 APPLIED COMPOSITION IS IN THE STRENGTH OF 20/ 160/ 25 while on fee-challan and master formulation the applied strength is 5/160/25mg

	Decision: Deferred for the justification that on Form- 5, applied composition is in the strength of 20/ 160/ 25 while on fee-challan and master formulation the applied strength is 5/160/25mg.	
3144.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited.Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Trimax 10/320/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besilate…10mg Valsartan…320mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee	Dy.No 41032 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Angiotensin- II Receptor Blocker and Diuretic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	EXFORGE HCT 10/320/25MG NOVARTIS PHARMA 069552
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP. ON FORM- 5 APPLIED COMPOSITION IS IN THE STRENGTH OF 20/ 320/ 25 while on fee-challan and master formulation the applied strength is 10/320/25mg.
	Decision: Deferred for the justification that on Form- 5, applied composition is in the strength of 20/ 320/ 25 while on fee-challan and master formulation the applied strength is 10/320/25mg.	
3145.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Gaftam 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Famotidine…20mg
	Diary No. Date of R& I & fee	Dy.No 44476 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	H_2 - Receptor Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Famotric 20mg tablet of M/s Klifton Pharma, Jamshoro (Reg. # 058312)
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3146.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Gaftam 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Famotidine…40mg
	Diary No. Date of R& I & fee	Dy.No 44475 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018

	Pharmacological Group	H_2 - Receptor Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Famotric 40mg tablet of M/s Klifton Pharma, Jamshoro (Reg. # 058313)
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3147.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Sofic N 50mg Tablet
	Composition	Each enteric- coated Tablet Contains: Diclofenac Sodium…50mg
	Diary No. Date of R& I & fee	Dy.No.44474 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Vorenac 50mg Tablet Mission, Karachi 080324
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3148.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Sofic N 75mg Tablet
	Composition	Each enteric- coated Tablet Contains: Diclofenac Sodium……...……75mg
	Diary No. Date of R& I & fee	Dy.No 44473 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Fedgesic Tablets 75mg of M/s Fedro Pharmaceutical, 079263
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3149.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Sofic N 10mg Tablet
	Composition	Each enteric- coated Tablet Contains:

		Diclofenac Sodium……100mg
	Diary No. Date of R& I & fee	Dy.No 44472 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dicast S.R Tablets Winbrain Research Laboratories, 078502
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3150.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Escold K 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…50mg
	Diary No. Date of R& I & fee	Dy.No 44478 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Caflam Tablet of M/s Novartis Pharma (Reg.# 021528)
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3151.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Escold K 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…75mg
	Diary No. Date of R& I & fee	Dy.No 44479 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nexfen Tablets 75 mg Libra Pharma 074597
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	Reference In master formulation diclofenac sodium is written.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**	

	• **Revision of formulation as per reference product along with submission of requisite fee.**	
3152.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Escold K 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac potassium…100mg
	Diary No. Date of R& I & fee	Dy.No 44480 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Declam Tablets 100mg Novamed Pharma 064842
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [xiii]	reference in master formulation Diclofenac potassium…50mg is written.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Revision of strength as per reference product along with submission of requisite fee.**	
3153.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi.
	Brand Name +Dosage Form + Strength	Gaftam Suspension 10mg/5ml
	Composition	Each 5ml contains: Famotidine…10mg
	Diary No. Date of R& I & fee	Dy.No 44477 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	H_2 - Receptor Antagonist
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	60ml, 90ml,120ml & as per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Atodine 10mg/5ml Suspension Macquins International 058116
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [xiii]	The applied formulation is non- pharmacopoeial. reference is as dry suspension and in the strength of 40mg/ 5ml.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
3154.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Agrifen Suspension 100mg/5ml
	Composition	Each 5ml contains: Ibuprofen……100mg
	Diary No. Date of R& I & fee	Dy.No.43944 dated 26-12-2018 Rs.20,000/- Dated 26-12-

		2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	60ml, 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ibuprofen 100mg/5ml Oral Suspension of (MHRA Approved)
	Me-too status	Nuprin 100mg Suspension M/s Reign Pharma 076477
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovator's specifications.	
3155.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Zinsol Syrup 20mg/5ml
	Composition	Each 5ml contains: Zinc Gluconate eq to elemental zinc…….20mg
	Diary No. Date of R& I & fee	Dy.No.43945 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	Mineral supplement
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml, 100ml & as per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Zincosyp Syrup Hiranis Karachi 076503
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3156.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Esmol Suspension 120mg/5ml
	Composition	Each 5ml contains: Paracetamol…120mg
	Diary No. Date of R& I & fee	Dy.No 43949 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	analgesic/ Anti- pyretic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	60ml, 90ml, 120ml & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Calpol Susp Wellcome Karachi 000354
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3157.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals, PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Esmol DS Suspension 250mg/5ml
	Composition	Each 5ml contains: Paracetamol…250mg
	Diary No. Date of R& I & fee	Dy.No 43949 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018
	Pharmacological Group	analgesic/ Anti- pyretic

	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	60ml, 90ml, 120ml & as per SRO
	Approval status of product in Reference Regulatory Authorities	Paracetamol 250mg/5ml oral suspension (MHRA approved)
	Me-too status	CALPOL 6 PLUS SUSP WELLCOME KARACHI 012427
	GMP status	28-09-2017 and good
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3158.	Name and address of manufacturer / Applicant	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Trapeze Plus XR Tablets 100mg/1000mg
	Composition	Each extended release tablet contains: Sitagliptin as phosphate monohydrate……100mg Metformin HCl……..1000mg
	Diary No. Date of R& I & fee	Dy.No 42026 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	7's, 2x 7's, 1x 10's & 10x 6's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 100/1000 Tablet Highnoon Laboratories Limited, 17.5 km Multan Road, Lahore 084651
	GMP status	17-10-2018 the panel unanimously recommends for grant of GMP certificate.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial. Stability data is required for this applied molecule.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3159.	Name and address of manufacturer / Applicant	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Nadal Tablets 80mg
	Composition	Each Tablet Contains: Nadolol…80mg
	Diary No. Date of R& I & fee	Dy.No 42027 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10 5x 10 10x 10 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Norgar Tablets 80mg Pulse Pharmaceutical, Mozay Badoke, Raiwind Road Lahore. 052730
	GMP status	17-10-2018 the panel unanimously recommends for grant of GMP certificate.
	Remarks of the Evaluator [XIII]	Attached fee- challan is of onscot 2.5mg tablet (Metolazone).
	Decision: Deferred for clarification that attached fee- challan is of Onscot 2.5mg tablet (Metolazone).	
3160.	Name and address of manufacturer / Applicant	M/s Liven Pharmaceuticals Pvt Ltd, 49 km, Lahore Multan Road.

	Brand Name +Dosage Form + Strength	Zoline 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…….600mg
	Diary No. Date of R& I & fee	Dy.No 40966 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	12's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Linzol Tablet 600mg Regal Pharmaceuticals, National industrial zone Rawat.Islamabad 081957
	GMP status	GMP certificate was issued on 31-07-2019 on evaluation conducted on 03-07-2019.
	Remarks of the Evaluator [XIII]	Registration Board; in its 291st DRB meeting, decided to approve applied drug product as per Innovator's specifications & with a condition that manufacturer shall use Linezolid polymorphic form II to keep applied formulation in- line with innovator Product.
	Decision: Approved with innovators' specifications.	
3161.	Name and address of manufacturer / Applicant	M/s Liven Pharmaceuticals Pvt Ltd, 49 km, Lahore Multan Road.
	Brand Name +Dosage Form + Strength	Thiodur 4mg Capsule
	Composition	Each Capsule Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy.No 40965 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Skeletal muscle relaxant
	Type of Form	Form- 5
	Finished product Specification	manufacturers
	Pack size & Demanded Price	10's, 20's & as per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM Approved
	Me-too status	Ezoside capsule 4mg of M/s Akhai Pharma (Reg. # 070427)
	GMP status	GMP certificate was issued on 31-07-2019 on evaluation conducted on 03-07-2019.
	Remarks of the Evaluator [XIII]	No USP or BP monograph is available for applied formulation.
	Decision: Approved with innovators' specifications.	
3162.	Name and address of manufacturer / Applicant	M/s Liven Pharmaceuticals Pvt Ltd, 49 km, Lahore Multan Road.
	Brand Name +Dosage Form + Strength	Tromanil 100mg/2ml Injection IV/ IM
	Composition	Each ml contains: Tramadol HCl……..50mg
	Diary No. Date of R& I & fee	Dy.No.40967 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in	MHRA Approved

	Reference Regulatory Authorities	
	Me-too status	Symol Injection of M/s Indus Pharma Karachi 081556
	GMP status	GMP certificate was issued on 31-07-2019 on evaluation conducted on 03-07-2019.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
3163.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore.
	Brand Name +Dosage Form + Strength	Doxilin Tablets 400mg
	Composition	Each Film Coated Tablet Contains: Doxofylline…400mg
	Diary No. Date of R& I & fee	Dy.No.40262 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	innovators' specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Italian Medicine Agency (AIFA) Italy approved as uncoated tablet
	Me-too status	Profylline tablet 400mg of M/s Kaizen (Reg. # 073744)
	GMP status	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial. Uncoated is approved while film- coated is applied.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.	
3164.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	Tramason SR 100mg Tablets
	Composition	Each SR Tablet Contains: Tramadol HCl…...100mg
	Diary No. Date of R& I & fee	Dy.No 40261 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Tramed-SR Tablets Platinum Pharma 024458
	GMP status	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations.
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3165.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	Dymiso Tablets 200mcg
	Composition	Each Tablet Contains:

		Misoprostol……200mcg
	Diary No. Date of R& I & fee	Dy.No.40260 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
	Pharmacological Group	Prostaglandin
	Type of Form	Form- 5
	Finished product Specification	innovators' specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Prosotec 200mcg Tablet Atco Laboratories Limited Karachi 058356
	GMP status	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations.
	Remarks of the Evaluator [XIII]	• Boxed warning in USFDA of birth defects and uterine rupture. • The applied formulation is available in International Pharmacopeia. • Mention the physical form of API. Moreover, also clarify whether it is 1:1 ratio dispersion of Misoprostol in HPMC or otherwise.
	Decision: Deferred for clarification of physical form of API whether it is 1:1 ratio dispersion of Misoprostol in HPMC or otherwise.	
3166.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	Aeva 12.5mg Tablets SR
	Composition	Each SR Tablet contains: Paroxetine as HCl……12.5mg
	Diary No. Date of R& I & fee	Dy.No 39867 dated 04-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Anti- depressant (SSRI)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Paroxin CR Tablets Shrooq Pharma 060471
	GMP status	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations.
	Remarks of the Evaluator [XIII]	
	Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee.	
3167.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	Aeva 25mg Tablets SR
	Composition	Each SR Tablet contains: Paroxetine as HCl…….25mg
	Diary No. Date of R& I & fee	Dy.No 39866 dated 04-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Anti- depressant (SSRI)
	Type of Form	Form- 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Paroxin CR Tablets Shrooq Pharma 060470
	GMP status	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations.
	Remarks of the Evaluator [XIII]	
	Decision: Decision: Deferred for revision of formulation as per the reference product along with submission of requisite fee.	
3168.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	Dyfine Tablets 125mg
	Composition	Each Tablet Contains: Terbinafine as HCl……..125mg
	Diary No. Date of R& I & fee	Dy.No 41778 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Terbisan Tablets Elko Organisation (Pvt) Ltd, Karachi. 027075
	GMP status	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3169.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	Dyfine Tablets 250mg
	Composition	Each Tablet Contains: Terbinafine as HCl……250mg
	Diary No. Date of R& I & fee	Dy.No 41777 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Lamisil Sandoz 250mg Tab Sandoz Karachi 013209
	GMP status	11-01-2019 satisfactory level of GMP compliance, hence panel recommended issuance of GMP certificate to the firm. Some advises were also given in the report to the firm for further up gradations.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.

	Decision: Approved with USP specifications.	
3170.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Zipro Syrup 30mg/5ml
	Composition	Each 5ml contains: Levodropropizine…30mg
	Diary No. Date of R& I & fee	Dy.No.43403 dated 20-12-2018 Rs.20,000/- Dated 20-12-2018
	Pharmacological Group	Anti- tussive
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml, 120ml & as per SRO
	Approval status of product in Reference Regulatory Authorities	AIFA; Italy Approved
	Me-too status	Rapitus Syrup of M/s Nexus Pharma Karachi 075975
	GMP status	24-10-2018 panel unanimously decided to recommend the issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovator's specifications.	
3171.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Paranext C 500/65mg Tablet
	Composition	Each Film Coated Tablet Contains: Paracetamol…500mg Caffeine…65mg
	Diary No. Date of R& I & fee	Dy.No.1037 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Analgesic/ cns Stimulan
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	20's, 100, 200 & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Cafimol Extra Tablets. Zinta Pharmaceutical Industry, 168-Industrial Estate, Hyatabad, Peshawar 038898
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	Applied master formulation and manufacturing outline is not submitted by the firm.
	Decision: Deferred for the submission of master formulation and manufacturing outline of the drug.	
3172.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited, Plot No. 44 A-B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Septronext 400/80mg Tablet
	Composition	Each Tablet Contains: Trimethoprim……..……..400mg Sulfamethoxazole…….……..….80mg
	Diary No. Date of R& I & fee	Dy.No.41353 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- infective
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	10 20 30 & as per SRO

	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Septrozole tablets of M/s Epoch Pharmaceuticals, Korangi Industrial Area, Karachi 020575
	GMP status	22-02-2018 satisfactory
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
3173.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Lespra Capsule 30mg
	Composition	Each delayed release capsule contains: Lansoprazole……...30mg
	Diary No. Date of R& I & fee	Dy.No 41230 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Drugs for peptic ulcer and GORD (PPIs)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5's, 7's, 10's, 20's, 30's, 40's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Lanzac 30mg Capsules Don Valley Pharmaceuticals Lahore 020293
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	All the data related to pellets is needed. General capsule section is available in the firm as mentioned in the submitted section approval letter. The official monograph for the applied formulation is available in USP.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
3174.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Qosmet XR 100/1000 mg Tablet
	Composition	Each Film Coated Sustained Release Tablet Contains: Sitagliptin as phosphate Monohydrate …100mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy.No.39924 dated 04-12-2018 Rs.20,000/- 04-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 40's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 100/1000 Tablet Highnoon Laboratories Limited, Multan Road, Lahore 084651
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	Stability data is required for the applied formulation. The applied formulation is non- pharmacopoeial. General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	

3175.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Qosmet XR 50/500 mg Tablet
	Composition	Each Film Coated Sustained Release Tablet Contains: Sitagliptin as phosphate Monohydrate …50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 39922 dated 04-12-2018 Rs.20,000/- 04-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 40's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 50/500 Tablet Highnoon Laboratories Limited, Multan Road, Lahore 084649
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	Stability data is required for the applied formulation. The applied formulation is non- pharmacopoeial. General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3176.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Qosmet XR 50/1000 mg Tablet
	Composition	Each Film Coated Sustained Release Tablet Contains: Sitagliptin…50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No 39923 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 40's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 50/1000 Tablet Highnoon Laboratories Limited, Multan Road, Lahore 084650
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	Stability data is required for the applied formulation. The applied formulation is non- pharmacopoeial. General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3177.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories Pvt. Ltd, 124/1, Quaid -e-Azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Dapawil- M XR Tablet 5/500mg
	Composition	Each extended release film coated tablet contains: Dapagliflozin…5mg

		Metformin HCL…500MG
	Diary No. Date of R& I & fee	Dy.No 41225 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5's, 7's, 10's, 20's, 30's, 40's, 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 06-11-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	Me- too status could not be confirmed. Stability data is required for the applied formulation. The applied formulation is non- pharmacopoeial. General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.	
3178.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Curoxaban 10mg Tablet
	Composition	Each film- coated Tablet Contains: Rivaroxaban…10mg
	Diary No. Date of R& I & fee	Dy.No 44482 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti- thrombotic agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rivar 10mg Tablet Hilton Pharma Kar. 081476
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial. gen tablet DML Applied master formulation is not submitted.
	Decision: Deferred for the submission of master formulation of the applied drug.	
3179.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cunomin-D 830mg/400IU Tablet
	Composition	Each film- coated Tablet Contains: Ossein mineral complex…830mg Vitamin D…400IU
	Diary No. Date of R& I & fee	Dy.No.44498 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	minerals and electrolytes(Multi nutrient for Arthritis) Vitamins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Could not be confirmed

	Reference Regulatory Authorities	
	Me-too status	Osam-D Tablet Getz Pharma Karachi 061106
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	Evidence of availability of atomic absorption spectrophotometer reference gen tablet DML
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of availability of atomic absorption spectrophotometer.**	
3180.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Aprelief 40mg Capsule
	Composition	Each capsule contains: Aprepitant……..40mg
	Diary No. Date of R& I & fee	Dy.No.44494 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti- emetic/ Anti- nauseants
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Apreon 40mg Capsules Ferozesons Labs, Ferozesons Amangarh Nowshera 068201
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3181.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan.
	Brand Name +Dosage Form + Strength	Aprelief 80mg Capsule
	Composition	Each capsule contains: Aprepitant……..80mg
	Diary No. Date of R& I & fee	Dy.No.44490 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti- emetic/ Anti- nauseants
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Apreon 80mg Capsules Ferozesons Labs, Ferozesons Amangarh Nowshera 068202
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3182.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan

	Brand Name +Dosage Form + Strength	Aprelief 125mg Capsule
	Composition	Each capsule contains: Aprepitant……..125mg
	Diary No. Date of R& I & fee	Dy.No.44493 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti- emetic/ Anti- nauseants
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Apreon 125mg Capsules Ferozesons Labs, Ferozesons Amangarh Nowshera 068203
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3183.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Aprelief 80/125mg Capsule Combo Pack
	Composition	i. Each Capsule Contains: Aprepitant…….80mg (2 cap) ii. Each Capsule Contains: Aprepitant ……..……125mg (1 cap)
	Diary No. Date of R& I & fee	Dy.No 44489 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti- emetic/ Anti- nauseants
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Apreon Combo Pack Capsules Ferozesons Labs, Ferozesons Amangarh Nowshera. 068204
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP. section facility for combo pack
	Decision: Deferred for the manufacturing facility of combo pack within the firm by Area FID.	
3184.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore,
	Brand Name +Dosage Form + Strength	Megabalin 300mg Capsule
	Composition	Each Capsule Contains: Pregabalin……300mg
	Diary No. Date of R& I & fee	Dy.No.44491 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Prelin Capsule 300mg Martin Dow Pharmaceuticals

		Lahore 050838
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The applied formualiton is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3185.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt. Ltd, Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ursojen Capsules 250mg
	Composition	Each Capsule Contains: Ursodeoxycholic acid……...250mg
	Diary No. Date of R& I & fee	Dy.No.44500 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Drugs for bile and liver therapy
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Ursode Capsule Shrooq Pharmaceuticals (Pvt) Ltd, 21-Km Ferozpur road, Lahore 064562
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications.	
3186.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt. Ltd, Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Ursojen Capsules 500mg
	Composition	Each Capsule Contains: Ursodeoxycholic acid……...500mg
	Diary No. Date of R& I & fee	Dy.No.44499 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Drugs for bile and liver therapy
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Ursode Capsule Shrooq Pharmaceuticals (Pvt.) Ltd, 21-Km Ferozpur road, Lah ore 064563
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications.	
3187.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt. Ltd, Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Biselect 5mg Tablet
	Composition	Each film- coated Tablet Contains: Bisoprolol Fumarate……..5mg
	Diary No. Date of R& I & fee	Dy.No.44486 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Bisfat Tablets 5mg Dyson Research Laboratories (Pvt.) Ltd, 28-KM, Ferozepur Road, Lahore. 077052
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3188.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt. Ltd, Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Biselect 10mg Tablet
	Composition	Each film- coated Tablet Contains: Bisoprolol Fumarate……..10mg
	Diary No. Date of R& I & fee	Dy.No.44481 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Bisfat Tablets 10mg Dyson Research Laboratories (Pvt.) Ltd, 28-KM, Ferozepur Road, Lahore. 077051
	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3189.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Remaco Tablet
	Composition	Each Film Coated Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy.No 43668 dated 21-12-2018 Rs.20,000/- Dated 21-12-2018
	Pharmacological Group	Vitamin B-12 (Anti- Anaemic)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in PMDA Japan as sugar- coated tablet
	Me-too status	Heam 500 mcg Tablet of M/s Linear Pharma (Reg. # 081876)
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	• Approved in PMDA Japan as sugar- coated tablet. • Japanese Pharmacopoeia
	Decision: Approved with JP specifications.	
3190.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Calcim 667mg Tablets

	Composition	Each Tablet Contains: Calcium acetate……..667mg
	Diary No. Date of R& I & fee	Dy.No 41305 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Drugs for Hyperkalemia
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	LoPhos Tablet English Pharma, Industries Link Katarband Road, ThokarNiaz Beg, Lahore 084829
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3191.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Nizadin Tablet 2mg
	Composition	Each film- coated Tablet Contains: Tizanidine HCl...……..…2mg
	Diary No. Date of R& I & fee	Dy.No 41303 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as uncoated tablet
	Me-too status	Tizadin 2mg Tablets Global Pharmaceuticals, Plot No 204-205, Kahuta Triangle, Industrial Area, Islamabad. 028366
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP. As HCl is not applied.
	Decision: Deferred for the following: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.** • **Revision of applied composition as in reference regulatory authorities the approved drug is "Tizanidine as HCl", while the applied drug is "Tizanidine HCl".**	
3192.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Nizadin Tablet 4mg
	Composition	Each film- coated tablet contains: Tizanidine HCl.……..…4mg
	Diary No. Date of R& I & fee	Dy.No.41304 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as uncoated tablet
	Me-too status	Tizax 4mg Tablet of M/s Searle, Karachi 076022
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Deferred for the following: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.** • **Revision of applied composition as in reference regulatory authorities the approved drug is "Tizanidine as HCl", while the applied drug is "Tizanidine HCl".**	
3193.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Triflo Tablet 80mg/ 80mg
	Composition	Each Film Coated Tablet Contains: Phloroglucinol Corresponding to anhydrous Phloroglucinol 62.233mg…80mg Trimethylphloroglucinol…80mg
	Diary No. Date of R& I & fee	Dy.No 43667 dated 21-12-2018 Rs.20,000/- Dated 21-12-2018
	Pharmacological Group	Antispasmodic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved as sugar- coated tablet
	Me-too status	Anafortan Plus Tablets Ali Gohar Pharmaceuticals (Pvt) Karachi 024504
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	ANSM; France Approved as sugar- coated tablet
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is sugar- coated tablet, while the applied drug is film- coated tablet.	
3194.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Paindraw Plus Tablet
	Composition	Each film- coated Tablet Contains: Tramadol HCl…37.50mg Paracetamol…325mg
	Diary No. Date of R& I & fee	Dy.No 40887 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Analgesic and Anti-Inflammatory Agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved

	Me-too status	Distalgesic Tablets by Atco laboratories, Karachi (R. No. 073865)
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The official monograph is available in USP.
	Decision: Approved with USP specifications.	
3195.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Alofin Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Dy.No 41306 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	NSAID
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Acfonac 100mg Tablets by M/s Medicraft Pharmaceuticals (Pvt) Ltd., (Reg.#081743)
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3196.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Mexet 20mg Tablet
	Composition	Each film- coated Tablet Contains: Paroxetine as HCl…20mg
	Diary No. Date of R& I & fee	Dy.No 40886 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	SSRIs (Anti- depressant)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Seroxat Tablets S.K&F Karachi 019501
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovator's specifications.	
3197.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Berox Tablet 20mg
	Composition	Each film- coated Tablet Contains:

		Piroxicam as beta cyclodextrine…20mg
	Diary No. Date of R& I & fee	Dy.No 41302 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved as uncoated tablet
	Me-too status	Piroxibet 20mg Tablets Lawari International, Saidu Sharif Swat 054939
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film- coated tablet.	
3198.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Lornix Tablet 8mg
	Composition	Each film- coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy.No 40891 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8mg tablet (Swiss Medic approved)
	Me-too status	Lornox 8mg tablet Ray Pharma Karachi 061083
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3199.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Butarin tablet 40mg
	Composition	Each uncoated Tablet Contains: Drotaverine…40mg
	Diary No. Date of R& I & fee	Dy.No 41321 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Drugs for functional GIT disorders
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by 3 EMA member states i.e. Poland, Hungary, Latvia
	Me-too status	Draza 40mg Tablet Opal Lab. Karachi 073709
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel,

		documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3200.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Biprofen 100mg Tablet
	Composition	Each film- coated Tablet Contains: Flurbiprofen……100mg
	Diary No. Date of R& I & fee	Dy.No 40888 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved
	Me-too status	ANSAID TAB of M/s KURRAM IBD 012299
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
3201.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Rostin-F Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. to Rosuvastatin….10mg Fenofibrate……145mg
	Diary No. Date of R& I & fee	Dy.No.43404 dated 20-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	reference me- too The applied formulation is non- pharmacopoeial.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	

3202.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cyclorin 15mg Capsule
	Composition	each capsule contains (extended- release pellets): Cyclobenzaprine HCl……15mg
	Diary No. Date of R& I & fee	Dy.No.43669 dated 21-12-2018 Rs.20,000/- Dated 21-12-2018
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Cyclorest- ER 15mg Capsule Martin Dow Karachi 080637
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	All the data related with pellets is needed. The official monograph for the applied formulation is available in USP.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
3203.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cyclorin 30mg Capsule
	Composition	each capsule contains (extended- release pellets): Cyclobenzaprine HCl……30mg
	Diary No. Date of R& I & fee	Dy.No.43670 dated 21-12-2018 Rs.20,000/- Dated 21-12-2018
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Cyclorest- ER 30mg Capsule Martin Dow Karachi 080638
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	All the data related with pellets is needed. The official monograph for the applied formulation is available in USP.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
3204.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Dexprofin Tablet 200mg
	Composition	Each film- coated tablet Contains: Dexibuprofen…200mg
	Diary No. Date of R& I & fee	Dy.No 40896 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti- inflammatory and anti- rheumatic
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AGES of Austria
	Me-too status	Tercica 200mg Tablet Sami Karachi 073697
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3205.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Dexprofin Tablet 300mg
	Composition	Each film- coated tablet Contains: Dexibuprofen…300mg
	Diary No. Date of R& I & fee	Dy.No 40895 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti- inflammatory and anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AGES of Austria
	Me-too status	Rodexib 300mg Tablet of M/s Platinum Karachi (Reg.#076397)
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	
3206.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Dexprofin Tablet 400mg
	Composition	Each film- coated tablet contains: Dexibuprofen……400mg
	Diary No. Date of R& I & fee	Dy.No 41312 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti- inflammatory and anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AGES of Austria
	Me-too status	Bekonil 400mg Tablet M/s Martin Dow Ltd. Karachi (Reg.#081040)
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved with innovator's specifications.	

3207.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Samco Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Dy.No 41307 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA as film- coated while applied tablet is uncoated
	Me-too status	Lacosbar 50mg Tablet Barrett Hodgson Kar 083224
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	Coating is not mentioned in the master formulation and manufacturing outline. Just under the heading of applied composition, in label claim film- coated is mentioned.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film-coated tablet, while the applied drug is uncoated tablet.	
3208.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Samco Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Dy.No 41308 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA as film- coated while applied tablet is uncoated
	Me-too status	Lacosbar 100mg Tablet Barrett Hodgson Kar 083223
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	Coating is not mentioned in the master formulation and manufacturing outline. Just under the heading of applied composition, in label claim film- coated is mentioned.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film-coated tablet, while the applied drug is uncoated tablet.	
3209.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Urobex Tablet 40mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…….40mg

	Diary No. Date of R& I & fee	Dy.No 41316 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	anti- gout preparations
	Type of Form	form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as coated while is applied as uncoated
	Me-too status	Febux Tablet 40mg CCL Pharma Lahore 068106
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	Coating is not mentioned in the master formulation and manufacturing outline. Just under the heading of applied composition, in label claim film- coated is mentioned.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film-coated tablet, while the applied drug is uncoated tablet.	
3210.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Urobex Tablet 80mg
	Composition	Each Film Coated Tablet Contains: Febuxostat……80mg
	Diary No. Date of R& I & fee	Dy.No 41317 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	anti- gout preparations
	Type of Form	form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as coated while is applied as uncoated
	Me-too status	Febux Tablet 40mg CCL Pharma Lahore 068106
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	Coating is not mentioned in the master formulation and manufacturing outline. Just under the heading of applied composition, in label claim film- coated is mentioned.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film-coated tablet, while the applied drug is uncoated tablet.	
3211.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Loxit Capsule 40mg
	Composition	Each Capsule Contains: Duloxetine HCl as enteric coated pellets eq. to Duloxetine……40mg
	Diary No. Date of R& I & fee	Dy.No.40889 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti- depressant
	Type of Form	form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Yentreve 40mg Capsule. Eli Lilly Pakistan (Pvt) Ltd., Karachi 045796
	GMP status	Last GMP inspection was conducted on 09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	All the data related to pellets is needed.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
3212.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Loxit Capsule 60mg
	Composition	Each Capsule Contains: Duloxetine HCl as enteric coated pellets eq. to Duloxetine…60mg
	Diary No. Date of R& I & fee	Dy.No.40890 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti- depressant
	Type of Form	form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Dulox 60mg Capsule Kaizen Pharma Kar 076231
	GMP status	Last GMP inspection was conducted on 09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	All the data related to pellets is needed.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
3213.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Lesart Tablet 20mg
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R& I & fee	Dy.No 40311 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II Receptor blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Telmas 20mg Tablets. Global Pharma 048333
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovator's specifications.	

3214.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Lesart Tablet 40mg
	Composition	Each Tablet Contains: Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy.No 40309 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II Receptor blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Telmas 40mg Tablets Global Pharma 048332
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovator's specifications.	
3215.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Lesart Tablet 80mg
	Composition	Each Tablet Contains: Telmisartan…80mg
	Diary No. Date of R& I & fee	Dy.No 40309 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Angiotensin II Receptor blocker
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Telmas 80mg Tablets Global Pharma 048331
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovator's specifications.	
3216.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Metfos Tablet 50/500mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Phosphate monohydrate…..……50mg Metformin HCl……...……500mg
	Diary No. Date of R& I & fee	Dy.No.41322 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as film- coated

	Me-too status	Sitaglu Met 50mg/ 500mg Tablet Hilton Pharma (Pvt.) Limited 13, Sector-15, Korangi Karachi 055161
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial. uncoated is applied while film- coated is approved master formulation and manufacturing outline reveals that the applied drug is uncoated
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film- coated tablet, while the applied drug is uncoated tablet.	
3217.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Metfos Tablet 50/ 1000mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phospate monohydrate……50mg Metformin HCl…….……...……..…1000mg
	Diary No. Date of R& I & fee	Dy.No.43671 dated 21-12-2018 Rs.20,000/- Dated 21-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as film coated while uncoated is applied
	Me-too status	Sitaglu Met 50mg/ 1000mg Tablet Hilton Pharma (Pvt.) Limited 13, Sector-15, Korangi Karachi 055162
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial. uncoated is applied while film- coated is approved master formulation and manufacturing outline reveals that the applied drug is uncoated.
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film- coated tablet, while the applied drug is uncoated tablet.	
3218.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Metfos Tablet 100/ 1000mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin as phospate monohydrate……100mg Metformin HCl……...……..…1000mg
	Diary No. Date of R& I & fee	Dy.No.43672 dated 21-12-2018 Rs.20,000/- Dated 21-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as extended release while is applied as uncoated tablet
	Me-too status	Could not be confirmed in the applied strength
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel,

		documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial. USFDA Approved as extended release while is applied as uncoated tablet Stability is required for this applied molecule.
	Decision: Deferred for the following: • **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is extended release tablet, while the applied drug is uncoated tablet.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Submission of stability study data as per the guidelines provided in 278th meeting of Registration Board along with submission of differential fees.**	
3219.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Glip Tablet 50/500mg
	Composition	Each uncoated Tablet Contains: Vildagliptin…50mg Metformin hcl…500mg
	Diary No. Date of R& I & fee	Dy.No 41318 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as film- coated
	Me-too status	Vildabar PLUS Tablet Barrett Hodgson Karachi. 085998
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	TGA; Australia Approved as film- coated
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film- coated tablet, while the applied drug is uncoated tablet.	
3220.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Glip Plus Tablet 50/850mg
	Composition	Each uncoated Tablet Contains: Vildagliptin…50mg Metformin hcl…850mg
	Diary No. Date of R& I & fee	Dy.No 41319 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as film- coated
	Me-too status	Vildabar PLUS Tablet Barrett Hodgson Karachi. 085997
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of

		inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	TGA; Australia Approved as film- coated
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film- coated tablet, while the applied drug is uncoated tablet.	
3221.	Name and address of manufacturer / Applicant	M/s Radiant Pharma Pvt Ltd, 43-E, Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	Glip Forte Tablet 50/1000mg
	Composition	Each uncoated Tablet Contains: Vildagliptin…50mg Metformin hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No 41320 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as film- coated
	Me-too status	Vildabar PLUS Tablet Barrett Hodgson Karachi. 085996
	GMP status	09-03-2018 Keeping in view the facilities like building, HVAC system, machinery and equipments, instruments, personnel, documentations, quality control, testing facilities, panel of inspectors is of the opinion to recommend the grant of dry powder injection sections to M/s Radiant Pharma Lahore.
	Remarks of the Evaluator [XIII]	TGA; Australia Approved as film- coated
	Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is film- coated tablet, while the applied drug is uncoated tablet.	
3222.	Name and address of manufacturer / Applicant	M/s Ipram International, Plot 26, S.S-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Iprolac 30mg/ml Injection I/V, I/M
	Composition	Each 1ml ampoule contains: Ketorolac Tromethamine……30mg
	Diary No. Date of R& I & fee	Dy.No 42020 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- inflammatory and anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Manufactures
	Pack size & Demanded Price	1mlx 5's & As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Ketolac Nimrall Laboratories Plot No.24, Street S.S.3, Industrial Zone Rawat 072387
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	Submitted fee- challan is of Ondansatron injection in TGA; Australia, it is approved as intra muscular The official monograph for the applied formulation is available in USP. General ampoule section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Deferred for clarification of submitted fee- challan as it is not of the applied drug.	
3223.	Name and address of manufacturer / Applicant	M/s Ipram International, Plot 26, S.S-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Cilitron 4mg/2ml Injection I/V, I/M

	Composition	Each 2ml Ampoule Contains: Ondansetron as Hcl dihydrate …4mg
	Diary No. Date of R& I & fee	Dy.No 42019 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- emetic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 5's ampoules & As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved I/V, I/M
	Me-too status	Ondanles Injection Neomedix Rawalpindi 020701
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	General ampoule section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
3224.	Name and address of manufacturer / Applicant	M/s Ipram International, Plot 26, S.S-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Cilitron 8mg/4ml Injection I/V, I/M
	Composition	Each 4ml Ampoule Contains: Ondansetron as HCl Dihydrate ……...……8mg
	Diary No. Date of R& I & fee	Dy.No.42018 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Anti- emetic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 5's ampoules & As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Ondanz 8mg Liquid Injection Wel Wink Pharmaceuticals, Gujranwala 077820
	GMP status	Last GMP inspection was conducted on 20-12-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	General ampoule section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved.	
3225.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals, Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Colistin Dry Powder sachet I million IU
	Composition	Each Vial Contains: lyophilized powder Colistimethate Sodium…1 Million IU
	Diary No. Date of R& I & fee	Dy.No 44470 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Colistat powder for Injection Medisure Lab, Karachi 076160
	GMP status	11-02-2019 the panel recommends the issuance of GMP certificate to Vision Pharma Islamabad as the firm is found at a good level of GMP as today.
	Remarks of the Evaluator [XIII]	Sachet is written under the heading of dosage form in form- 5 while each vial contains is written under the heading of applied composition. And under the heading of proposed route of administration injection is written.

		firm has lyophilized section Are they making powder by themselves or they will refill the powder imported from outside.
	Decision: Deferred for following: • **Clarification of applied dosage form as sachet (brand name) or injection.** • **If injection is applied then clarification is required regarding lyophilised powder that are they making powder by themselves or they will refill the powder imported from outside.**	
3226.	Name and address of manufacturer / Applicant	M/s Liven Pharmaceuticals Pvt Ltd, 49 km, Lahore Multan Road.
	Brand Name +Dosage Form + Strength	Thiodur 4mg/ 2ml Injection I/V, I/M
	Composition	Each ml contains: Thiocolchicoside ……..…….2mg
	Diary No. Date of R& I & fee	Dy.No.40964 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2ml x 6's & As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved
	Me-too status	Myovi 4mg/ 2ml Injection of M/s Macter International (Pvt.) Ltd, Karachi (Reg. # 058692)
	GMP status	GMP certificate was issued on 31-07-2019 on evaluation conducted on 03-07-2019.
	Remarks of the Evaluator [XIII]	
	Decision: Approved with innovators' specifications.	
3227.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A, Sundar Industrial Estate, Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Bravia 18mcg Rotacaps
	Composition	Each rotacap contains: Tiotropium as Bromide Monohydrate……..…22.5mcg Eq to Tiotropium……18mcg
	Diary No. Date of R& I & fee	Dy.No 39852 dated 04-12-2018 Rs.20,000/- Dated 27-11-2018
	Pharmacological Group	Dugs for obstructive airway disease
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Apollo Capsule Nexus Pharma, Sector 21, Korangi Industrial Area, Karachi 075831
	GMP status	Last GMP inspection was 29-03-2019 was operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• General capsule DML. • Non- pharmacopoeial. • Manufacturing facility for the rotacaps needs to be confirmed.
	Decision: Deferred for confirmation of required manufacturing facility / section of rotacaps from Licensing Division.	

a. Deferred cases

Following cases were deferred in 292 meeting for for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore. Now the cases are reproduced here for consideration of Board with reference to the report on assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore presented in the instant meeting.

3228.	Name and address of manufacturer/ Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name + Dosage Form + Strength	Longaceph 250mg I/V Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……..….. 250mg
	Diary No. Date of R & I & fee	Dy.No.26971; 06-08-2018; Rs.50,000 (06-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rocephin Roche I/V Inj of M/s Roche (Reg. # 008433)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-01-2019 and the report concludes good level of GMP compliance.
	Previous Remarks of the Evaluator	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Previous decision	Registration Board decided to defer in 292nd DRB meeting for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.
	Evaluation by PEC- Evaluator XIII	
	Decision: Approved.	
3229.	Name and address of manufacturer/ Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name + Dosage Form + Strength	Longaceph 500mg I/V Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……..….. 500mg
	Diary No. Date of R & I & fee	Dy.No.26969; 06-08-2018; Rs.50,000 (06-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rocephin Roche I/V Inj of M/s Roche (Reg. # 008435)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was

		issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-01-2019 and the report concludes good level of GMP compliance.
	Previous Remarks of the Evaluator	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Previous decision	Registration Board decided to defer in 292nd DRB meeting for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.
	Evaluation by PEC- Evaluator [xiii]	
	Decision: Approved.	
3230.	Name and address of manufacturer/ Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name + Dosage Form + Strength	Longaceph 250mg I/M Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……..….. 250mg
	Diary No. Date of R & I & fee	Dy.No.26971; 06-08-2018; Rs.50,000 (06-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Topcef 250mg Injection IV/IM of M/s Pride (R # 025876)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-01-2019 and the report concludes good level of GMP compliance.
	Previous Remarks of the Evaluator	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Previous decision	Registration Board decided to defer in 292nd DRB meeting for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.
	Evaluation by PEC- Evaluator [xiii]	
	Decision: Approved.	
3231.	Name and address of manufacturer/ Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name + Dosage Form + Strength	Longaceph 500mg I/M Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……..….. 500mg
	Diary No. Date of R & I & fee	Dy.No.26710; 03-08-2018; Rs.50,000 (03-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form- 5

	Finished product Specification	USP
	Pack size & Demanded Price	1 x 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Topcef 500mg Injection IV/IM of M/s Pride (R # 025877)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-01-2019 and the report concludes good level of GMP compliance.
	Previous Remarks of the Evaluator	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Previous decision	Registration Board decided to defer in 292nd DRB meeting for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.
	Evaluation by PEC- Evaluator XIII	
	Decision: Approved.	
3232.	Name and address of manufacturer/ Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name + Dosage Form + Strength	Longaceph 1g I/V Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……..….. …..1g
	Diary No. Date of R & I & fee	Dy.No.26711; 03-08-2018; Rs.50,000 (03-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Topcef 500mg Injection IV/IM of M/s Pride Pharma (Reg. # 025878)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-01-2019 and the report concludes good level of GMP compliance.
	Previous Remarks of the Evaluator	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Previous decision	Registration Board decided to defer in 292nd DRB meeting for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.
	Evaluation by PEC- Evaluator XIII	
	Decision: Approved.	

3233.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals Pvt. Ltd, 26-km, Lahore Sharaqpur Road, Sheikhupura. Contract Manufacturer M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan.
	Brand Name +Dosage Form + Strength	Mecomal 500mcg Injection I/V
	Composition	Each 1ml Ampoule contains: Mecobalamin……500mcg
	Diary No. Date of R& I & fee	Dy.No.37829 dated 15-11-2018 Rs.50,000/- Dated 15-11-2018
	Pharmacological Group	Vitamin B- 12
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1ml x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA; Japan Approved
	Me-too status	Cocobal Injection of M/s Consolidated Chemical Laboratories (Reg. # 020338)
	GMP status	M/s Jenner: Last GMP inspection was conducted on 06-11-17 and the report concludes that the GMP of the firm is satisfactory regarding building, equipment and functioning of HVAC system. However they were advised to improve their documentation regarding the production and quality control, they agreed. M/s Unison: Last GMP inspection was conducted on 06 -08- 2018 and GMP certificate was issued to the firm on the evaluation conducted on date mentioned above.
	Previous remarks of the Evaluator	• M/s Unison has liquid ampoule injection (General) section as mentioned in the submitted section approval letter. • No. of sections of applicant needs to be submitted. • No. of already registered drugs on contract needs to be submitted. • The name of applied drug is not mentioned on the original agreement. • Letter was issued to the firm on 12th December, 2019 but still no reply has been received by the firm yet.
	Previous decision	Deferred in 293rd DRB meeting for the following reasons:- • Number of sections of applicant needs to be submitted. • Number of already registered drugs on contract needs to be submitted.
	Evaluation by PEC- Evaluator [xiii]	• Firm has submitted the reply that they have 03 approved sections and 12 already registered products on contract basis. • Further, firm has submitted the original agreement between the two firms mentioning the name of applied drug i.e. Mecomal 500mcg injection.
	Decision: Approved with innovator's specifications.	
3234.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals Pvt. Ltd, 26-km, Lahore Sharaqpur Road, Sheikhupura. Contract Manufacturer M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan.

	Brand Name +Dosage Form + Strength	Jen- D Injection 5mg/ml I/M
	Composition	Each 1ml Ampoule contains: Cholecalciferol…….....5mg
	Diary No. Date of R& I & fee	Dy. No. 37830; 15-11-2018; Rs.50,000 (15-11-2018)
	Pharmacological Group	Vitamin- D
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	1 ampoule of 1ml, 5 ampoules of 1ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France approved
	Me-too status	Drol- D injection Regal Pharma (Reg. # 082005)
	GMP status	M/s Jenner: Last GMP inspection was conducted on 06-11-17 and the report concludes that the GMP of the firm is satisfactory regarding building, equipment and functioning of HVAC system. However they were advised to improve their documentation regarding the production and quality control, they agreed. M/s Unison: Last GMP inspection was conducted on 06 -08- 2018 and GMP certificate was issued to the firm on the evaluation conducted on date mentioned above.
	Previous remarks of the Evaluator	• M/s Unison has liquid ampoule injection (General) section as mentioned in the submitted section approval letter. • No. of sections of applicant needs to be submitted. • No. of already registered drugs on contract needs to be submitted. • The name of applied drug is not mentioned on the original agreement. • Letter was issued to the firm on 12th December, 2019 but still no reply has been received by the firm yet.
	Previous decision	Deferred in 293rd DRB meeting for the following reasons:- • Number of sections of applicant needs to be submitted. • Number of already registered drugs on contract needs to be submitted.
	Evaluation by PEC- Evaluator XIII	• Firm has submitted the reply that they have 03 approved sections and 12 already registered products on contract basis. • Further, firm has submitted the original agreement between the two firms mentioning the name of applied drug i.e. Jen- D Injection 5mg/ml I/M.
	Decision: Approved.	
3235.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Colside tablet 4mg
	Composition	Each film- coated tablet contains: Thiocolchicoside ……..……..4mg
	Diary No. Date of R& I & fee	Dy.No.473; 04-01-2018;Rs.20,000/-(04-01-2018)
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	In- house
	Pack size & Demanded Price	As per SRO & as per SRO
	Approval status of product in Reference	Approved in ANSM (France) as uncoated tablet

	Regulatory Authorities	
	Me-too status	Wodnik 4mg tablet of M/s Martin Dow (Reg. # 081138)
	GMP status	Last GMP inspection was conducted on 30-09-2018 & 29-10-2018 and the report concludes that firm is GMP compliant with need of some improvements and the panel recommends grant of GMP certificate.
	Previous remarks of the Evaluator	• Firm has General Tablet section as mentioned in the submitted GMP report. • Approved in ANSM (France) as uncoated tablet while is applied as film-coated.
	Previous decision	Deferred in 288th DRB meeting for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film coated tablet.
	Evaluation by PEC- Evaluator XIII	Firm has revised the applied formulation as per reference i.e. uncoated tablet with submission of requisite fees i.e. Rs. 5000/-.
	Decision: Approved with innovator's specifications.	
3236.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd, Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Benzarel capsule 15mg
	Composition	Each SR capsule contains: Cyclobenzaprine HCl as Sustained Release Pellets…..15mg
	Diary No. Date of R& I & fee	Dy.No.35907; 30-10-2018; Rs.20,000 (29-10-2018)
	Pharmacological Group	Skeletal Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Emrix- SR 15mg capsule of M/s Getz Pharma (Pvt.) Ltd (Reg. # 070450)
	GMP status	Last GMP inspection was conducted on 04-10-2017 and the report concludes grant of DML.
	Previous remarks of the Evaluator	• General capsule section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP. • All the data related to the pellets is needed i.e. source of pellets, CoA of manufacturer of pellets, stability data of pellets and GMP certificate of manufacturer of pellets is needed. • Letter was issued to the firm on 18th Nov, 2019 but still no reply has been received yet.
	Previous decision	Deferred in 293rd DRB meeting for source of pellets, along with stability studies data, GMP certificate of supplier, CoA of manufacturer of pellets and differential fee in case of import of pellets.
	Evaluation by PEC- Evaluator XIII	• Firm has submitted source of pellets as M/s Vision Pharma, Islamabad. GMP certificate of the manufacture, CoA of pellets and stability data of pellets is also submitted.
	Decision: Approved with USP specifications.	

3237.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd, Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Benzarel capsule 30mg
	Composition	Each SR capsule contains: Cyclobenzaprine HCl as Sustained Release Pellets……...……...30mg
	Diary No. Date of R& I & fee	Dy.No.35908; 30-10-2018; Rs.20,000 (29-10-2018)
	Pharmacological Group	Skeletal Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Emrix- SR 30mg capsule of M/s Getz Pharma (Pvt.) Ltd (Reg. # 070451)
	GMP status	Last GMP inspection was conducted on 04-10-2017 and the report concludes grant of DML.
	Previous remarks of the Evaluator	• General capsule section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in USP. • All the data related to the pellets is needed i.e. source of pellets, CoA of manufacturer of pellets, stability data of pellets and GMP certificate of manufacturer of pellets is needed. • Letter was issued to the firm on 18th Nov, 2019 but still no reply has been received yet.
	Previous decision	Deferred in 293rd DRB meeting for source of pellets, along with stability studies data, GMP certificate of supplier, CoA of manufacturer of pellets and differential fee in case of import of pellets.
	Evaluation by PEC- Evaluator [xiii]	• Firm has submitted source of pellets as M/s Vision Pharma, Islamabad. GMP certificate of the manufacture, CoA of pellets and stability data of pellets is also submitted.
	Decision: Approved with USP specifications.	
3238.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Katif 1mg/ 5ml Liquid Syrup
	Composition	Each 5ml contains: Ketotifen (as hydrogen fumarate) ……..… 1mg
	Diary No. Date of R& I & fee	Dy.No.41105;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Zaditen 1mg/5ml oral solution by M/s Sigma Tau, ANSM approved
	Me-too status	Tifien Syrup of M/s Hicon Pharma (Reg. # 041474)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Previous remarks of the Evaluator	• No USP or BP monograph is available for the applied formulation.
	Previous decision	Deferred in 289 DRB meeting for evidence of approval of applied formulation in reference agencies as applied

		formulation is Ketotifen (as hydrogen fumarate) 1mg/5ml syrup, which is different from quoted reference i.e. ketotifen (as fumarate) 1mg/5ml syrup.
	Evaluation by PEC- Evaluator XIII	• Firm has submitted reference of an already registered drug named Kestox 1mg tablet in 286th DRB meeting while the applied formulation is a liquid syrup.
	Previous decision of 291st DRB meeting: Deferred in 291st DRB meeting for revision of formulation as per reference product along with submission of fee for revision of formulation. Second evaluation by PEC-XIII: Firm has not revised the formulation according to the reference and not submitted the requisite fees.	
	Decision: Deferred for revision of formulation as per reference product along with submission of fee for revision of formulation.	
3239.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028, H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Calcidol 0.5mcg tablet
	Composition	Each uncoated tablet contains: Alfacalcidol……0.5mcg
	Diary No. Date of R& I & fee	Dy.No.20315; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Vitamin- D Analogue
	Type of Form	Form- 5
	Finished product Specification	Innovator's
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Alfacal tablet 0.5mcg of M/s Platinum Pharma (Reg. # 026683)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good GMP compliance.
	Previous remarks of the Evaluator	• The applied formulation is non- pharmacopoeial. • General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • International availability could not be confirmed.
	Previous decision	Deferred in 291st DRB meeting for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were declared/approved by the Registration Board in its 275th meeting.
	Evaluation by PEC- Evaluator XIII	• The applied formulation is found approved in PMDA Japan.
	Decision: Approved.	
3240.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Lornox Tablet 8mg
	Composition	Each film- coated contains: Lornoxicam……..8mg
	Diary No. Date of R& I & fee	Dy.No.27065; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- inflammatory and Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Film tabletten by M/s Takeda Pharma AG,(Swiss Medic Approved)
	Me-too status	Lornox 8mg tablet of M/s Ray Pharma (Reg. # 061083)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the

		report concludes good level of GMP compliance.
	Previous remarks of the Evaluator	• No USP or BP monograph is available for the applied formulation. • Applied brand name may be changed as it resembles with an already approved brand name of another firm. • General tablet section is available in the firm as mentioned in the submitted DML. • Initially, 4mg was written throughout the dossier instead of 8mg while fee challan is of 8mg. • Now, the firm has revised all the documents as 8mg tablet.
	Previous decision	Deferred in 292nd DRB meeting for submission of fees for revision of strength of applied formulation.
	Evaluation by PEC- Evaluator XIII	Firm has revised Form- 5 and applied master formulation as 8mg and has submitted the fees for revision of strength of applied formulation i.e. Rs. 20,000/- under deposit slip no. 0816347 dated: 15-04-2020. Applied brand name may be changed as it resembles with an already approved brand name of another firm.
	Decision: Approved with innovators' specifications and change of brand name.	

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

a. **New Cases**

3241.	Name and address of manufacturer/ Applicant	M/s Elko Organization Pvt Ltd, Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Zolcarb Injection 85mg/ ml
	Composition	Each ml contains: Imidocarb as Dipropionate …….……85mg
	Diary No. Date of R & I & fee	Dy.No 1878 dated 15-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	Anti- protozoal agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10ml & Decontrolled
	Me-too status	Zolcarb Injection of M/s Elko 100ml (090648)
	GMP status	Last GMP inspection was conducted on 06-07-2017 and the report concludes good level of GMP compliance with advice of some improvements of some minor observations.
	Remarks of the Evaluator	Firm has General vial/ ampoule liquid vet section as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovators' specifications.	
3242.	Name and address of manufacturer/ Applicant	M/s Elko Organization Pvt Ltd, Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	X20 Injection 20IU/ml
	Composition	Each ml contains: Oxytocin ……..…20IU
	Diary No. Date of R & I & fee	Dy.No 1876 dated 15-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	Peptide hormone
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250ml & Decontrolled
	Me-too status	X20 Injection 100ml of M/s Elko 085466
	GMP status	Last GMP inspection was conducted on 06-07-2017 and

		the report concludes good level of GMP compliance with advice of some improvements of some minor observations.
	Remarks of the Evaluator	Firm has General vial/ ampoule liquid vet section as mentioned in the submitted GMP inspection report.
	Decision: Deferred for confirmation of manufacturing facility.	
3243.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bio Lincocol Powder
	Composition	Each gram contains: Lincomycin HCl….....100mg Colistin Sulphate….....800,000IU
	Diary No. Date of R & I & fee	Dy.No.1164 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500g, 1kg & Decontrolled
	Me-too status	Lincocol-W/S Powder of M/s International Champharma Lahore (Reg. # 016204)
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator	Oral powder vet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
3244.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bio Neocin 72 Powder
	Composition	Each gram contains: Neomycin Sulphate….....720mg
	Diary No. Date of R & I & fee	Dy.No 1167 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Aminoglycoside antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100g, 500g, 1000g & Decontrolled
	Me-too status	Neocin-72 Water Soluble Powder of M/s Alina Combine Pharmaceuticals Karachi (Reg. # 046511)
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator	Oral powder vet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
3245.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bio ZBC 100mg powder
	Composition	Each gram contains: Zinc bacitracin…100mg
	Diary No. Date of R & I & fee	Dy.No 1163 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250kg & Decontrolled
	Me-too status	Bacilichin Powder of M/s U.M.Enterprises (Reg. # 019032)

	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator	Oral powder vet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Deferred for the evidence of availability of manufacturing facility for the applied pack size.	
3246.	Name and address of manufacturer/ Applicant	M/s Bio Labs Pvt Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name + Dosage Form + Strength	Bioxy 95 Powder
	Composition	Each gram contains: Oxytetracycline HCl….....950mg
	Diary No. Date of R & I & fee	Dy.No 1162 dated 09-01-2019 Rs.20,000/- Dated 04-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100mg, 500mg, 1000mg & Decontrolled
	Me-too status	Oxy-Tec Powder of M/s Evergreen Pharma, Lahore (Reg.# 090651)
	GMP status	The firm has submitted a GMP certificate issued to them on 21st May, 2019 which was based on the inspection and evaluation conducted on 23-04- 2019.
	Remarks of the Evaluator	Oral powder vet section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
3247.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Adevit Excell Oral Solution
	Composition	Each 100ml contains: Vitamin A….....1 MIU Vitamin D3.....…0.2 MIU Vitamin E….....400mg Vitamin K3.....…200mg
	Diary No. Date of R & I & fee	Dy.No 1890 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500ml, 1 litre & Decontrolled
	Me-too status	Adek Excel Oral Solution of M/s Nawan Laboratories (Pvt) Ltd, Karachi (Reg. # 058985)
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	• Firm has Oral liquid syrup section as mentioned in teh submitted GMP inspection report.
	Decision: Approved with innovators' specifications.	
3248.	Name and address of manufacturer/ Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name + Dosage Form + Strength	Lactomax Powder
	Composition	Each kg contains: Vitamin A….....0.80g Vitamin D3….....0.160g Vitamin E….....0.38g Vitamin B1.....…1g

		Vitamin B2.....…1.25g Vitamin B12.....0.001g Vitamin B3.....6.25g Vitamin B6.....4g CU.....0.25g Magnesium Suplhate.....25g Ca.....0.023g Zinc sulphate.....2.17g Magnese sulphate.....10g Potassium iodide I2.....0.50g Sodium selenite.....0.01g DCP Phosphorous.....150g Sodium chloride.....120g
	Diary No. Date of R & I & fee	Dy.No 1150 dated 09-01-2019 Rs.20,000/- Dated 09-01-2019
	Pharmacological Group	Vitamins dietary supplement
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2.5kg, 5kg, 10kg, 25kg polybags ; HDPE bottles 100g, 500g, 1000g & Decontrolled
	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. # 058842)
	GMP status	Last GMP inspection was conducted on 26-10-2017 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator	Firm has oral powder vet section as mentioned in the submitted GMP inspection report.
	Decision: Deferred for revision of formulation as per the already approved generic products along with submission of requisite fee.	
3249.	Name and address of manufacturer/ Applicant	M/s Elko Organization Pvt Ltd, Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Hemophos Injection 400mg/ ml
	Composition	Each ml contains: Sodium Acid Phospate.....…400mg
	Diary No. Date of R & I & fee	Dy.No 1877 dated 15-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	General Tonic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml & Decontrolled
	Me-too status	Alphos- 40 Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. #046573)
	GMP status	Last GMP inspection was conducted on 06-07-2017 and the report concludes good level of GMP compliance with advice of some improvements of some minor observations.
	Remarks of the Evaluator	Firm has General vial/ ampoule liquid vet section as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovators' specifications.	
3250.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Neomit Plus Water Soluble Powder
	Composition	Each kg contains: Colistin Sulphate….....4g Neomycin Sulphate….....70g Chlotetracycline HCl….....80g Bromhexine HCl.....…5g
	Diary No. Date of R & I & fee	Dy.No 440 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019

	Pharmacological Group	Antibiotics/ Mucolytic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500g, 1kg, 2.5 kg & Decontrolled
	Me-too status	Neocolicin Plus Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. # 044949)
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator	General Oral powder section (Veterinary) is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
3251.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Ty- Brox Liquid
	Composition	Each 1000ml contains: Doxycycline Hyclate….....200gm Tylosin Tartrate….....100gm Colistin Sulphate….....500 MIU Bromhexine….....12gm
	Diary No. Date of R & I & fee	Dy.No 441 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Mucolytic / Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml & Decontrolled
	Me-too status	Ty-Dox Plus Liquid of M/s Breeze Pharma Kahuta Road, Islamabad. (Reg. # 075670)
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator	General Drench section section (Veterinary) is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
3252.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Fenmit 10% Solution
	Composition	Each ml contains: Florfenicol….....100mg
	Diary No. Date of R & I & fee	Dy.No 447 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Bactericidal
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml & Decontrolled
	Me-too status	Fenlor Solution of M/s Selmore Pharma (Pvt) Ltd., Lahore (Reg. # 071080)
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator	General Drench section section (Veterinary) is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
3253.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Amantacin Solution
	Composition	Each ml contains: Enrofloxacin….....100mg Amantadine as HCl….....40mg

	Diary No. Date of R & I & fee	Dy.No 446 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Anti- bacterial/ anti- viral
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250ml, 500ml, 1000ml & Decontrolled
	Me-too status	Mantaflox Solution of M/s Selmore Pharma (Pvt) Ltd., Lahore (Reg. # 071077)
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator	General Drench section section (Veterinary) is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Deferred for the applied combination as anti- viral and anti- bacterial.	
3254.	Name and address of manufacturer/ Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd, Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name + Dosage Form + Strength	Bupacon 5% Injection I/M
	Composition	Each ml contains: Buparvaquone….....50mg
	Diary No. Date of R & I & fee	Dy.No 445 dated 03-01-2019 Rs.20,000/- Dated 03-01-2019
	Pharmacological Group	Anti- protozoal
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10ml, 20ml, 40ml, 100ml & Decontrolled
	Me-too status	Parvon Injection of M/s Selmore Pharma (Pvt) Ltd., Lahore. (Reg. # 034580)
	GMP status	Last GMP inspection was conducted on 03-11-17 and the report concludes satisfactory GMP compliance of the firm.
	Remarks of the Evaluator	General liquid injectable section section (Veterinary) is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
3255.	Name and address of manufacturer/ Applicant	M/s Star Laboratories Pvt Ltd, 23-km, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Gentocin-100 50ml Injection I/M, S/C
	Composition	Each ml contains: Gentamicin Sulfate….....100mg
	Diary No. Date of R & I & fee	Dy.No 2058 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Anti- bacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	50ml vial, Decontrolled
	Me-too status	Legent-10 Injection Leads Pharma (Pvt) Ltd., Islamabad. 062195
	GMP status	12 11 2018 satisfactory
	Remarks of the Evaluator	Liquid injection Antibiotic vial Vet section GMP report
	Decision: Approved with innovators' specifications.	
3256.	Name and address of manufacturer/ Applicant	M/s Star Laboratories Pvt Ltd, 23-km, Multan Road, Lahore.
	Brand Name + Dosage Form + Strength	Gentocin-50 50ml Injection I/M, S/C
	Composition	Each ml contains: Gentamicin Sulfate….....50mg
	Diary No. Date of R & I & fee	Dy.No 2057 dated 17-01-2019 Rs.20,000/- Dated 16-01-2019
	Pharmacological Group	Anti- bacterial

	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	50ml vial, Decontrolled
	Me-too status	Gentavet 5% Injection. Zakfas Pharmaceutical (Pvt) Ltd., Multan. 046537
	GMP status	12 11 2018 satisfactory
	Remarks of the Evaluator	Liquid injection Antibiotic vial Vet section GMP report
	Decision: Approved with innovators' specifications.	
3257.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Tylodoxin Plus Soluble Powder
	Composition	Each 1000gm Contains: Tylosin Tartrate……200gm Doxycycline HCl……..…400gm Colistin sulphate……...…500 MIU Bromhexine HCl……..…5gm
	Diary No. Date of R & I & fee	Dy.No 1887 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	Firm has vet powder Antibiotic section as mentioned in the submitted GMP inspection report Me- too could not be confirmed.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
3258.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	CNF-250 Soluble Powder
	Composition	Each 1000gm Contains: Chlortetracycline HCl……..100gm Neomycin Sulphate……30gm Furaltadone HCl……75gm
	Diary No. Date of R & I & fee	Dy.No 1886 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	Trifle Powder Selmore Pharmaceuticals (Pvt) Ltd., Lahore 029615
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	• Neomycin "as" Sulphate is available in me- too. • Firm has vet powder Antibiotic section as mentioned in the submitted GMP inspection report.
	Decision: Deferred as "Neomycin Sulphate" is applied while it is approved as Neomycin "as" Sulphate.	

3259.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noaflox- Plus Soluble Powder
	Composition	Each 1000gm contains: Florfenicol….....150gm Chlortetracycline HCl….....150gm
	Diary No. Date of R & I & fee	Dy.No 1885 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	Me- too could not be confirmed Firm has vet powder Antibiotic section as mentioned in the submitted GMP inspection report
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
3260.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noaflotin Oral Solution
	Composition	Each 100ml Contains: Florfenicol…23gm Colistin Sulphate…50 MIU
	Diary No. Date of R & I & fee	Dy.No 1892 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Me-too status	FLOTIN Liquid D-Maarson Pharmaceuticals, Plot # 17, Street SS-2, National Industrial Zone, Rawat, Islamabad. 072680
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	Oral liquid vet section needs to be verified.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
3261.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noa Esel Super Oral Solution
	Composition	Each 100ml Contains: Vitamine E…15gm Sodium Selenite Pentahydrate…0.20gm Vitamin C…....0.40gm Zinc Sulphate…1gm
	Diary No. Date of R & I & fee	Dy.No 1893 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Immunity booster veterinary preparation
	Type of Form	Form-5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	500ml, 1 litre & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	Me- too could not be confirmed Firm has oral liquid syrup section as mentioned in the submitteed GMP inspection report.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
3262.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noaflox- Excel Soluble Powder
	Composition	Each 1000gm Contains: Chlortetracycline Hcl…300gm Neomycin Sulphate…150gm Florfenicol…100gm
	Diary No. Date of R & I & fee	Dy.No 1889 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	Me- too could not be confirmed Firm has vet powder antibiotic section as mentioned in the submitted GMP inspection report
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
3263.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	CNF Super Soluble Powder
	Composition	Each 1000gm Contains: Chlortetracycline…400gm Neomycin Sulphate…120gm Furaltadone Hcl…300gm
	Diary No. Date of R & I & fee	Dy.No 1888 dated 15-01-2019 Rs.20,000/- 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	250g, 500g, 1kg, 2.5kg, 5kg & Decontrolled
	Me-too status	N.C.Bak Water Soluble Powder of M/s Attabak Pharmaceuticals Islamabad. 053905
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	• Firm has vet powder antibiotic section as mentioned in the submitted gmp inspection report. • Neomycin "as" Sulphate Is Available In Me- Too.
	Decision: Deferred as "Neomycin Sulphate" is applied while it is approved as Neomycin "as" Sulphate.	

3264.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Tylodoxin-Excel Oral Solution
	Composition	Each 100ml Contains: Tylosin Tartrate…20gm Doxycycline HCL…40gm Colistin sulphate…50 MIU Bromhexine hcl…500mg
	Diary No. Date of R & I & fee	Dy.No 1895 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	Me- too could not be confirmed. Oral liquid vet section needs to be verified.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Confirmation of required manufacturing facility / section from Licensing Division.**	
3265.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noatil-250 Oral Solution
	Composition	Each 100ml Contains: Tilmicosin…25gm
	Diary No. Date of R & I & fee	Dy.No 1894 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 200ml, 500 ml, 1 litre & Decontrolled
	Me-too status	Hicos 250 Oral Solution Hilton Pharma (Pvt) Ltd., Karachi 044909
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	Oral liquid vet section needs to be verified.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
3266.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Noaflor-30 Oral Solution
	Composition	Each 100ml Contains: Florfenicol…30gm
	Diary No. Date of R & I & fee	Dy.No 1891 dated 15-01-2019 Rs.20,000/- Dated 15-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled

	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 20-03-2018 and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP.
	Remarks of the Evaluator	Oral liquid vet section needs to be verified. Me- too could not be confirmed
	Decision: Deferred for following: • **Confirmation of required manufacturing facility / section from Licensing Division.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

3267.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd, Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Polidox-C Powder
	Composition	Each 1000gm contains: Tylosine Tartrate…100gm Doxycycline HCl……200gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 41750 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm & Decontrolled
	Me-too status	Roxycol Oral Powder of M/s Mallard Pharmaceutical (Pvt.) Ltd, Multan 049729
	GMP status	Last GMP inspection was conducted on 26-10-2018 and the report concludes: GMP is a continual process of improvement. In context to the current inspection; it is concluded that M/s Hawk Bio Pharma, Plot no 10, S- 6, Rawat has made adequate measures for complying the observations from previous inspection as stated in the table and is working in compliance with the GMP guidelines with a good approach for improvement.
	Remarks of the Evaluator [XIII]	Vet oral powder (Antibiotic) section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	
3268.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd, Plot # 10, Street # S-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Tylohawk 50 Powder
	Composition	Each 1000gm contains: Tylosine Tartrate…….500gm
	Diary No. Date of R& I & fee	Dy.No.41748 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100gm 500gm 1000gm 2500gm & as per SRO
	Me-too status	Tylo-50 Water Soluble Powder Of Symans Pharmaceuticals (Pvt) Ltd, Lahore 063847
	GMP status	Last GMP inspection was conducted on 26-10-2018 and the report concludes: GMP is a continual process of improvement. In context to the current inspection; it is concluded that M/s Hawk Bio Pharma, Plot no 10, S- 6, Rawat has made adequate

		measures for complying the observations from previous inspection as stated in the table and is working in compliance with the GMP guidelines with a good approach for improvement.
	Remarks of the Evaluator [XIII]	Vet oral powder (Antibiotic) section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	
3269.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd, Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Tetrabiotic Powder
	Composition	Each 1000gm contains: Tylosine Tartrate…100gm Doxycycline HCL…200gm Colistin Sulphate…500 MIU Bromhexine HCL…5gm
	Diary No. Date of R& I & fee	Dy.No 41749 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100g 500g 1000g 2500g & Decontrolled
	Me-too status	Crd-Raze Water Soluble Powder Attabak Pharmaceuticals, Islamabad. 049712
	GMP status	Last GMP inspection was conducted on 26-10-2018 and the report concludes: GMP is a continual process of improvement. In context to the current inspection; it is concluded that M/s Hawk Bio Pharma, Plot no 10, S- 6, Rawat has made adequate measures for complying the observations from previous inspection as stated in the table and is working in compliance with the GMP guidelines with a good approach for improvement.
	Remarks of the Evaluator [XIII]	Vet oral powder (Antibiotic) section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	
3270.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd, Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Doxyhawk 50 Powder
	Composition	Each 1000gm contains: Doxycycline HCL…500gm
	Diary No. Date of R& I & fee	Dy.No 41747 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100g 500g 1000g 2500g & Decontrolled
	Me-too status	Doxitin 500 Water Soluble Powder M/S. Elegance Pharmaceuticals, Rawalpindi 078274
	GMP status	Last GMP inspection was conducted on 26-10-2018 and the report concludes: GMP is a continual process of improvement. In context to the current inspection; it is concluded that M/s Hawk Bio Pharma, Plot no 10, S- 6, Rawat has made adequate measures for complying the observations from previous inspection as stated in the table and is working in compliance with the GMP guidelines with a good approach for improvement.

	Remarks of the Evaluator [XIII]	Vet oral powder (Antibiotic) section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	
3271.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd, Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Bromohawk 5% Powder
	Composition	Each ml contains: Bromhexine HCl……50mg
	Diary No. Date of R& I & fee	Dy.No.42756 dated 14-12-2018 Rs.20,000/- Dated 14-12-2018
	Pharmacological Group	Expectorant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 500ml, 1 litre, 2.5 litre & As per SRO
	Me-too status	Brombar-5 Oral Liquid Baariq Pharmaceuticals, Sunder Raiwind Road, Lahore. 073947
	GMP status	Last GMP inspection was conducted on 26-10-2018 and the report concludes: GMP is a continual process of improvement. In context to the current inspection; it is concluded that M/s Hawk Bio Pharma, Plot no 10, S- 6, Rawat has made adequate measures for complying the observations from previous inspection as stated in the table and is working in compliance with the GMP guidelines with a good approach for improvement.
	Remarks of the Evaluator [XIII]	Vet oral powder (Antibiotic) section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	
3272.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd, Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	TDB 455 Powder
	Composition	Each 1000 gm contains: Tylosine Tartrate…200gm Doxycycline HCL…250gm Bromhexine HCL…5000mg
	Diary No. Date of R& I & fee	Dy.No 42758 dated 14-12-2018 Rs.20,000/- Dated 14-12-2018
	Pharmacological Group	Antibiotic/ expectorant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100g 500g 1000g 2500g & Decontrolled
	Me-too status	Bromodox Water Soluble Powder Symans Pharmaceuticals (Pvt) Ltd, Lahore 063846
	GMP status	Last GMP inspection was conducted on 26-10-2018 and the report concludes: GMP is a continual process of improvement. In context to the current inspection; it is concluded that M/s Hawk Bio Pharma, Plot no 10, S- 6, Rawat has made adequate measures for complying the observations from previous inspection as stated in the table and is working in compliance with the GMP guidelines with a good approach for improvement.
	Remarks of the Evaluator [XIII]	Vet oral powder (Antibiotic) section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	

3273.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd, Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Enicol Oral Liquid
	Composition	Each 1000ml contains: Florfenicol…...200gm
	Diary No. Date of R& I & fee	Dy.No 42757 dated 14-12-2018 Rs.20,000/- Dated 14-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml & Decontrolled
	Me-too status	Pri-Florecol 20 Oral Liquid M/S. Prix Pharmaceutica (Pvt) Ltd, Plot # 5 Pharma City, 30-Km Multan Road, Lahore. 080928
	GMP status	Last GMP inspection was conducted on 26-10-2018 and the report concludes: GMP is a continual process of improvement. In context to the current inspection; it is concluded that M/s Hawk Bio Pharma, Plot no 10, S- 6, Rawat has made adequate measures for complying the observations from previous inspection as stated in the table and is working in compliance with the GMP guidelines with a good approach for improvement.
	Remarks of the Evaluator [XIII]	Vet oral Liquid (Antibiotic) section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	
3274.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd, Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Vita- C 25 Powder
	Composition	Each 1000gm contains: Vitamin C…250gm
	Diary No. Date of R& I & fee	Dy.No 42755 dated 14-12-2018 Rs.50,000/- Dated 14-12-2018
	Pharmacological Group	Vitamins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	50g, 100g, 500g, 1000g, 2500g & Decontrolled
	Me-too status	C- MIX 25 POWDER DELUX CHEMICAL INDUSTRIES, KARACHI. 026584
	GMP status	Last GMP inspection was conducted on 26-10-2018 and the report concludes: GMP is a continual process of improvement. In context to the current inspection; it is concluded that M/s Hawk Bio Pharma, Plot no 10, S- 6, Rawat has made adequate measures for complying the observations from previous inspection as stated in the table and is working in compliance with the GMP guidelines with a good approach for improvement.
	Remarks of the Evaluator [XIII]	Vet oral powder (Antibiotic) section is available in the firm as mentioned in the submitted DML.
	Decision: Approved with innovators' specifications.	
3275.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/ 1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	IS E Oral Liquid
	Composition	Each 100ml contains: Vitamin E Acetate……..40,000IU

	Diary No. Date of R& I & fee	Dy.No.42765 dated 14-12-2018 Rs.20,000/- Dated 14-12-2018
	Pharmacological Group	Vitamin supplement
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml & Decontrolled
	Me-too status	Could not be confirmed in the applied strength as 100mg/ml is available
	GMP status	Not provided
	Remarks of the Evaluator [XIII]	• me- too could not be verified • 20% overage is added in the applied formulation to maintain the stability upto 2 years. • GMP report is not submitted • Section needs to be verified.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm,** • **Scientific justification of 20% overage in the applied formulation.** • **Updated GMP status of the firm from QA & LT Division.** • **Confirmation of required manufacturing facility / section from Licensing Division.**	
3276.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/ 1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Nercobal Tablet 500mcg
	Composition	Each Tablet Contains: Mecobalamin…….500mcg
	Diary No. Date of R& I & fee	Dy.No 42760 dated 14-12-2018 Rs.20,000/- Dated 14-12-2018
	Pharmacological Group	Vitamin B- 12
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10x 10's & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Not provided
	Remarks of the Evaluator [XIII]	me- too could not be verified GMP report is not submitted 20% overage is added in the applied formulation to maintain the stability upto 2 years. section
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm,** • **Scientific justification of 20% overage in the applied formulation.** • **Updated GMP status of the firm from QA & LT Division.** • **Confirmation of required manufacturing facility / section from Licensing Division.**	
3277.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/ 1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	IS- K Capsule 250mg
	Composition	Each Capsule Contains: Vit K3…250mg
	Diary No. Date of R& I & fee	Dy.No 42761 dated 14-12-2018 Rs.20,000/- Dated 14-12-2018
	Pharmacological Group	Vitamin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 5's & Decontrolled
	Me-too status	Could not be confirmed in the applied strength as 252 mg capsules are available under Reg. # 021283

	GMP status	Not provided
	Remarks of the Evaluator [XIII]	• me- too could not be verified • GMP report is not submitted • Section needs to be verified.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm,** • **Updated GMP status of the firm from QA & LT Division.** • **Confirmation of required manufacturing facility / section from Licensing Division.**	

b. Deferred Cases

3278.	Name and address of manufacturer/ Applicant	M/s Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Amoxiclav Water Soluble Powder
	Composition	Each gm contains: Amoxicillin as Amoxicillin Trihydrate……160 mg Clavulanic Acid as Potassium Clavulanate…..40 mg
	Diary No. Date of R & I & fee	Dy.No.21174; 18-10-2019; Rs.20,000 (18-10-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	100gm, 250gm, 500g, 1kg, 5kg, 10kg, 25kg & Decontrolled
	Me-too status	Primox- Plus Water Soluble Powder of M/s Prix Pharma, Lahore (Reg. # 074026)
	GMP status	New Section of Veterinary Oral Powder Penicillin was approved on 12th September, 2019 by CLB.
	Previous Remarks of the Evaluator	
	Previous decision	Deferred in 293rd DRB meeting for further deliberation regarding ratio of Amoxiciliin & Clavulanic acid in the applied formulation.
	Evaluation by PEC- Evaluator [XIII]	Firm has replied that the ratio between Amoxicillin and Clavulanic acid is 4:1 which is being marketed internationally and in local market.
	Decision: Deferred for review of formulation by expert working group on Veterinary Drugs.	
3279.	Name and address of manufacturer/ Applicant	M/s Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Grand ABC Water Soluble Powder
	Composition	Each 100 gm contains: Amoxicillin as Amoxicillin Trihydrate……16 gm Clavulanic Acid as Potassium Clavulanate..……..4 gm Bromhexine ……..…..0.5 gm
	Diary No. Date of R & I & fee	Dy.No.21176; 18-10-2019; Rs.20,000 (18-10-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	100gm, 250gm, 500g, 1kg, 5kg, 10kg, 25kg & Decontrolled
	Me-too status	Clavmox-Forte Water Soluble Powder of M/s Sanna Laboratories (Reg. # 081697)
	GMP status	New Section of Veterinary Oral Powder Penicillin was approved on 12th September, 2019 by CLB.
	Previous Remarks of the Evaluator	
	Previous decision	Deferred in 293rd DRB meeting for further deliberation regarding ratio of Amoxiciliin & Clavulanic acid in the applied formulation.

	Evaluation by PEC- Evaluator XIII	Firm has replied that the ratio between Amoxicillin and Clavulanic acid is 4:1 which is being marketed internationally and in local market.
	Decision: Deferred for review of formulation by expert working group on Veterinary Drugs.	
3280.	Name and address of manufacturer/ Applicant	M/s Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Augment- C Water Soluble Powder
	Composition	Each 100 gm contains: Amoxicillin as Amoxicillin Trihydrate...……20 gm Clavulanic Acid as Potassium Clavulanate…...4 gm Colistin Sulphate…….……..….4 gm
	Diary No. Date of R & I & fee	Dy.No.21181; 18-10-2019; Rs.20,000 (18-10-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	100gm, 500gm, 1kg, 2.5kh, 5kg, 25kg; Decontrolled
	Me-too status	Clau Mox- 28 Water Soluble Powder of M/s D-Maarson (Reg. # 072682)
	GMP status	New Section of Veterinary Oral Powder Penicillin was approved on 12th September, 2019 by CLB.
	Previous Remarks of the Evaluator	
	Previous decision	Deferred in 293rd DRB meeting for further deliberation regarding ratio of Amoxiciliin & Clavulanic acid in the applied formulation.
	Evaluation by PEC- Evaluator XIII	Firm has replied that the ratio between Amoxicillin and Clavulanic acid is 5:1 which is being marketed in local market.
	Decision: Deferred for review of formulation by expert working group on Veterinary Drugs.	
3281.	Name and address of manufacturer/ Applicant	M/s Grand Pharma Pvt. Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	ZipcoStrep Powder
	Composition	Each kg contains: Zinc Bacitracin…….……...52 gm Procaine Penicillin……..……...12 gm Streptomycin Sulphate….……...….36 gm Colistin Sulphate….…….……60 MIU
	Diary No. Date of R & I & fee	Dy.No.21184; 18-10-2019; Rs.20,000 (18-10-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1kg, 2.5kg, 5kg, 10kg, 25kg & Decontrolled
	Me-too status	Zeptocol Powder of M/s Selmore Pharma (Reg. #080962)
	GMP status	New Section of Veterinary Oral Powder Penicillin was approved on 12th September, 2019 by CLB.
	Previous Remarks of the Evaluator	
	Previous decision	Deferred in 293rd DRB meeting for the review of formulation.
	Evaluation by PEC- Evaluator XIII	Instead of reviewing the formulation, firm submitted me-too.
	Decision: Deferred for review of formulation by expert working group on Veterinary Drugs.	
3282.	Name and address of manufacturer/ Applicant	M/s Grand Pharma Pvt. Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Probact Zee Powder
	Composition	Each kg contains:

		Procaine Penicillin.……..…....12 gm Streptomycin Sulphate.……..……...…36 gm Zinc Bacitracin 10%…….…….……..…..52 gm Neomycin Sulphate.……...…10 gm
	Diary No. Date of R & I & fee	Dy.No.21185; 18-10-2019; Rs.20,000 (18-10-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	100gm, 500gm, 1kg, 2.5kh, 5kg, 25kg; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	New Section of Veterinary Oral Powder Penicillin was approved on 12th September, 2019 by CLB.
	Previous Remarks of the Evaluator	
	Previous decision	Deferred in 293rd DRB meeting for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Evaluation by PEC- Evaluator XIII	Me- too has been verified as: PSB- Excel Powder of M/s Nawan Laboratories, Karachi (Reg. # 082489).
	Decision: Approved with innovators' specifications.	
3283.	Name and address of manufacturer/ Applicant	M/s Grand Pharma Pvt Ltd Plot No. 5-A, Street No. N5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Super Mox- 80 Water Soluble Powder
	Composition	Each 100 gm contains: Amoxicillin Trihydrate eq to 70 gm Amoxicillin base.....80 gm
	Diary No. Date of R & I & fee	Dy.No.21169; 18-10-2019; Rs.20,000 (18-10-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	100gm, 500gm, 1kg, 2.5kg, 5kg, 10kg; Decontrolled
	Me-too status	Bio- Amoxyllin 70% of M/s Biolabs Pharma (Reg. # 079850)
	GMP status	New Section of Veterinary Oral Powder Penicillin was approved on 12th September, 2019 by CLB.
	Previous Remarks of the Evaluator	
	Previous decision	Deferred in 293rd DRB meeting for the proposed label claim.
	Evaluation by PEC- Evaluator XIII	Firm has revised its label claim as: Each 100 gm contains: Amoxicillin Trihydrate eq to Amoxicillin.....70 gm
	Decision: Approved with innovators' specifications.	

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

c. Deferred cases

3284.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 69/2 phase 2 industrial area, Hattar.
	Brand Name +Dosage Form + Strength	ACEFOLDS Sachet 200mg
	Composition	Each sachet contains: Acetylcysteine……200 mg
	Diary No. Date of R& I & fee	Dy. No: 490 dated 12-03- 2015, 20,000/-
	Pharmacological Group	Expectorant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ 30's
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Mucolator Sachet of Abbott Laboratories
	GMP status	Last GMP inspection conducted on 15-09-2017 concludes the firm to be GMP compliant.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for confirmation of formulation in reference drug agencies (M-246).
	Evaluation by PEC	Approval status of applied formulation has been confirmed in MHRA.
	Decision: Approved with innovator's specifications.	
3285.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 69/2 phase 2 industrial area, Hattar.
	Brand Name +Dosage Form + Strength	Virowns 300mg tablet
	Composition	Each film coated tablet contains: Tenofovir Disproxil Fumarate…….300mg eq to Tenofovir Disproxil…..245mg
	Diary No. Date of R& I & fee	Dy. No.53; 17-11-2014; Rs.12,000/- (17-11-2014); Rs.8,000/- (12-11-2010)
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification's
	Pack size & Demanded Price	Not Provided, As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Viread by Gilead Pharma USFDA
	Me-too status	Tenovir by Pharmix
	GMP status	Last GMP inspection conducted on 15-09-2017 concludes the firm to be GMP compliant.
	Previous remarks of the Evaluator.	Pack size is not provided. Firm claimed 5% overage in master formulation without scientific justification. The formulation is present in IP
	Previous decision(s)	Deferred for following reasons: (M-272) a) Submission of justification for 5% overage of active ingredient in master formulation. b) Submission of pack size
	Evaluation by PEC	The firm has submitted master formulation without overage alongwith submission of fee of Rs. 5000/- (Deposit slip # 2002913) dated 27-02-2020. Pack size is As per SRO.
	Decision: Approved with International Pharmacopoeia specifications.	

3286.	Name and address of manufacturer / Applicant	M/s WinBrains Research Laboratories, Plot # 69/1, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Fusid-B cream 2%w/w (20mg)+ 1% w/w(10mg)
	Composition	Dy. No. 3379, 14-04-2017, Rs.20000/-
	Diary No. Date of R& I & fee	Each gram contains:- Fusidic acid …. 20mg Betamethasone (as Velarate)…….. 10 mg
	Pharmacological Group	Antibiotic/Steroid
	Type of Form	Form-5
	Finished product Specification	As per Innovator's
	Pack size & Demanded Price	1's (5g, 15g) ; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream by M/s Goapharma (MHRA Approved)
	Me-too status	Monfusi -B Cream by M/s Epharm Labs (Reg#048404)
	GMP status	Panel Inspection conducted on 03-02-2017 recommends renewal of DML and grant of four additional sections.
	Previous remarks of the Evaluator.	i. Evidence of Me Too status and approval of applied formulation in applied strength in Reference Regulatory Authorities is required. ii. Firm has claimed Innovator Specifications, & the applied formulation does not exist in available USP & B.P.
	Previous decision(s)	Deferred in 270th meeting for: Evidence of me-too status and approval of applied formulation (in applied strength and dosage form) in Reference Regulatory Authorities. Deferred for submission of fee for revised strength (M-273)
	Evaluation by PEC	Firm has stated as under: We have mistakenly written in our dossier Betamethasone (as valerate) …10mg (1%w/w) and you are requested to treat it Betamethasone (as valerate)… 1mg (0.1%w/w) The firm has submitted fee challan of Rs. 20,000/- (deposit slip # 1909910) dated 20-12-2019.
	Decision: Approved with following composition: **Each gram contains:-** **Fusidic acid……...20mg (2%w/w)** **Betamethasone (as Velarate)……..1mg (0.1% w/w)**	
3287.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid e Azam Industrial Estate,Kot, Lakhpat,Lahore Contract manufactured by: M/s Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi, Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Faast IV 40mg Injection
	Composition	Each vial contains: Omeprazole Sodium equivalent to Omeprazole (Lyophilized powder)…..……..…40mg
	Diary No. Date of R& I & fee	Duplicate dossier : duplicate fee challan of Rs. 50,000/- (06-04-2017) (Challan#0560178) Dy.No 38003 dated 19-11-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazol 40mg injection of (MHRA approved)

	Me-too status	Fymezole Dry Powder Injection IV of M/s Fynk Pharmaceuticals
	GMP status	M/s CCL Pharmaceuticals (Pvt) Ltd. copy of GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance. & Last GMP of Nabiqasim Inspection conducted on 03- 08-2018 and report concludes that firm is considered to be operating at an acceptable level of compliance of GMP requirements.
	Previous remarks of the Evaluator.	• Contract manufacturing agreement: attached. • Duplicate dossier was forwarded from R-V with letter No.F.8-6/2013-Reg-V dated 04-12-2018. Letter states that 'same formulation already registered in import (Reg#052245). Now the firm intends to manufacture same formulation locally.'
	Previous decision(s)	Deferred for clarification as firm has registration of same product with same brand name in import **(M-290).**
	Evaluation by PEC	The firm has submitted that we applied for de-registration of our imported product vide letter no. CCL/19/R-330 dated 28th June 2019. Accordingly Registration Board approved de-registration of Imported Faast I.V. Injection (Reg# 052245) in its 291st meeting. Letter of de-registration is attached. Now the present case is fresh application for registration on contract manufacturing.
	Decision: Approved with innovator's specifications.	
3288.	Name and address of manufacturer / Applicant	M/s. Hilton Pharma, (Pvt.) Ltd. Plot no: 13-14, Sector 15, Korangi industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Transamin Tablets 250mg
	Composition	Each film coated tablet contains: Tranexamic acid…….250mg
	Diary No. Date of R& I & fee	17784, 11-10-2017, 20,000/-, 02-10-2017
	Pharmacological Group	Anti-fibrinolytic agent
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities.	Transamin Tablets 250mg of M/s Daiichi Sankyo, PMDA Japan
	Me-too status	Traumax 250mg Tablet of M/s. Siza (Reg#024786)
	GMP status	Inspection report 19-7-2017 firm was considered to be operating at satisfactory level of compliance with GMP.
	Previous remarks of the Evaluator.	Firm has requested to hold approval of transamin tablet 250mg, 500mg because their principal has informed them that they will be sending few additional documents in support for registration of our originator molecule tranexamic acid in tablet form. The firm has requested to defer their product till documents are received from the principal.
	Previous decision(s)	Registration Board acceded to the firm's request to defer the case till the submission of necessary documents as product is under license of M/s Daiichi Sankyo, Japan (M-284)
	Evaluation by PEC	The firm has stated that we hereby submit the letter of authorization as received from our principal to register, manufacture and market the said product in Pakistan under their license as **originator brand**.
	Decision: Approved.	

3289.	Name and address of manufacturer / Applicant	M/s. Hilton Pharma, (Pvt.) Ltd. Plot no: 13-14, Sector 15, Korangi industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Transamin Tablets 500mg
	Composition	Each film coated tablet contains: Tranexamic acid…….500mg
	Diary No. Date of R& I & fee	17785, 11-10-2017, 20,000/-, 02-10-2017
	Pharmacological Group	Anti-fibrinolytic agent
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities.	Cyklo-F 500mg Film Coated Tablet of Mylan Products, (MHRA approved)
	Me-too status	Traumax 500mg Tablet of M/s. Siza (Reg#024787)
	GMP status	Inspection report 19-7-2017 firm was considered to be operating at satisfactory level of compliance with GMP.
	Previous remarks of the Evaluator.	Firm has requested to hold approval of transamin tablet 250mg, 500mg because their principal has informed them that they will be sending few additional documents in support for registration of our originator molecule tranexamic acid in tablet form. The firm has requested to defer their product till documents are received from the principal.
	Previous decision(s)	Registration Board acceded to the firm's request to defer the case till the submission of necessary documents as product is under license of M/s Daiichi Sankyo, Japan (M-284)
	Evaluation by PEC	The firm has stated that we hereby submit the letter of authorization as received from our principal to register, manufacture and market the said product in Pakistan under their license as **originator brand**.
	Decision: Approved.	
3290.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd.Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Velna XR Capsules 75mg
	Composition	Diary No: 24124 , 13-12-2017 , Rs: 20,000/-
	Diary No. Date of R& I & fee	Each capsule contains: Sustained release pellets (33%) of venlafaxine hydrochloride equivalent to venlafaxine……75mg
	Pharmacological Group	Serotonin-norepinephrine reuptake inhibitors/ Atypical Antidepressant.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alventa XL 75mg Capsule by M/s Consilient Health Ltd.(MHRA approved)
	Me-too status	Efexor XR 75mg Capsule by M/s Wyeth Pakistan Ltd. (Reg#023658)
	GMP status	13-07-2017 Grant of new DML, Panel recommends grant of new DML.
	Previous remarks of the Evaluator.	Source of pellets Vision Pharmaceuticls, Islamabad. Submitted source of Pellets is not of USP grade.
	Previous decision(s)	Deferred for confirmation whether the pellets of Venlafaxine are of USP grade or otherwise (M-278).
	Evaluation by PEC	The firm has submitted that Registration Board in its 290th meeting decided that Venlafaxine hydrochloride SR pellets 33% of M/s Vision Pharma, Islamabad comply with the

		USP monograph. The firm has been granted GMP certificate based on inspection conducted on 25-07-2019.
	Decision: Approved.	
3291.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd., Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Fudix Powder for Oral Suspension 250mg/5ml
	Composition	Each 5ml reconstituted suspension contains: Fusidic acid ……250mg
	Diary No. Date of R& I & fee	Diary No: 24208, 13-12-2017 , Rs: 20,000/-
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	BP (oral suspension)
	Pack size & Demanded Price	90ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fumont 250mg/5ml Dry Suspension by Leo Pharmaceutical Australia (Not confirmed)
	Me-too status	Fumont Dry Suspension 250mg/5ml by M/s De Mont Research laboratories (Pvt) Ltd (Reg#084090)
	GMP status	13-07-2017 Grant of new DML, Panel recommends grant of new DML.
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting (M-279). Deferred for evidence of required manufacturing facility i.e., Oral liquid section since the firm has revised dosage from dry powder suspension to liquid suspension (M-293).
	Evaluation by PEC	The firm has submitted revised Form-5 with change in dosage from dry suspension to liquid suspension alongwith submission of fee challan of Rs. 20,000/- (deposit slip # 0805216) dated 03-12-2019. Each 5ml contains: Fusidic acid…….250mg Me-too reference: Zudic suspension of NabiQasim (Reg#055588). International availability: Fucidin 250mg / 5ml oral suspension by Leo Laboratories (MHRA approved). The firm has provided Syrup (General) (Human) section for applied formulation confirmed from vide letter No.F.1-17/2005-Lic. The firm has been granted GMP certificate based on inspection conducted on 25-07-2019.
	Decision: Approved with following composition: **Each 5ml contains:** **Fusidic acid…….250mg**	
3292.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd., Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Colistim Injection 150mg
	Composition	Each vial contains: Colistimethate (as sodium) powder for reconstitution ……150mg
	Diary No. Date of R& I & fee	Diary No: 24091 , 13-12-2017 , Rs: 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5

	Finished product Specification	USP
	Pack size & Demanded Price	1's, 10's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colistimethate for injection150mg/vial by M/s X-Gen Pharmaceutical USA (USFDA Approved)
	Me-too status	Colistat by Medisure (Reg. No. 076160) (Formulation is not same as for applied product)
	GMP status	13-07-2017 Grant of new DML, Panel recommends grant of new DML.
	Previous remarks of the Evaluator.	• Me-too status not confirmed from available database.
	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm **(M-278)**.
	Evaluation by PEC	The firm has submitted revised Form-5 with following label claim: Each vial contains: Colistimethate sodium (lyophilized powder)…….2 MIU Fee of Rs. 20,000/- (deposit slip # 0805249) dated 05-03-2020 has been submitted for change in strength of applied formulation. **International availability**: Approved in MHRA **Me-too status:** Not confirmed The firm has been granted GMP certificate based on inspection conducted on 25-07-2019.
	Decision: Deferred for submission of stability studies data as per decision of 278th meeting of Registration Board.	
3293.	Name and address of manufacturer / Applicant	M/s Arsons Pharmaceutical Industries (Pvt) Ltd., Lahore
	Brand Name +Dosage Form + Strength	Prexin Tablet
	Composition	Each dispersible tablet contains: Piroxicam betacyclodextrine 191.2mg eq to Piroxicam…..…..20mg
	Diary No. Date of R& I & fee	Dy. No.54; 16-3-2011; Rs.12,000/- (6-1-2015); Rs.8,000/- (16-03-2011) Duplicate
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PIROXICAM MYLAN 20 mg, dispersible, scored tablet (ANSM Approved)
	Me-too status	Beta cyclo dispers 20mg by Winbrains (Reg#078504)
	GMP status	Last Inspection report 30-1-2017 and 22-03-2017 The panel recommended the grant of additional section
	Previous remarks of the Evaluator.	Fee challan photocopies are attached.
	Previous decision(s)	Deferred for submission of last GMP inspection report conducted within a year (M-274).
	Evaluation by PEC	The firm has submitted copy of GMP inspection dated 18-09-2019 concludes that the firm is operating at satisfactory level of GMP compliance.
	Decision: Approved with innovator's specifications.	
3294.	Name and address of manufacturer / Applicant	M/s Arsons Pharmaceutical Industries (Pvt) Ltd., Lahore
	Brand Name +Dosage Form + Strength	Metrozole Tablet 200mg
	Composition	Each film coated tablet contains: Metronidazole…….200mg

	Diary No. Date of R& I & fee	Dy. No.2514; 21-6-2011; Rs.12,000/- (6-1-2015); Rs.8,000/- (21-06-2011)
	Pharmacological Group	Antiamoebic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved
	Me-too status	Robecide by Roack Pharma
	GMP status	Last Inspection report 30-1-2017 and 22-03-2017. The panel recommended grant of additional section.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for submission of last GMP inspection report conducted within a year (M-274).
	Evaluation by PEC	The firm has submitted copy of GMP inspection dated 18-09-2019 concludes that the firm is operating at satisfactory level of GMP compliance.
	Decision: Approved.	
3295.	Name and address of manufacturer / Applicant	M/s Arsons Pharmaceutical Industries (Pvt) Ltd., Lahore
	Brand Name +Dosage Form + Strength	Atistine 10mg Tablet
	Composition	Each film coated tablet contains: Ebastine…….10mg
	Diary No. Date of R& I & fee	Dy. No.2514; 21-6-2011; Rs.12,000/- (6-1-2015); Rs.8,000/- (22-06-2011) Duplicate file
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Kestine 10mg tablet by M/s Almirall Pharmaceuticals, (ANSM France Approved)
	Me-too status	Ebofor 10mg Tablet by M/s Genome Pharmaceutical (Reg No:042519)
	GMP status	Last Inspection report 30-1-2017 and 22-03-2017 The panel recommended the grant of additional section.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for submission of last GMP inspection report conducted within a year (M-274).
	Evaluation by PEC	The firm has submitted copy of GMP inspection dated 18-09-2019 concludes that the firm is operating at satisfactory level of GMP compliance.
	Decision: Approved with innovator's specifications.	
3296.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Terbinovo Cream
	Composition	Terbinafine Hydrochloride……. 1% (w/w)
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 R/s 20,000
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Aluminum tube 10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Terbinafine HCl 1% cream by M/s Taro, USFDA Approved
	Me-too status	Terbisan caream 1% by M/s Elko organization (Pvt) ltd. Reg # 27076
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of

		deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Cream/ Ointment section.
	Decision: Approved with Japanese Pharmacopoeia specifications.	
3297.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Novodic Cream
	Composition	Fusidic acid……2% (w/w)
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	Aluminum tube 15g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fucidin of MHRA Approved
	Me-too status	Ucid 2% Cream by Ciba Pharma (Reg. No. 081566)
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Cream/ Ointment section.
	Decision: Approved.	
3298.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Novobact Ointment
	Composition	Mupirocin…… 2% (20mg/g)
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	Aluminum tube 15g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	076451; Mupream 20mg Cream M/s Sante Pvt. Karachi.
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Cream/ Ointment section. Salt form of applied formulation is not mentioned.
	Decision: Deferred for revision of formulation as per reference product.	
3299.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Sap-Dox Tablet
	Composition	Each film coated tablet contains Doxycycline as Hyclate…….. 100mg

	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	Blister pack of 30's
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	SIZADEX 100mg Tablet by M/s Siza (Reg#010362)
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Tablet General section. Evidence of approval of applied formulation in reference regulatory authority could not be verified.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting of Registration Board.	
3300.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Acnox Cream
	Composition	Adapalene…… 0.1% (w/w)
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Anti-acne
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Aluminum tube 15g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Differin 0.1% w/w Cream Of (MHRA Approved)
	Me-too status	Adac 1mg/g (0.1% w/w) Cream M/ Sigma Pharma
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Cream/ Ointment section.
	Decision: Approved with BP specifications.	
3301.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Novomax Lotion
	Composition	Minoxidil……5% (w/v)
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Vasodilator
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	60ml plastic bottle; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MINOXIDIL EXTRA STRENGTH (FOR MEN). MINOXIDIL EXTRA STRENGTH (FOR WOMEN). USFDA approved as OTC product.
	Me-too status	Follinox 5% Solution. Reg. No. 82173
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of

		deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Cream/ Ointment section. Evidence of manufacturing facility is required.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
3302.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Clindacin Cream
	Composition	Clindamycin as phosphate……2% (w/w)
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	Aluminum tube 10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	CLIMAX -V of M/s MAX pharmaceuticals.
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Cream/ Ointment section.
	Decision: Approved.	
3303.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Novoket Lotion
	Composition	Ketoconazole……2% w/v
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60ml plastic bottle; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nizora Anti-Dandruff Shampoo 2%w/w by M/s McNeil Products Limited (MHRA Approved)
	Me-too status	Ketonaz Lotion by M/s Sante (Reg#073453)
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Cream/ Ointment section.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	

3304.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Terbinovo Tablet
	Composition	Each tablet contains: Terbinafine as hydrochloride…….125 mg
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	Blister of 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil® Tablets 125mg by M/s Novartis Pharmaceuticals Australia Pty Limited, TGA Australia approved.
	Me-too status	Logirid Tablet 125mg by M/s Lowitt Pharmaceutical (Pvt) Ltd, Reg No. 80846
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Tablet General section.
	Decision: Approved.	
3305.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S Industrial Area Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Sapidin Tablet
	Composition	Each film coated tablet contains: Desloratadine…….5mg
	Diary No. Date of R& I & fee	22-07-10, 14-05-13 Rs 20,000/-
	Pharmacological Group	Antiallergic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Blister of 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarinex 5mg film coated tablet by M/s MSD, USFDA Approved.
	Me-too status	Desora 5mg tablet of M/s Continental (Reg. 037421)
	GMP status	19-04-13 Satisfactory level of GMP after fulfillment of deficiencies/ shortcomings pointed out.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for GMP inspection by panel comprising of Director DTL Lahore, DDG (E & M) & Area FID **(M-242)**.
	Evaluation by PEC	Panel inspection dated 19-09-2019 and 18-11-2019 recommended renewal of DML. The firm has provided Tablet General section.
	Decision: Approved with innovator's specifications.	
3306.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Feldex 20mg Injection
	Composition	Each ampoule contains:- Piroxicam……..20mg
	Diary No. Date of R& I & fee	Dy No. 2705 dated 16-06-2016 Rs.20,000/-
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO/1x5's & 1x10's
	Approval status of product in Reference	ANSM approved.

	Regulatory Authorities.	
	Me-too status	Pcam 20mg by M/s Merck (Pvt) Limited
	GMP status	
	Previous remarks of the Evaluator.	Approval status in reference countries is not provided.
	Previous decision(s)	Deferred for confirmation of approval status by reference regulatory authorities (M-260).
	Evaluation by PEC	Approval status of applied formulation has been confirmed in ANSM France. (PIROXICAM TEVA 20 mg / 1 ml, solution for injection (IM)). The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Decision: Approved with innovator's specifications.	
3307.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Pyritec 150mg Injection
	Composition	Each ampoule 1ml contains:- Paracetamol…….150mg
	Diary No. Date of R& I & fee	Dy No. 2712 dated 16-06-2016 Rs.20,000/-
	Pharmacological Group	Analgesic & antipyretic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO/1x5's & 1x10's
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Pravos 150mg injection by M/s Sami Pharmaceuticals (Pvt) Limited.
	GMP status	
	Previous remarks of the Evaluator.	Approval status in reference countries is not provided.
	Previous decision(s)	Deferred for confirmation of approval status by reference regulatory authorities (M-260).
	Evaluation by PEC	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting of Registration Board.	
3308.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Indocin 1mg Injection
	Composition	Each vial contains:- Indomethacin sodium ready to fill powder equivalent to Indomethacin…….1mg
	Diary No. Date of R& I & fee	Dy No. 2711 dated 16-06-2016, Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO/1's
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Liometacen Injection by M/s Chiesi Pharmaceuticals (Pvt) Limited.
	GMP status	
	Previous remarks of the Evaluator.	Approval status in reference countries is not provided.
	Previous decision(s)	Deferred as product is more than 10 (M-260).
	Evaluation by PEC	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate. The firm has provided "Sterile Dry Powder Injectable Vials section".

	Decision: Deferred for clarification of reference product whether lyophilized / dry powder and requisite facility.	
3309.	Name and address of manufacturer / Applicant	M/s. Rock Pharmaceutical Laboratories (Pvt) Ltd., Plot # 134-B & 135-B Nowshera Industrial Estate, Risalpur
	Brand Name +Dosage Form + Strength	Romylin DM Syrup
	Composition	Each 5ml contains:- Diphenhydramine HCl…..5mg Dextromethorphan HBr.6.25mg
	Diary No. Date of R& I & fee	Dy.No.118, 24-2-2015, Rs.20,000/-
	Pharmacological Group	Antihistamine/Antitussive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	120ml, 60 ml (As Per SRO)
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Triaminic DM Syrup of GSK (Reg#083966)
	GMP status	GMP inspection report dated 18-07-2018 which recommended the grant of cGMP certificate
	Previous remarks of the Evaluator.	• Letter dated 8, May, 2017 • GMP inspection is not within the period of last 1 year • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Provided reference is incorrect. Hydryllin DM also contain some other actives. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.
	Previous decision(s)	Deferred for fee for the change of formulation and for the evidence of applied new formulation/drug already approved by DRAP (generic / me-too status) and evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting (M-274). Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting (M-287).
	Evaluation by PEC	• The firm has changed its formulation and submitted a new dossier. • New composition is: Each 5ml contains:- Pseudoephedrine HCl…..30mg Dextromethorphan HBr…10 mg Photocopy of fee challan of Rs. 20,000/- (deposit slip # 0512895) dated 19-12-2017 has been submitted. Me-too reference: Triaminic DM Syrup of GSK

		(Reg#083966) International Reference: Almus Dry Cough Linctus with Decongestant (MHRA approved) Proposed Brand name: MINIC DM Syrup
	Decision: Registration Board deferred the case for further deliberation regarding change in composition of applied formulation.	
3310.	Name and address of manufacturer / Applicant	M/s. Rock Pharmaceutical Laboratories (Pvt) Ltd., Plot # 134-B & 135-B Nowshera Industrial Estate, Risalpur
	Brand Name +Dosage Form + Strength	Romylin Syrup
	Composition	Each 5ml contains:- Aminophylline…...…….32mg Diphenhydramine HCl……...8mg Ammonium Chloride……..30mg
	Diary No. Date of R& I & fee	Dy.No.117, 24-2-2015, Rs.20,000/-
	Pharmacological Group	Xanthine derivative /Antihistamine/Expectorant
	Type of Form	Form-5
	Finished product Specification	..
	Pack size & Demanded Price	120ml As Per SRO
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Triaminic Flu, Cough and Fever Syrup of Novartis (Reg#035413)
	GMP status	GMP inspection report dated 18-07-2018 which recommended the grant of cGMP certificate
	Previous remarks of the Evaluator.	• Letter dated 8, May, 2017 • GMP inspection is not within the period of last 1 year • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting. • Undertaking to conduct & submit stability studies along with data as per guidelines/requirements approved by the Registration Board.
	Previous decision(s)	
	Evaluation by PEC	• The firm has changed its formulation and submitted a new dossier New composition is: Each 5ml contains: Pseudoephedrine HCl..…….15 mg Dexomethorphan HBr….7.5 mg Paracetamol……..160 mg Chlorpheniramine……1mg Photocopy of fee challan of Rs. 20,000/- (deposit slip # 0512851) dated 19-12-2017 has been submitted. Me-too: Triaminic Flu, Cough and Fever Syrup of Novartis (Reg#035413) Int. reference: BENYLIN FOR CHILDREN ALL-IN-ONE COLD & FEVER (Health Canada approved) Website address: //health-products.canada.ca/dpd-

		bdpp/info.do?lang=en&code=79105 Proposed brand name: MINIC Syrup
	Decision: Registration Board deferred the case for further deliberation regarding change in composition of applied formulation.	
3311.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area Karach
	Brand Name +Dosage Form + Strength	Mesiline 400mg Tablet
	Composition	Each tablet contains: Mesalazine…….400mg
	Diary No. Date of R& I & fee	8,000/-, 31-05-2010, 12,000/- 08-05-2013
	Pharmacological Group	Intestinal anti-inflammatory agents (Aminosalicylic acid and similar agents)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per policy
	Approval status of product in Reference Regulatory Authorities.	ASACOL mesalazine 400mg enteric coated by M/s Emerge Health Pty Ltd (TGA approved)
	Me-too status	Mesacam 400mg EC Tablets by M/s Genome pharma (Reg#084212)
	GMP status	Last GMP inspection report dated 09-08-2018 confirming good compliance to GMP.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for product specific inspection by Area FID and Director DTL Karachi (M-248).
	Evaluation by PEC	In contrary to reference formulation which is available as enteric coated tablet, firm has applied plain tablet. Clarification/correction is required.
	Decision: Deferred for revision of formulation as per reference product alongwith applicable fee.	
3312.	Name and address of manufacturer / Applicant	M/s Lotus Pharmaceuticals, Plot # 118-A, St # 08, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Amolin Tablets 5mg
	Composition	Each uncoated tablet contains: Amlodipine besylate …….5mg
	Diary No. Date of R& I & fee	Dy. No.2679; 29-12-2014; Rs.20,000/- (26-12-2014)
	Pharmacological Group	Calcium antagonist
	Type of Form	Form-5
	Finished product Specification	Not provided
	Pack size & Demanded Price	2x10's; Rs.105/-
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Norvasc tablet 5mg of M/s Pfizer Pharmaceuticals
	GMP status	Last inspection was conducted on 27-02-2017 and the report concludes satisfactory compliance of GMP.
	Previous remarks of the Evaluator.	i. The firm has not provided the application with correct spelling of the applied drug and signature of the authorized person is also not available. ii. The applied drug is not mentioned as film-coated on Form-5. iii. Incomplete address of the firm is mentioned on Form-5 as industrial area is not mentioned. iv. Firm fails to provide the specifications of the applied product. v. Firm has not submitted the evidence of availability of the applied drug in reference regulatory authorities. vi. The firm has not submitted facility for water processing, environmental control processing and type of container/packaging i.e. Form -5 is incomplete.

	Previous decision(s)	• Deferred for following submissions: (M-273) • The firm has not provided the application with correct spelling of the applied drug and signature of the authorized person is also not available. • The applied drug is not mentioned as film-coated on Form-5.
	Evaluation by PEC	The firm has submitted revised Form-5 for uncoated tablet formulation alongwith submission of fee challan of Rs. 5000/- (deposit slip # 2012609 & 2016962) dated 02-01-2020.
	Decision: Approved with USP specifications.	
3313.	Name and address of manufacturer / Applicant	M/s Wilsons Pharmaceuticals, 387-388, I-9 Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Pathocin Suspension 250mg/5ml
	Composition	Each 5ml of suspension contains: Clarithromycin……250mg
	Diary No. Date of R& I & fee	Dy. No.4015; 27-12-2016; Rs.20,000/- (27-12-2016)
	Pharmacological Group	Antibacterial/ Macrolides
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Klaricid Paediatric of M/s Abbott Laboratories (UK)
	Me-too status	Maclacin of M/s Bosch Pharma
	GMP status	Last GMP was conducted on 24-10-2016 and the report concludes good level of GMP Compliance.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. Moreover, Registration Board also directed the firm to submit source of Clarithromycin granules along with relevant documents (M-277).
	Evaluation by PEC	The firm has submitted copy of GMP inspection report dated 24-01-2018 which concludes that Overall, the firm was found to be operating at a very good level of GMP compliance, at the time of inspection. Source of pellets: M/s Surge Laboratories (Pvt.) Ltd., Sheikhupura.
	Decision: Approved.	
3314.	Name and address of manufacturer / Applicant	M/s Cibex (Pvt) Limited, F-405, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Zolenta Capsules 500mg
	Composition	Each capsule contains:- Azithromycin as dihydrate……..500mg
	Diary No. Date of R& I & fee	Dated 30/04/14, Dy No: 631, 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	Pack of 6's/ As per PRC
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Azrowin of Wnsfield Pharmaceuticals
	GMP status	The firm is granted GMP certificate based on inspection conducted on 21st May, 2019.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for review of formulation by Review Committee

		(M-245).
	Evaluation by PEC	The firm has submitted fresh dossier and revised the dosage form from capsule to tablet alongwith submission of fee of PKR 20,000/- (deposit slip # 0788249) dated 24-02-2019. Each film coated tablet contains: Azithromycin as dihydrate……..500mg Int. availability: MHRA Approved Me-too: Azic 500mg Tablet by M/s NabiQasim Brand name: ZABIO Tablet
	Decision: Approved with following composition and USP specifications. **Each film coated tablet contains:** **Azithromycin as dihydrate……...500mg**	
3315.	Name and address of manufacturer / Applicant	M/s Cibex (Pvt) Limited, F-405, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Cibex ORS Solution (Bubble Gum flavor)
	Composition	Each ml contains: Sodium chloride……1.75g Trisodium citrate dihydrate……..1.45g Potassium chloride…….….0.75g Glucose anhydrous……10g
	Diary No. Date of R& I & fee	Dy No. 583, 30-4-2014, Rs.20,000/-
	Pharmacological Group	Electrolyte replacement agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml / As per PRC
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Pedialyte by Abbott
	GMP status	The firm is granted GMP certificate based on inspection conducted on 21st May, 2019.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for clarification whether the formulation contains preservative or otherwise (M-277)
	Evaluation by PEC	The firm has submitted that the product does not contain any preservative.
	Decision: Deferred for confirmation of method of terminal sterilization adopted by the firm.	
3316.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	RIBAN 20mg tablets
	Composition	Each film coated tablet contains: Rivaroxaban…….20mg
	Diary No. Date of R& I & fee	Dy. No.305; 16-03-2016; Rs.20,000/- (15-03-2016)
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Xarelto of M/s Bayer Health Care (Reg.# 072550)
	GMP status	Last GMP inspection report dated 02-01-2017 confirms good compliance to GMP
	Previous remarks of the Evaluator.	• Coating ingredients not mentioned in the master formulation. • No USP or BP monograph is available for applied formulation

	Previous decision(s)	Deferred for clarification of dosage form whether coated or uncoated as coating ingredients were not mentioned in the master formulation (M-274). Deferred for submission of fee for revision of formulation (M-291).
	Evaluation by PEC	The firm has submitted revised master formulation with film coating composition. The firm has submitted fee challan of PKR 5000/- (deposit slip # 0814038) dated 07-11-2019 for revision of formulation.
	Decision: Approved with innovator's specifications.	
3317.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	RIBAN 15mg tablets
	Composition	Each film coated tablet contains: Rivaroxaban……..….15mg
	Diary No. Date of R& I & fee	Dy. No.304; 16-03-2016; Rs.20,000/- (15-03-2016)
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Xarelto of M/s Bayer Health Care (Reg.# 072549)
	GMP status	Last GMP inspection report dated 02-01-2017 confirms good compliance to GMP
	Previous remarks of the Evaluator.	• Coating ingredients not mentioned in the master formulation. • No USP or BP monograph is available for applied formulation
	Previous decision(s)	Deferred for clarification of dosage form whether coated or uncoated as coating ingredients were not mentioned in the master formulation (M-274). Deferred for submission of fee for revision of formulation (M-291).
	Evaluation by PEC	The firm has submitted revised master formulation with film coating composition. The firm has submitted fee challan of PKR 5,000/- (deposit slip # 0814039) dated 07-11-2019 for revision of formulation.
	Decision: Approved with innovator's specifications.	
3318.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	RIBAN 10mg tablets
	Composition	Each film coated tablet contains: Rivaroxaban…….10mg
	Diary No. Date of R& I & fee	Dy. No.303; 16-03-2016; Rs.20,000/- (15-03-2016)
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Xarelto of M/s Bayer Health Care (Reg.# 059057)
	GMP status	Last GMP inspection report dated 02-01-2017 confirms good compliance to GMP

	Previous remarks of the Evaluator.	• Coating ingredients not mentioned in the master formulation. • No USP or BP monograph is available for applied formulation
	Previous decision(s)	Deferred for clarification of dosage form whether coated or uncoated as coating ingredients were not mentioned in the master formulation (M-274). Deferred for submission of fee for revision of formulation (M-291).
	Evaluation by PEC	The firm has submitted revised master formulation with film coating composition. The firm has submitted fee challan of PKR 5,000/- (deposit slip # 0814037) dated 07-11-2019 for revision of formulation.
	Decision: Approved with innovator's specifications.	
3319.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Neomet CR Tablet
	Composition	Each Tablet Contains: Doxylamine succinate……..…10mg Pyridoxine hydrochloride…….10mg
	Diary No. Date of R& I & fee	Dy.No 8893 (09-03-2018) Rs.20,000/- 08-03-2018
	Pharmacological Group	Aminoalkyl ethers in combination with vitamin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	3x10's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxylamine Succinate And Pyridoxine Hydrochloride (10/10) | ANDA #205811 | Tablet, Delayed Release;Oral | Prescription | Actavis Labs Fl Inc. Approved in USFDA
	Me-too status	Femiroz Tablet by M/s Efroze (Reg#061026)
	GMP status	26-07-2018 & 28-12-2018 Based on the areas inspected, the people met and documents reviewed and the panel unanimously recommended the renewal of DML 000773 by way of formulation of M/s Saibins Pharmaceuticals Islamabad.
	Previous remarks of the Evaluator.	• Firm has applied as film coated tablet whereas, formulation approved by USFDA is delayed release film-coated tablet. • Brand name needs to be changed as CR suggests controlled release.
	Previous decision(s)	Deferred for revision of formulation along with submission of requisite fee (M-290).
	Evaluation by PEC	The firm has submitted revised master formulation for controlled release tablet with submission of fee challan of PKR 5,000/- (deposit slip # 0814035) dated 07-11-2019. However, formulation approved by USFDA is delayed release film-coated tablet
	Decision: Deferred for revision of formulation as per reference product that is delayed release film coated tablet.	
3320.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	SAIFLOX 750mg tablet
	Composition	Each film coated tablet contains: Levofloxacin (as hemihydrate)……..…750mg
	Diary No. Date of R& I & fee	Dy. No.432; 21-03-2016; Rs.20,000/- (18-03-2016)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Tevoflox Tablets 750 mg of M/s Pearl Pharmaceuticals (068560)
	GMP status	26-07-2018 & 28-12-2018 Based on the areas inspected, the people met and documents reviewed and the panel unanimously recommended the renewal of DML 000773 by way of formulation of M/s Saibins Pharmaceuticals Islamabad.
	Previous remarks of the Evaluator.	Coating ingredients not mentioned in the master formulation.
	Previous decision(s)	Deferred for clarification of dosage form whether coated or uncoated as coating ingredients were not mentioned in the master formulation (M-274). Deferred for submission of fee for revision of formulation (M-291)
	Evaluation by PEC	The firm has submitted revised master formulation with Film coating composition. The firm has submitted fee challan of PKR 5000/- (deposit slip # 0814044) dated 07-11-2019.
	Decision: Approved.	
3321.	Name and address of manufacturer / Applicant	M/s. Dyson Research laboratories, Lahore
	Brand Name +Dosage Form + Strength	Maveric Tablets 200mg
	Composition	Each film coated tablet contains:- Mebeverine Hydrochloride ……200mg
	Diary No. Date of R& I & fee	Dy No. 9638, 14-10-2010, Fee.8000/-, 12000/-, 24-7-2014
	Pharmacological Group	Smooth muscle relaxant, Anti-spasmodic
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colofac MR tablets by Mylan (MHRA Approved)
	Me-too status	Despas tablets by S.J & G Fazul Ellahie
	GMP status	GMP inspection of M/s Dyson Research laboratories, lahore dated 11-01-2019 concluded that the firm has maintained satisfactory conformance to cGMP compliance in the manufacturing and Quality Control operations on the day of inspection.
	Previous remarks of the Evaluator.	• Coating ingredients not mentioned in the master formulation. • No USP or BP monograph is available for applied formulation
	Previous decision(s)	Deferred for clarification of the applied formulation whether it is in the form of MR tablet or not (M-265)
	Evaluation by PEC	The firm has submitted that applied formulation of our product is Modified Release Tablets.
	Decision: Deferred for submission of revised Form-5 and master formulation for change in formulation alongwith submission of fee of Rs. 20,000/- .	
3322.	Name and address of manufacturer / Applicant	M/s Hygeia Pharmaceuticals, 295, Industrial Triangles, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Direin 50mg Capsule
	Composition	Each capsule contains Diacerein……..…50mg
	Diary No. Date of R& I & fee	Rs. 20,000/-, Rs. 8000/- vide Dy.# 472 dated 27-06-2012

		Rs. 12000/-vide Dy#415 dated 20-02-2013
	Pharmacological Group	Anthraquinone Derivative
	Type of Form	Form-5
	Finished product Specification	In-house specification
	Pack size & Demanded Price	3x10's /as per SRO
	Approval status of product in Reference Regulatory Authorities.	Diacerein 50 mg hard capsule by M/s BIOGARAN (ANSM France Approved)
	Me-too status	Dibro 50mg capsules by M/s Winbrains Research Laboratories (Reg#071639).
	GMP status	GMP inspection report conducted on 21-09-2017 concludes that the firm is operating at satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Registration Board advised PE & R Division to evaluate already deferred cases of formulations containing Diacerin as per the checklist approved in 251st meeting (M-269).
	Evaluation by PEC	
	Decision: Keeping in view the approval status of Diacerein capsule 50mg by Austrian Agency for Health and Food Safety (reference regulatory authority as per decision of Registration Board in 249th meeting), the Registration Board approved the formulation of Diacerein 50mg capsule only for the following clinical indication. **□ Treatment of symptoms of osteoarthritis of the hip or knee joint.**	
3323.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries (Private) Limited, 17/24, Korangi Industrial Area, Korangi, Karachi.
	Brand Name +Dosage Form + Strength	Bacip Dry Suspension
	Composition	Each 5ml (after reconstitution) contains: Ciprofloxacin as HCl……..….250mg
	Diary No. Date of R& I & fee	31-12-2013 dated Dy.No.2086 Rs.20,000/-, 31-12-2013
	Pharmacological Group	Quinolones
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml,60ml As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ciproxin 250 mg/5 ml granules and solvent for oral suspension by M/s Bayer Healthcare, MHRA approved.
	Me-too status	Hiflox Dry suspension 250mg/5ml by M/s Hilton (Reg#067499)
	GMP status	M/s NabiQasim Pvt Ltd Karachi 02-08-2018 Conclusion: Based on the area inspected, people met, and documents reviewed and considering the finding of the inspection, M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of GMP requirements at the time of inspection.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for revision of formulation as per decision of 250th DRB meeting (M-250)
	Evaluation by PEC	The firm has submitted revised form-5 with Ciprofloxacin base as per reference product. Each 5ml (after reconstitution) contains: Ciprofloxacin (as taste masked granules) ……..….250mg Source of pellets: Ms Surge Laboratories, Sheikhupura. Fee challan of PKR 5000/- (deposit slip # 1964620) dated 24-09-2019 has been submitted.
	Decision: Approved with following composition: **Each 5ml (after reconstitution) contains:** **Ciprofloxacin (as taste masked granules) ……..….250mg**	

3324.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Brethease 100mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate……6mcg Budesonide……100mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective beta$_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Symbicort 100/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 100mcg + 6mcg capsule of M/s Highnoon
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications **(M-243)**: • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form. Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting **(M-289)**. Deferred for confirmation of manufacturing and testing facility for DPI as decided by registration Board in 290th meeting **(M-293)**.
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."* Approval status of applied formulation has been confirmed in MHRA. The firm has submitted as under : • We are using micronized material which is already DPI grade and hence specialized mixer not require to fine the material particle size and same is the industrial practice. (Refer to DRAP panel inspection report & materials CoA's in Annex 2.1 for details). • We have separate manufacturing facility for capsules (General) & capsules (steroidal). With necessary equipment's, mean-while a separate dispensing booth for steroidal dispensing also available. (Refer to DML panel inspection report in Annex 3.) • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade

		Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. (Revised FP specifications, test method and Cascade impactor qualification documents attached in Annex 4). • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. (Refer to Annex 1 for details). • We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly we also include target delivery dose in our product specifications. (Refer to Annex 4.1).
	Decision: Registration Board deferred the case for further deliberation in the light of decision of 290th meeting of Registration Board.	
3325.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Brethease 200mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate…….6mcg Budesonide…….200mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective $beta_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Symbicort 200/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 200mcg + 6mcg capsule of M/s Highnoon
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications (M-243): • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form. Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting (M-289). Deferred for confirmation of manufacturing and testing facility for DPI as decided by registration Board in 290th meeting **(M-293)**.
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."*

		Approval status of applied formulation has been confirmed in MHRA. The firm has submitted as under : • We are using micronized material which is already DPI grade and hence specialized mixer not require to fine the material particle size and same is the industrial practice. (Refer to DRAP panel inspection report & materials CoA's in Annex 2.1 for details). • We have separate manufacturing facility for capsules (General) & capsules (steroidal). With necessary equipment's, mean-while a separate dispensing booth for steroidal dispensing also available. (Refer to DML panel inspection report in Annex 3.) • We have revised the finished product specifications and testing method and include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution". We also arrange Andersen Cascade Impactor, USP apparatus 1 & 3 for these tests. Manufactured by Copley Scientific, UK. (Revised FP specifications, test method and Cascade impactor qualification documents attached in Annex 4). • We have Andersen Cascade impactor for determining the aerodynamic particle size of API in formulation blend in micron range. United States pharmacopoeia/British Pharmacopoeia recommend any one of the Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. (Refer to Annex 1 for details). We have mentioned our drug delivery device as CAPSUHALE in our submitted product specifications. Similarly we also include target delivery dose in our product specifications. (Refer to Annex 4.1)
	Decision: Registration Board deferred the case for further deliberation in the light of decision of 290th meeting of Registration Board.	
3326.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals (Pvt.) Ltd.,124/A Kahut Road, Industrial Triangle Zone, Islamabad
	Brand Name +Dosage Form + Strength	Dronate Tablets
	Composition	Each film coated tablet contains: Risedronate as Sodium……50mg
	Diary No. Date of R& I & fee	Dy. No.2752; 17-04-2015; Rs.20,000/- (15-04-2015)
	Pharmacological Group	Bisphosphonate
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; Not demanded
	Approval status of product in Reference Regulatory Authorities.	Risedronate Sodium Tablets by M/s TEVA UK, Ltd (MHRA Approved)
	Me-too status	Atconate 35mg tablets of M/s Atco labs
	GMP status	
	Previous remarks of the Evaluator.	➢ Shortcomings: • Latest GMP inspection report conducted within the period of last one year. • Clarification regarding quantity of API as salt and its equivalent weight as base.
	Previous decision(s)	Deferred for submission of following: (M-274) • Latest GMP inspection report conducted within last one year. • Clarification regarding quantity of API as salt and its

		equivalent weight as base.
	Evaluation by PEC	The firm has revised the strength of applied formulation as per reference as below: Each film coated tablet contains: Risedronate sodium……35mg Fee of Rs. 5000 (deposit slip # 1909489) dated 05-12-2019 has been submitted. Remaining fee of Rs. 15000/- is required for change in strength of applied formulation.
	Decision: Deferred for submission of differential fee of Rs. 15,000/- for change in strength of applied formulation.	
3327.	Name and address of manufacturer / Applicant	M/s Sapient Pharmaceuticals, 123/S Quaid-e-Azam industrial estate, Kot Lakhpat Lahore Contract manufacturing by M/s Bio Labs (Pvt) Ltd, Islamabad
	Brand Name +Dosage Form + Strength	Rose Mark Injection
	Composition	Each 5 ml ampoule contains:- Iron sucrose eq. to elemental iron……100mg
	Diary No. Date of R& I & fee	Dy. No. 642, 20-3-15, 50,000/-
	Pharmacological Group	Anti-anaemic
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	1's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Vortex 100mg/ 5ml injection of M/s Saturn Pharma (Reg # 071281)
	GMP status	Panel inspection of M/s Sapient Phamra dated 19-09-2019 and 18-11-2019 recommended renewal of DML. M/s Bio-Labs was granted GMP certificate based on inspection dated 23-04-2019.
	Previous remarks of the Evaluator.	• The firm has 6 sections (General Tablet, Oral liquid, ointment cream, external preparation, eye and ear drops and suppositories). • The firm has 4 products on contract manufacturing as per information verified from the registration section.
	Previous decision(s)	Deferred for clarification of salt form of API (M-277).
	Evaluation by PEC	The firm has revised salt form as below: Each 5 ml ampoule contains:- Iron(III)-hydroxide sucrose complex eq. to elemental iron……100mg Fee challan of Rs. 5000/- (deposit slip # 0146377) dated 01-02-2020 submitted for revision in formulation.
	Decision: Approved.	
3328.	Name and address of manufacturer / Applicant	M/s. Nimrall Laboratories, Plot #24. Street # S.S3,Rawat industrial zone, Islamabad
	Brand Name +Dosage Form + Strength	Cefpodom Dry Suspension
	Composition	When reconstituted each 5ml suspension contains: Cefpodoxime as proxetil……. 40mg
	Diary No. Date of R& I & fee	Dy No.1957, 20-04-2016, Rs.20,000/-
	Pharmacological Group	Third generation Cephalosporin
	Type of Form	Form-5
	Finished product Specification	AS per innovator
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefpodoxime 40mg/5ml granules for oral suspension by Milpharm Limited (MHRA)
	Me-too status	Xipodox 40mg /5ml by M/s. Vega Pharmaceuticals, Lahore
	GMP status	Last Inspection report 25-2-2016, 11-3-2016 The panel

		recommend for the issuance of GMP certificate
	Previous remarks of the Evaluator.	• Latest GMP inspection report (which should have been conducted within the period of last one year) missing • Dry powder and capsule (cephalosporin) section present
	Previous decision(s)	Deferred for latest GMP inspection report conducted within past one year (M-274). Deferred for rectification of shortcomings as reported in last inspection report (M-287).
	Evaluation by PEC	QA division vide letter No. F.4-17/2006-QA (Pt) dated 31st July, 2019 has informed that on the recommendations of panel, given in report dated 17-07-2019 & 24-07-2019 and subsequent approval by Director QA & LT, resumption of production was granted with immediate effect.
	Decision: Approved.	
3329.	Name and address of manufacturer / Applicant	M/s Medicraft Pharmaceuticals (Pvt) Ltd., Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Procidine Injection
	Composition	Each 2ml contains:- Procyclidine…….10mg
	Diary No. Date of R& I & fee	08-04-2013 vide diary No. 198 R&I, Rs.20,000/-
	Pharmacological Group	Anticholinergic agents
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved
	Me-too status	Epsent 10mg / 2ml by M/s Genetics.
	GMP status	Panel inspection dated 30-01-2018 concluded that the management of the firm promised that they would continue improvement. In the light of observation at the time of inspection, documents reviewed and representatives of the firm commitment, the firm may be considered to be operative in good level of cGMP compliance.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for confirmation of approval status by reference Regulatory authorities (M-258). Deferred for following: Clarification of primary packaging material whether ampoule or vial of applied formulation Confirmation of required manufacturing facility (M-293).
	Evaluation by PEC	The firm has submitted that we have applied for 2ml glass ampoule. The firm has provided Ampoule (General)/ infusion microdose for applied formulation. Panel inspection conducted on 21-03-2019 recommended grant of GMP certificate to the firm.
	Decision: Deferred for revision of formulation as per reference product that is as Procyclidine hydrochloride.	
3330.	Name and address of manufacturer / Applicant	M/s Medicraft Pharmaceuticals (Pvt) Ltd., Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Pizen Syrup
	Composition	Each 5ml contains:- Pizotifen (as hydrogen maleate)……....0.25mg
	Diary No. Date of R& I & fee	21-5-2012, Rs.8,000/-, Rs.12000/-, Dated 29-7-2013,
	Pharmacological Group	Anti-migraine
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	20's, Rs. 265/-
	Approval status of product in Reference Regulatory Authorities.	Sanomigran Elixir 0.25mg /5ml by M/s phoenix, (MHRA approve)
	Me-too status	Pizotifen By Novartis Pharma
	GMP status	Panel inspection dated 30-01-2018 concluded that the management of the firm promised that they would continue improvement. In the light of observation at the time of inspection, documents reviewed and representatives of the firm commitment, the firm may be considered to be operative in good level of cGMP compliance.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for: (M-262) Finished product specs. Last GMP inspection report conducted within 1 year. Commitment & undertaking as per 251st DRB meeting. Deferred for following: (M-286) • Clarification of pharmacological group. • Submission of finished product specifications. Registration Board referred the case to QA & LT division for updated GMP status of the firm on priority (M-292).
	Evaluation by PEC	The firm has submitted pharmacological group as "anti-migraine". The firm has claimed in-house specifications. The firm has submitted copy of panel inspection conducted on 21-03-2019 which recommends grant of GMP certificate to the firm.
	Decision: Approved with innovator's specifications.	
3331.	Name and address of manufacturer / Applicant	M/s Welwink Pharmaceuticals, Gujranwala Cantt.
	Brand Name +Dosage Form + Strength	Smacs CR12.5gm Tablet
	Composition	Each tablet contains: Paroxetine as HCl ……..12.5 mg
	Diary No. Date of R& I & fee	Dy. No. 4311; 13-03-2017; Rs.20,000/- (13-03-2017)
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO / 10's
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as extended release tablet
	Me-too status	Paroxin CR 12.5mg Tablet by M/s Sharooq Pharmaceuticals
	GMP status	Last GMP inspection was conducted on 20-12-2017 and the report concludes : "Firm was operating at satisfactory level of GMP compliance for all sections except Liquid Injectable section for which the firm was advised to provide Liquid Particle counter and TOC at earliest."
	Previous remarks of the Evaluator.	Film-coated & controlled/extended release is not mentioned on Form 5. Addition of Methylene chloride in master formulation needs justification.
	Previous decision(s)	Deferred for following (M-279): • Submission of master formulation & manufacturing method as per reference product. • Change of composition for film coating since methylene chloride is banned excipient. Deferred for submission of fee for revision of formulation

		(M-285). Deferred for submission of differential fee of Rs. 15,000/- for revision of formulation (M-293).
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation with following label claim: Each enteric, film coated controlled release tablet contains: Paroxetine as HCl……12.5mg The firm has submitted coating composition without methylene chloride The firm has deposited fee challan of Rs. 5,000/- (deposit slip # 2009655) dated 17-10-2019. The firm has submitted differential fee of Rs. 15000/- (deposit slip # 1981442) dated 04-05-2020.
	Decision: Approved with following composition: **Each enteric, film coated controlled release tablet contains:** **Paroxetine as HCl……12.5mg**	
3332.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi
	Brand Name +Dosage Form + Strength	Soseget Injection 30mg/ml
	Composition	Each 1ml ampoule contain: Pentazocine ……30mg
	Diary No. Date of R& I & fee	Dy No. 5150: 06-02-2019 PKR 20,000/-: 06-02-2019
	Pharmacological Group	Benzomorphan derivatives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5's /As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA Approved in PMDA as base
	Me-too status	Omsis 30mg/ml injection by SAMI Pharma (Reg#50746)
	GMP status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Previous remarks of the Evaluator.	Approval Status of Product in Reference Regulatory Authorities not confirmed.
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting (M-289). Deferred for revision of salt form of applied formulation as per reference product (M-292).
	Evaluation by PEC	The firm has submitted revised Form-5 with correct salt form as below: Pentazocin as lactate……30mg Fee of Rs. 5000/- (deposit slip # 1904524) dated 03-01-2020 for correction of salt form. Evidence of approval of applied formulation in reference country not verified.
	Decision: Deferred for confirmation of status in reference regulatory authorities	
3333.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	TALOSIN 0.4mg Capsules
	Composition	Each Capsule contains: Tamsulosin HCl …….0.4mg
	Diary No. Date of R& I & fee	Dy. No.1429;15-3-2017 ; Rs.20,000/- (15-3-2017)
	Pharmacological Group	alpha1-adrenoceptor blocker
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1x10's, As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Duodart Of GSK
	GMP status	Last GMP inspection was conducted on 10-04-2017 and the report concludes: "The firm is advised to keep and maintain all the consumption scale/storage record as per SOPs and intimate the undersigned upon consumption of raw material for verification and issue of consumption certificate".
	Previous remarks of the Evaluator.	●
	Previous decision(s)	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-293).
	Evaluation by PEC	Source of pellets: M/s Vision Pharmaceuticals, Islamabad Analytical procedure for tamsulosin pellets, stability studies of pellets, and GMP certificate of supplier has been submitted. GMP is not within period of three years.
	Decision: Registration Board referred the case to QA & LT to conduct GMP of the firm on priority.	
3334.	Name and address of manufacturer / Applicant	M/s MTI Medical (Pvt) Limited, 586-587 Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	CYTO Suspension
	Composition	Each 5ml (after reconstitution) contains: Ciprofloxacin (as taste masked granules)……..250mg Source of granules = M/s Vision Pharma, Islamabad.
	Diary No. Date of R& I & fee	Dy No: 1259 dated 20-10-2014, 20,000/-
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO/ 60ml bottle
	Approval status of product in Reference Regulatory Authorities.	Ciproxin 250 mg/5 ml granules and solvent for oral suspension by M/s Bayer Healthcare, MHRA approved.
	Me-too status	Hiflox Dry suspension 250mg/5ml by M/s Hilton (Reg#067499)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 25-09-2019.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred till review of formulation by Review Committee (M-249).
	Evaluation by PEC	The firm has revised formulation of Ciprofloxacin to base form as per reference instead of hydrochloride salt. Firm has also submitted 5,000 fee for revision of formulation. The firm has provided Oral Dry powder suspension section.
	Decision: Approved along with diluent as per innovator's product.	
3335.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Glu VID-500mg / 50mg Tablet
	Composition	Each film coated tablet contains: Metformin hydrochloride…….500mg Vildagliptin……..50mg
	Diary No. Date of R& I & fee	26745, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Biguanide / DPP-4 inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	2 ×7's; As per SRO
	Approval status of product in Reference	GALVUMET 50/500 film coated tablet by M/s Novartis

	Regulatory Authorities.	Pharma Ltd. Approved in TGA Australia.
	Me-too status	Galvus Met 50/500mg Tablets of M/s Novartis (Reg#078106)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Previous remarks of the Evaluator.	The firm has submitted revised master formulation and manufacturing outline without submission of fee.
	Previous decision(s)	Deferred for submission of fee for revision of formulation (M-291).
	Evaluation by PEC	The firm has deposited fee challan of Rs. 5000/- (deposit slip # 1955537) dated 15-10-2019 for revision of formulation.
	Decision: Approved with innovator's specifications with a shelf life of 18 months.	
3336.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Glu VID-1000mg / 50mg Tablet
	Composition	Each film coated tablet contains: Metformin hydrochloride…….1000mg Vildagliptin……..50mg
	Diary No. Date of R& I & fee	26757, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Biguanide / DPP-4 inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	2 ×7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/1000 film coated tablet by M/s Novartis Pharma Ltd. Approved in TGA Australia.
	Me-too status	Galvus Met 50/1000mg Tablets of M/s Novartis. (Reg#066107)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Previous remarks of the Evaluator.	The firm has submitted revised master formulation and manufacturing outline without submission of fee.
	Previous decision(s)	Deferred for submission of fee for revision of formulation (M-291).
	Evaluation by PEC	The firm has deposited fee challan of Rs. 5000/- (deposit slip # 1955538) dated 15-10-2019 for revision of formulation.
	Decision: Approved with innovator's specifications with a shelf life of 18 months.	
3337.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	EFFIBer TABLET 10mg
	Composition	Each film coated tablet contains: Prasugrel as hydrochloride……..……10mg
	Diary No. Date of R& I & fee	26755, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Platelet aggregation inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Effient (USFDA approved)
	Me-too status	Effin 10mg tablet of M/s Macter International, Karachi
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.

	Previous remarks of the Evaluator.	• Correction of salt form with requisite fee
	Previous decision(s)	Deferred for correction of salt form of applied formulation alongwith requisite fee (M-291).
	Evaluation by PEC	The firm has submitted revised form-5 with correct salt form alongwith fee challan of Rs. 5000/- (deposit slip # 1955540) dated 15-10-2019 for revision of formulation.
	Decision: Approved with innovator's specifications.	
3338.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	OMJET-40 CAPSULE
	Composition	Each capsule contains: Omeprazole (as enteric coated pellets)……..40mg
	Diary No. Date of R& I & fee	26744, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP specs
	Pack size & Demanded Price	2 ×7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA
	Me-too status	Acizole Capsule 40mg by M/s Cirin Pharmaceuticals, (Reg# 034369)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Previous remarks of the Evaluator.	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets is required to be submitted.
	Previous decision(s)	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-291).
	Evaluation by PEC	The firm has submitted that source of pellets already approved for our product which is as: Source of pellets: M/s Smilax Laboratories Ltd, India
	Decision: Deferred for submission of differential fee of Rs. 80,000/- since source is of imported pellets.	
3339.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	EFFIBer TABLET 5mg
	Composition	Each film coated Tablet contains: Prasugrel as hydrochloride……5mg
	Diary No. Date of R& I & fee	26720, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Antiplatelet
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Eficlot Tablet 5mg of CCL Pharma (Reg#067765)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Previous remarks of the Evaluator.	• Correction of salt form with requisite fee
	Previous decision(s)	Deferred for correction of salt form of applied formulation alongwith requisite fee (M-291).
	Evaluation by PEC	The firm has submitted revised form-5 with correct salt form alongwith fee challan of Rs. 5000/- (deposit slip #

		1955540) dated 15-10-2019 for revision of formulation.
	Decision: Approved with innovator's specifications.	
3340.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerZINE TABLET 10mg
	Composition	Each film coated Tablet contains: Cetirizine Dihydrochloride……10mg
	Diary No. Date of R& I & fee	26729, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Antihistamines
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cetec 10 mg film-coated tablets by M/s Bristol Laboratories Ltd (MHRA Approved)
	Me-too status	RIGIX 10mg TABLET by M/s GLAXO (Reg#011248)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Previous remarks of the Evaluator.	• The firm has submitted revised Form-5 with correct label claim.
	Previous decision(s)	Deferred for submission of fee for revision of formulation (M-291).
	Evaluation by PEC	The firm has submitted fee of Rs. 5000/- (deposit slip # 1955541) dated 15-10-2019 for revision of formulation.
	Decision: Approved.	
3341.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	MEDIFEN-50 CAPSULE
	Composition	Each Capsule Contains: Diclofenac sodium (as enteric coated pellets)……50mg
	Diary No. Date of R& I & fee	26725, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by HPRA of Ireland
	Me-too status	Phlogin 50mg capsules of M/s Brookes pharma
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Previous remarks of the Evaluator.	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets is required to be submitted.
	Previous decision(s)	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-291).
	Evaluation by PEC	The firm has submitted following: Source of pellets : M/s Smilax Laboratories Ltd, India
	Decision: Deferred for submission of differential fee of Rs. 80,000/- since source is of imported pellets.	
3342.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	ARY 200mg/5ml Dry Suspension
	Composition	Form-5 Dy.No 41063 dated 06-12-2018 Rs.20,000/- Dated

		06-12-2018
	Diary No. Date of R& I & fee	Each 5ml reconstituted suspension contains: Acyclovir…200mg
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	USP (oral suspension)
	Pack size & Demanded Price	60ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zovirax Suspension 200mg/5ml by M/s Mylan Pharma Inc.(USFDA Approved)
	Me-too status	Acylex Suspension 200mg/5ml by M/s Ferozsons Labs (Reg#012684)
	GMP status	19-09-2018 Grant of Additional sections Panel Recommended grant of additional sections
	Previous remarks of the Evaluator.	• Availability of applied formulation as Powder for suspension could not be confirmed from Reference Regulatory Authorities and available me too database
	Previous decision(s)	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm Deferred for evidence of required manufacturing facility i.e., Oral liquid section since the firm has revised dosage from dry powder suspension to liquid suspension (M-293).
	Evaluation by PEC	The firm has submitted form-5 with revised dosage form from dry suspension to oral suspension alongwith submission of fee challan of Rs. 20,000/- (deposit slip # 1932263) dated 10-12-2019. Each 5ml suspension contains : Acyclovir……..…200mg The firm has provided section approval letter for oral liquid (General) section.
	Decision: Approved with following composition: **Each 5ml contains :** **Acyclovir……..…200mg**	
3343.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd.Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	SEDOX 400mg Capsule
	Composition	Diary No:8007 ,07/07/2017 , Rs: 20,000/-
	Diary No. Date of R& I & fee	Each Capsule Contains: Ceftibuten (as dihydrate)…400mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	ISOCEF 400 mg (containing ceftibuten base) capsule rigide by Exeltis Poland Sp. z o.o., approved by AIFA, Italy
	Me-too status	Xigris 400mg capsule by Wilshire/Horizon (Reg#053635)
	GMP status	30-03-2017; Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	• Applied formulation is discontinued in USFDA.
	Previous decision(s)	Deferred for evidence of approval of applied formulation by

		reference regulatory authorities (M-274).
	Evaluation by PEC	Approval status of applied formulation has been confirmed in AIFA, Italy
	Decision: Approved with innovator's specifications.	
3344.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd.Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Lapanib tablet 250mg
	Composition	Each film coated tablet contains: Lapatinib (as ditosylate monohydrate)…… 250 mg
	Diary No. Date of R& I & fee	Dy. No. 8182, 10-07-2017, Rs. 20,000/-
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	70's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved In US-FDA
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted 30-03-2017 Wherein Panel recommends grant of Additional Sections, including the "Capsule (Oncology)".
	Previous remarks of the Evaluator.	Applied formulation is not present in available USP and BP.
	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-274).
	Evaluation by PEC	The firm has submitted me too reference Tykerb Tablets 250mg by GSK (Reg # 059030) which has been verified from available database.
	Decision: Approved with innovator's specifications.	
3345.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 69/2 phase 2 industrial area, Hattar.
	Brand Name +Dosage Form + Strength	Tranxam 250mg Capsule
	Composition	Each capsule contains:- Tranexamic acid…….250mg
	Diary No. Date of R& I & fee	Dy No. 40, 29-12-2010, Rs.8000/-, Rs.12000/-,17-11-2014
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Aneptil 250mg capsules of M/s Alina Combine Pakistan (Reg. # 020510)
	GMP status	Last GMP inspection was conducted on 15-09-2017 and the report concludes the firm to be GMP compliant.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for evidence of approval status in reference regulatory authorities in capsule dosage form (M-263).
	Evaluation by PEC	The approval status of applied formulation has been confirmed in AIFA. Registration Board approved the case in 293rd meeting however, the strength of the formulation was mistakenly written as 500mg instead of 250mg. Accordingly correction has been made and placed before the Board for consideration.
	Decision: Approved with innovator's specifications.	
3346.	Name and address of manufacturer /	M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial

	Applicant	Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	OCTERO 0.05mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Octreotide (as acetate)……0.05mg
	Diary No. Date of R& I & fee	Diary No:8686, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Somatostatin analogue (Cytostatics)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Pack of 5 Amp x 1ml, MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	SANDOSTATIN (octreotide acetate)50mcg injection, solution by M/s Novartis Pharmaceuticals Corporation **(USFDA Approved)**
	Me-too status	Sandostatin 0.05mg injection by Novartis (Reg. No. 013473)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of the applied product in Liquid Ampoule (Oncology) section as applied product is not cytotoxic anti-cancer. Moreover, source of Octreotide (synthetic or biological) shall be submitted by the applicant along with relevant documents (M-275). Deferred for clarification of origin of API whether biological source or synthetic (M-287). Registration Board deferred the case for further delibration regarding source of API (M-289).
	Evaluation by PEC	The firm is granted GMP certificate based on inspection conducted on 17-03-2017. The firm has submitted that API source is BCN peptides, SPAIN and Octreotide produced by BCN peptides is claimed as synthetic origin material. (Declaration from BCN peptides, Spain and Certificate of analysis of is attached herewith).
	Decision: Registration Board deferred the case for confirmation of source of API whether biological or synthetic.	
3347.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	OCTERO 0.1mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Octreotide (as acetate)……0.1mg
	Diary No. Date of R& I & fee	Diary No:8685, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Somatostatin analogue (Cytostatics)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Pack of 5 Amp x 1ml, MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	SANDOSTATIN (octreotide acetate)100mcg injection, solution by M/s Novartis Pharmaceuticals Corporation (USFDA Approved)
	Me-too status	Sandostatin 0.1mg injection by Novartis (Reg. No. 013472)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of

		the applied product in Liquid Ampoule (Oncology) section as applied product is not cytotoxic anti-cancer. Moreover, source of Octreotide (synthetic or biological) shall be submitted by the applicant along with relevant documents (M-275). Deferred for clarification of origin of API whether biological source or synthetic (M-287). Registration Board deferred the case for further delibration regarding source of API (M-289).
	Evaluation by PEC	The firm is granted GMP certificate based on inspection conducted on 17-03-2017. The firm has submitted that API source is BCN peptides, SPAIN and Octreotide produced by BCN peptides is claimed as synthetic origin material. (Declaration from BCN peptides, Spain and Certificate of analysis of is attached herewith).
	Decision: Registration Board deferred the case for confirmation of source of API whether biological or synthetic.	

Case no. 02 Registration applications of import cases

c. Deferred Cases (Human)

3348.	Name and address of Applicant	M/s Zam Zam pharmaceuticals suit # 16, Beaumont Road, 6-cl-10 Beaumont Road, Karachi.
	Detail of Drug Sale License	Address: M/s Zam Zam pharmaceuticals suit # 16, Beaumont Road, 6-cl-10 Beaumont Road, Karachi Validity: 15-Feb-2020 Status: Drug License by Way of wholesale
	Name and address of manufacturer	**Manufacture of Bulk product:** M/S Rottendorf pharma, GmbH ostenfelder dstraBe 51-6159320,enigerloh Germany **Packing of the finished product:** M/s Rottendorf pharma, GmbH ostenfelder dstraBe 51-6159320,enigerloh Germany **Quality testing and the quality release of the finished product:** M/s Medinova AG, eggbuhlstr 28 8050 zurich Switzerland **Microbiological quality testing:** M/s Labor Zollinger AG scarenmoostr 105 8050 zurich Switzerland M/s Labor LS SE & Co. KG mangelsfeld 4-6 97708 Bad Bocklet Germany
	Name and address of marketing authorization holder (Product license holder)	M/s Pierre fabre pharma gmbH Jechtinger str.13 79111 Freiburg Germany
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.29861 Dated 5-9-2018
	Fee including differential fee	Rs. 50,000/- Dated 3-9-20178
	Brand Name +Dosage Form + Strength	Fluomizin vaginal tablet
	Composition	Each tablet Contains: Dequalinium chloride ……10 mg
	Finished Product Specification	Manufacturer
	Pharmacological Group	Gynecological anti-infective and antiseptic.
	Shelf life	36 months

	Demanded Price	Rs. 1705/-
	Pack size	1 blister (PVC/PE/PVdc) of 6 vaginal tablet
	International availability	Fluomizin 10 mg vaginal tablets (MHRA approved)
	Me-too status	NA
	Detail of certificates attached	**CoPP** Original legalized CoPP confirms free sale status in the exporting country With following details: Certificate No: Pierre fabre phrma-005-2017 Certifying Authority: Regierungsprasidium Tubingen Leitstelle Arzneimitteluberwachung Baden-Wurttemberg Konrad-Adenauer-Strasse 20 D-72072 Tubingen Date of issue: 13-October-2017 **Letter of authorization** The firm has submitted notarized copy of letter of authorization between Medinova, AG Switzerland and Zam Zam pharmaceuticals Issue Date: 7-June 2018
	Remarks of the Evaluator.	The firm has submitted Stability study data for following 3 batches as per Zone IV-B conditions. 380088 380098 380152 Upon clarification, the firm has submitted that Medinova AG is the marketing authorization holder in Switzerland. Pierre fabre pharma GmbH located at Germany is the distribution partner of Medinova AG for Fluomizin Vaginal Tablets. Pierre fabre pharma GmbH is the marketing authorization holder in Germany and therefore the CoPP issued by German authorities is indicating Pierre Fabre GmbH as the product licence holder.
	Deferred for clarification regarding details of marketing authorization holder of applied formulation (M-291). **Evaluation by PEC:** The firm has submitted clarification from principal as below: "We, Medinova AG, located at Eggbühlastrasse 28, 8050 Zürich confirm that Medinova AG is the product owner of Floumizin vaginal tablets that is marketed currently in 60 countries. Medinova AG is the marketing authorization holder in Switzerland, however, has licensed the distribution of Fluomizin vaginal tablets to pharmaceutical companies in different countries. The collaboration between Medinova AG and Pierre fabre pharma GmbH is defined in distribution agreement like the one with Zam Zam Pharmaceuticals, our distribution partner for Pakistan. Pierre fabre pharma GmbH is the marketing authorization holder in Germany and therefore the CoPP issued by German authorities is indicating Pierre Fabre GmbH as the product licence holder."	
	Registration Board deferred the case for clarification regarding details of marketing authorization holder of applied product (M-292). **Evaluation by PEC:** The firm has submitted copy of CoPP (certificate No. 20001403) issued on 23/03/2020. According to which the product is available in market of exporting country and GMP is as per WHO recommendation. The firm has submitted that they will submit original legalized CoPP at the time of issuance of letter and has clarified that the product License holder is M/s Medinova AG, Switzerland which is true according to submitted copy of CoPP. **Following details were provided in the CoPP** **Name and address of Product licence holder:** M/s Medinova AG, Eggbuhlstr 28 CH-8050 Zurich Switzerland **Name and address of manufacturer:**	

	M/S Rottendorf pharma, GmbH Ostenfelder str 51-61 DE-59320,Enigerloh Germany **Exporting Country:** Switzerland **Letter of authorization** The firm has submitted notarized copy of letter of authorization between Medinova, AG Switzerland and Zam Zam pharmaceuticals Issue Date: 7-June 2018 **Additional manufacturers** **A. Active pharmaceutical Ingredient (API)** **----------X----------** **B. Packaging** M/S Rottendorf pharma, GmbH Am Fleigendahl 3 DE-59320,Enigerloh Germany **C. Analysis** M/s Medinova AG, Eggbuhlstr 28 CH-8050 zurich Switzerland M/s Labor Zollinger AG Scharenmoostr 105 CH-8050 zurich Switzerland **D. Batch release** M/s Medinova AG, Eggbuhlstr 28 CH-8050 zurich Switzerland The firm has submitted of Fee of Rs. 5000/- (deposit slip # 0789383) dated 19-05-2020 for variation in application. The firm has submitted Revised Form-5A with correct address of manufacturer and applicant.
	Decision: Approved as per policy for inspection of manufacturer abroad.

Case no. 03 Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

3349.	Name and address of manufacturer / Applicant	M/s Scilife Pharma (Pvt.) Limited., Plot # FD-57/58-A2, Korangi Creek Industrial park, Karachi
	Brand Name +Dosage Form + Strength	INTREZTU 24/26mg Tablet
	Composition	Each film coated tablet contains: Sacubitril…….24mg Valsartan ……26mg
	Diary No. Date of R& I & fee	05, 13-03-2017, 50,000/-, 13-03-2017
	Pharmacological Group	Angiotensin II Receptor Blockers
	Type of Form	Form-5
	Finished Product Specification	Manufactuer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	N/A
	GMP status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines
	Remarks of Evaluator	

STABILITY STUDY DATA			
Drug	INTREZTU 24/26mg Tablet		
Name of Manufacturer	M/s Scilife Pharma (Pvt.) Limited., Plot # FD-57/58-A2, Korangi Creek Industrial park, Karachi		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd, China, Address: No.2, Tonghai Si Ro ad, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china		
API Lot No.	201612001		
Description of Pack (Container closure system)	Alu Alu Blister with unit carton		
Stability Storage Condition	Accelerated: $40^{o}C \pm 2^{o}C/75\%\pm5\%$ RH Real Time: $30^{o}C \pm 2^{o}C/65\%\pm5\%$ RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Real Time: 0,1,3,6 (06months) Accelerated: 0,1,3,6 (06 months)		
Batch No.	182B18	197B18	198B18
Batch Size	2500 Tablets	1250 Tablets	1250 Tablets
Manufacturing Date	22-10-2018	23-11-2018	23-11-2018
Date of Initiation	10-01-2019	10-01-2019	10-01-2019
No. of Batches	03		
Date of Submission	25236 (27-11-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	Copy of COA (Batch# 201612001) from M/s Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued to M/s Nantong Chanyoo Pharmatech Co., Ltd, China by Nantong Food and Drug administration. Valid up to 07-09-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice attested by ADC, DRAP, Karachi dated 26-01-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response of the firm
1.	GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority is required.	As the China Food and Drug Administration (CFDA) has closed the issuance of cGMP since January 2019. Instead, the city FDA that is Nantong Food and Drug Administration issues the provided cGMP having validity 07-09-2020. Moreover, the firm has enclosed the copy of Drug manufacturing license issued by provincial FDA has been submitted.
2.	Justify dissolution specifications NLT 80% (Q) in 45 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min	The firm has submitted that based on scientific rationale, we have revised dissolution specifications of our subject product range i.e., NLT 80% (Q+5%) in 25 min in line with USFDA approved product Entresto and performed onward stability study on this revised specification. A complete study report on dissolution study is enclosed.

3350.	Name and address of manufacturer / Applicant	M/s Scilife Pharma (Pvt.) Limited., Plot # FD-57/58-A2, Korangi Creek Industrial park, Karachi
	Brand Name +Dosage Form + Strength	INTREZTU 49/51mg Tablet
	Composition	Each film coated tablet contains: Sacubitril…….49mg Valsartan ……51mg
	Diary No. Date of R& I & fee	06, 13-03-2017, 50,000/-, 13-03-2017
	Pharmacological Group	Angiotensin II Receptor Blockers
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	**USFDA approved**
	Me-too status	N/A
	GMP status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines

	Remarks of Evaluator	

STABILITY STUDY DATA

Drug	INTREZTU 49/51mg Tablet		
Name of Manufacturer	M/s Scilife Pharma (Pvt.) Limited., Plot # FD-57/58-A2, Korangi Creek Industrial park, Karachi		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd, China, Address: No.2, Tonghai Si Ro ad, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china		
API Lot No.	201612001		
Description of Pack (Container closure system)	Alu Alu Blister with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Real Time: 0,1,3,6 (06months) Accelerated: 0,1,3,6 (06 months)		
Batch No.	183B18	199B18	200B18
Batch Size	2500 Tablets	1250 Tablets	1250 Tablets
Manufacturing Date	22-10-2018	23-11-2018	23-11-2018
Date of Initiation	10-01-2019	10-01-2019	10-01-2019
No. of Batches	03		
Date of Submission	25237 (27-11-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# 201612001) from M/s Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued to M/s Nantong Chanyoo Pharmatech Co., Ltd, China by Nantong Food and Drug administration. Valid up to 07-09-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice attested by ADC, DRAP, Karachi dated 26-01-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response of the firm
1.	GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority is required.	As the China Food and Drug Administration (CFDA) has closed the issuance of cGMP since January 2019. Instead, the city FDA that is Nantong Food and Drug Administration issues the provided cGMP having validity 07-09-2020. Moreover, the firm has enclosed the copy of Drug manufacturing license issued by provincial FDA has been submitted.
2.	Justify dissolution specifications NLT 80% (Q) in 45 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min	The firm has submitted that based on scientific rationale, we have revised dissolution specifications of our subject product range i.e., NLT 80% (Q+5%) in 25 min in line with USFDA approved product Entresto and performed onward stability study on this revised specification. A complete study report on dissolution study is enclosed.

3351.	Name and address of manufacturer / Applicant	M/s Scilife Pharma (Pvt.) Limited., Plot # FD-57/58-A2, Korangi Creek Industrial park, Karachi
	Brand Name +Dosage Form + Strength	INTREZTU 97/103mg Tablet
	Composition	Each film coated tablet contains: Sacubitril…….97mg Valsartan ……103mg
	Diary No. Date of R& I & fee	912, 21-03-2017, 50,000/-, 08-03-2017
	Pharmacological Group	Angiotensin II Receptor Blockers
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	**USFDA approved**
	Me-too status	N/A
	GMP status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines
	Remarks of Evaluator	

STABILITY STUDY DATA

Drug	INTREZTU 97/103mg Tablet		
Name of Manufacturer	M/s Scilife Pharma (Pvt.) Limited., Plot # FD-57/58-A2, Korangi Creek Industrial park, Karachi		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd, China, Address: No.2, Tonghai Si Ro ad, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china		
API Lot No.	201612001		
Description of Pack (Container closure system)	Alu Alu Blister with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Real Time: 0,1,3,6 (06months) Accelerated: 0,1,3,6 (06 months)		
Batch No.	184B18	201B18	200B18

Batch Size	1250 Tablets	625 Tablets	625 Tablets
Manufacturing Date	22-10-2018	23-11-2018	23-11-2018
Date of Initiation	10-01-2019	10-01-2019	10-01-2019
No. of Batches	03		
Date of Submission	25238 (27-11-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# 201612001) from M/s Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued to M/s Nantong Chanyoo Pharmatech Co., Ltd, China by Nantong Food and Drug administration. Valid up to 07-09-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice attested by ADC, DRAP, Karachi dated 26-01-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response of the firm
1.	GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority is required.	As the China Food and Drug Administration (CFDA) has closed the issuance of cGMP since January 2019. Instead, the city FDA that is Nantong Food and Drug Administration issues the provided cGMP having validity 07-09-2020. Moreover, the firm has enclosed the copy of Drug manufacturing license issued by provincial FDA has been submitted.
2.	Justify dissolution specifications NLT 80% (Q) in 45 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min	The firm has submitted that based on scientific rationale, we have revised dissolution specifications of our subject product range i.e., NLT 80% (Q+5%) in 25 min in line with USFDA approved product Entresto and performed onward stability study on this revised specification. A complete study report on dissolution study is enclosed.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Intreztu 24/26mg, 49/51mg and 97/103mg (Sacubitril + Valsartan) Tablets by M/s. Scilife Pharma (Pvt) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi.

Reference No: F.1-2/2020-PEC dated 22nd April, 2020.
Investigation Date and Time: 05-05-2020 (Morning).
Investigation Site: Factory premises of M/s. Scilife Pharma (Pvt) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi.
Background:
Registration Board meeting considered the applications of M/s. Scilife Pharma (Pvt) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi for registration of Intreztu 24/26mg, 49/51mg and 97/103mg (Sacubitril + Valsartan) Tablets. Registration Board considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm as per decision of Registration Board and to submit report for further consideration.
Composition of Panel:

4. Mr. Syed Adnan Rizvi, Director, Drug Testing Laboratory, Government of Sindh, Karachi.
5. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
6. Dr. Krishan Das, Assistant Director, DRAP, Karachi.

Scope of investigation:
Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.
Tools for Investigation:
The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API?	Firm has imported 2.0 kg Sacubitril + Valsartan trisodium hemipentahydrate (LCZ696) from M/s Nantong Chanyoo Pharmatech Co. Ltd, China having Invoice No CY116378 Dated: 29-12-2016, Batch number 201612001 and material is cleared by DRAP Karachi on 26-01-2017.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation criteria being implemented by the firm. The parameters included in this criteria are, DMF status, GMP certificate, Stability data, provision of reference standard of API and impurities standards etc. The source is already qualified with respect to NDMA & NEMA. The firm has evaluated on these criteria and selected accordingly.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has documents confirming the import of reference standard of the API having invoice number CY118172 dated 13-06-2018 while impurity standards received directly from manufacturer.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis of the API, reference standard and impurities standards.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has GMP certificate of API manufacturer issued by NANTONG FOOD AND DRUG ADMINISTRATION CHINA (Valid till 07-09-2020).
6.	Do you use API manufacturer method of testing?	Firm has used API manufacturer`s method for testing Sacubitril + Valsartan API (LCZ696).
7.	Do you have stability studies reports on API?	Firm has stability studies reports on API as provided by the manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed as per Stability Indicating Method (SIM) and impurities/related substances/degradation products quantified.

<table>
<tr><td>9.</td><td>Do you have method for quantifying the impurities in the API?</td><td>The firm has method for quantifying the impurities in the API. The method has been provided by the API manufacturer.</td></tr>
<tr><td>10.</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>The firm has remaining quantities of the API, reference standards of API and impurities standards.</td></tr>
<tr><td>11.</td><td>Have you used pharmaceutical grade excipients?</td><td>Firm has used pharmaceutical grade excipients including Microcrystalline Cellulose 102, Crospovidone, Magnesium Stearate, Talcum Powder, Aerosil 200, Hydroxy propyl cellulose low substituted, PEG 6000, HPMC 6CPs, Titanium dioxide and Ferric Oxide Red.</td></tr>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>Firm has purchased some excipients from the local market and other imported. Necessary documents available and the certificate of analysis for all the excipients available.</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>Firm has test reports and other records on the excipients used.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of the product?</td><td>Firm has written and authorized protocol for the development of the product.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipients compatibility studies?</td><td>Firm has not performed Drug-excipients compatibility studies as their formulation is similar to that of the innovator formulation (Entresto Tablets).</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with Entresto 24/26 mg, 49/51mg and 97/103mg tablets of M/S. Novartis Europharm limited UK. All strengths of the firm‘s product results are comparable to that of the Reference product strengths which are given below,
Strength: 24/26mg tablets:
<table>
<tr><td>Reference Product</td><td colspan="2">Entresto Tablets</td></tr>
<tr><td>Batch number / EXP.</td><td colspan="2">TK479 / EXP. 05/2020</td></tr>
<tr><td>Strength</td><td>24mg (Sacubitril)</td><td>26mg (Valsartan)</td></tr>
<tr><td>CPD Results Obtained</td><td></td><td></td></tr>
<tr><td>Similarity Factor at pH 1.2</td><td>55.51</td><td>58.20</td></tr>
<tr><td>Similarity Factor at pH 4.5</td><td>59.74</td><td>61.05</td></tr>
<tr><td>Similarity Factor at pH 6.8</td><td>51.66</td><td>53.36</td></tr>
<tr><td>Limit</td><td>F2 ≥ 50</td><td>F2 ≥ 50</td></tr>
<tr><td>Remarks</td><td>Satisfactory</td><td>Satisfactory</td></tr>
</table>
Strength: 49/51mg tablets:
<table>
<tr><td>Reference P oduct</td><td colspan="2">Entres o Tablets</td></tr>
<tr><td>Bat h number / EXP.</td><td colspan="2">TJ910 / EXP. 04/2020</td></tr>
<tr><td>Strength</td><td>49mg (Sacu itril)</td><td>51mg (Valsartan)</td></tr>
<tr><td>C D Results Obtained</td><td></td><td></td></tr>
<tr><td>Similarity Factor at pH 1.2</td><td>6.71</td><td>68.02</td></tr>
<tr><td>Similarity Factor at pH 4.5</td><td>63.05</td><td>61.44</td></tr>
<tr><td>Similarity Factor at pH 6.8</td><td>54.33</td><td>55.58</td></tr>
<tr><td>Limit</td><td>F2 ≥ 50</td><td>F2 ≥ 50</td></tr>
<tr><td>Re arks</td><td>Satisfactory</td><td>Satisfactory</td></tr>
</table>
Strength: 97/103mg tablets:
<table>
<tr><td>Reference Product</td><td>Entre to Tablets</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>Batch number / EXP.</td><td colspan="2">TL308 / EXP. 06/20 0</td></tr>
<tr><td>Strength</td><td>97mg (Sacubitril)</td><td>103mg (Valsartan)</td></tr>
<tr><td>CPD Results Obtained</td><td></td><td></td></tr>
<tr><td>Similarity Factor at pH 1.</td><td>68. 0</td><td>74.69</td></tr>
<tr><td>Similarity Factor at pH 4.5</td><td>77.59</td><td>78.32</td></tr>
<tr><td>Similarity Factor at pH 6.8</td><td>51.27</td><td>51.88</td></tr>
<tr><td>Limit</td><td>F2 ≥ 50</td><td>F2 ≥ 50</td></tr>
<tr><td>Remarks</td><td>Satisfactory</td><td>Satis actory</td></tr>
</table>
</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section?</td><td>The firm has dedicated product development (R&D) section.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment's available in product development section for development of the product?</td><td>Firm has necessary equipment for production of tablets in product development section.</td></tr>
<tr><td>19.</td><td>Are the equipment's in product development section qualified?</td><td>Equipment in product development section are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>Firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has trained and qualified staff in product development section including two pharmacists and three chemists, with proper knowledge and training in product development.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of the product as required?</td><td>The firm has manufactured three stability batches for the stability studies of Intreztu 24/26mg, Intreztu 49/51mg tablets and Intreztu 97/103mg tablets respectively. The details are given below,
<table>
<tr><td rowspan="2">S. #</td><td colspan="2">Intreztu 24/26mg,</td><td colspan="2">Intreztu 49/51mg,</td><td colspan="2">Intreztu 97/103mg,</td></tr>
<tr><td>B. No.</td><td>B. Size</td><td>B. No.</td><td>B. Size</td><td>B. No.</td><td>B. Size</td></tr>
<tr><td>1</td><td>182B18</td><td>2,500</td><td>183B18</td><td>2,500</td><td>184B18</td><td>1,250</td></tr>
<tr><td>2</td><td>197B18</td><td>1,250</td><td>199B18</td><td>1,250</td><td>201B18</td><td>625</td></tr>
<tr><td>3</td><td>198B18</td><td>1,250</td><td>200B18</td><td>1,250</td><td>202B18</td><td>625</td></tr>
</table>
</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches, as informed by the firm, was based on the quantity required for stability study (i.e. number of tablets per testing frequency and number of testing frequencies / intervals).</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>Firm has complete record of production of stability batches.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>Firm has detailed protocol for stability testing of stability batches.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The Firm has developed and performed detailed analytical method validation studies for testing of stability batches.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>Firm has not conducted method transfer studies, however, they have validated their method properly.</td></tr>
</table>

28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug.
29.	Do your method of analysis stability indicating?	Firm's method of analysis is stability indicating as evidenced by records of forced degradation and impurities spiking studies.
30.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record of the firm. Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available.
31.	Can you show Audit Trail reports on product testing?	Audit trail reports were available and randomly checked.
32.	Do you have some remaining quantities of degradation products and stability batches?	Firm has remaining quantities of stability batches.
33.	Do you have stability batches kept on stability testing?	Firm has completed the accelerated stability testing on the three stability batches of every strength however the real time stability testing is in progress on all the stability batches. Currently 12 months' study has been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment's used in production and analysis?	Firm has valid calibration status for the equipment used in production and analysis of the product.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
36.	Do related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities are rated as GMP compliant.
37.	To verify whether the firm has revised their dissolution specification as per innovator in the finished product specification document.	The firm has revised their dissolution specification as per innovator in the finished product specification document which is NLT 80% (Q+5%) in 25 minutes and performed studies on all strengths kept on real time study at 14 months as a special case which will be followed onward for stability batches.

Conclusions:

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

Recommendations:

The Firm may kindly be granted registration Intreztu 24/26mg, 49/51mg and 97/103mg (Sacubitril + Valsartan) Tablets.

Decision: Registration Board decided to approve registrations of "Intreztu 24/26mg, 49/51mg and 97/103mg (Sacubitril + Valsartan) Tablets by M/s Scilife Pharma (Pvt.) Limited., Plot # FD-57/58-A2, Korangi Creek Industrial park, Karachi. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
3352.	M/s Genome Pharmaceuticals (Pvt.) Ltd., Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK	VALSAC 24mg/26mg Tablet Each film coated tablet contains: Sacubitril…..24mg Valsartan…...26mg Angiotensin Receptor Neprilysin Inhibitor In-house	Form-5D 353 dated 21-12-2015, Rs. 50,000/- dated 15-12-2015 2 ×7's , 4×7's As recommended by the PRC	Approved in USFDA (Entresto Tablet of Novartis pharms) Savel tablet 24/26mg by PharmEvo. Panel inspection conducted on 14-01-2017 and report concludes that firm is following the GMP guidelines.	

STABILITY STUDY DATA			
Drug	VALSAC 24mg/26mg Tablet		
Name of Manufacturer	M/s Genome Pharmaceuticals (Pvt.) Ltd., Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK		
Manufacturer of API	M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China		
API Lot No.	17121502		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0,1,2,3,4,6 (months) Real Time: 0,3,6 (months)		
Batch No.	VLC50-T001	VLC50-T002	VLC50-T003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	09-07-2018	09-07-2018	10-07-2018
Date of Initiation	11-07-2018	12-07-2018	12-07-2018
No. of Batches	03		
Date of Submission	11-07-2019 (Dy. No. 11530)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA of Sacubitril-Valsartan (LCZ696) from M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China is submitted.

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate (Certificate#ZJ20160065) for M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China issued by China Food and Drug Administration, China. It is valid till 05-12-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Sacubitril-Valsartan (1.5Kg) attested by ADC, DRAP Peshawar dated 08-05-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response by the applicant
1.	Justify dissolution specifications NLT 75% (Q) in 30 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min.	The firm has submitted that dissolution rate of both test and reference product submitted in phosphate buffer (pH 6.8) is more than 85% in 10min as shown in dissolution comparison. So for routine quality control test of dissolution in commercial batches we will adopt the innovator specifications i.e., NLT 80% (Q) in 25 minutes.
2.	Stability study data sheet shows that there is a difference of 8 months from date of manufacturing and date of initiation of stability studies. Clarification is required.	The firm has submitted that in stability reports the manufacturing 15-12-2017 and Expiry 14-12-2019 is mentioned for API mistakenly instead of the Mfg and expiry of product.We apologize for our mistake and committed to avoid such mistake in coming dossiers.

Decision:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
3353.	M/s Genome Pharmaceuticals (Pvt.) Ltd., Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK	VALSAC 49mg/51mg Tablet Each film coated tablet contains:	Form-5D 351 dated 15-12-2015, Rs. 50,000/- dated 15-12-2015 2 ×7's , 4×7's	Approved in USFDA (Entresto Tablet of Novartis pharms)	

		Sacubitril…..49mg Valsartan…...51mg Angiotensin Receptor Neprilysin Inhibitor In-house	As recommended by the PRC	Savel tablet 24/26mg by PharmEvo. Panel inspection conducted on 14-01-2017 and report concludes that firm is following the GMP guidelines.	

STABILITY STUDY DATA			
Drug	VALSAC 49mg/51mg Tablet		
Name of Manufacturer	M/s Genome Pharmaceuticals (Pvt.) Ltd., Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK		
Manufacturer of API	M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China		
API Lot No.	17121502		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0,1,2,3,4,6 (months) Real Time: 0,3,6 (months)		
Batch No.	VLC100-T001	VLC100-T002	VLC100-T003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	30-07-2018	30-07-2018	30-07-2018
Date of Initiation	01-08-2018	01-08-2018	01-08-2018
No. of Batches	03		
Date of Submission	11-07-2019 (Dy. No. 11531)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA of Sacubitril-Valsartan (LCZ696) from M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate (Certificate#ZJ20160065) for M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China issued by China Food and Drug Administration, China. It is valid till 05-12-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Sacubitril-Valsartan (LCZ969) (1.5Kg) attested by ADC, DRAP Peshawar dated 08-05-2018.

6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

PREVIOUS REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response by the applicant
1.	Justify dissolution specifications NLT 75% (Q) in 30 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min.	The firm has submitted that dissolution rate of both test and reference product submitted in phosphate buffer (pH 6.8) is more than 85% in 10min as shown in dissolution comparison. So for routine quality control test of dissolution in commercial batches we will adopt the innovator specifications i.e., NLT 80% (Q) in 25 minutes.
2.	Stability study data sheet shows that there is a difference of 8 months from date of manufacturing and date of initiation of stability studies. Clarification is required.	The firm has submitted that in stability reports the manufacturing 15-12-2017 and Expiry 14-12-2019 is mentioned for API mistakenly instead of the Mfg and expiry of product.We apologize for our mistake and committed to avoid such mistake in coming dossiers.

Decision:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
3354.	M/s Genome Pharmaceuticals (Pvt.) Ltd., Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK	VALSAC 97mg/103mg Tablet Each film coated tablet contains: Sacubitril…..97mg Valsartan…..103mg Angiotensin Receptor Neprilysin Inhibitor In-house	Form-5D 352 dated 21-12-2015, Rs. 50,000/- dated 15-12-2015 2 ×7's , 4×7's As recommended by the PRC	Approved in USFDA (Entresto Tablet of Novartis pharms) Savel tablet 24/26mg by PharmEvo. Panel inspection conducted on 14-01-2017 and report concludes that firm is following the GMP guidelines.	

STABILITY STUDY DATA

Drug	VALSAC 97mg/103mg Tablet
Name of Manufacturer	M/s Genome Pharmaceuticals (Pvt.) Ltd., Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK
Manufacturer of API	M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China

API Lot No.	17121502		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (months) Real Time: 0,3,6 (months)		
Batch No.	VLC200-T001	VLC200-T002	VLC200-T003
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	02-08-2018	02-08-2018	02-08-2018
Date of Initiation	04-08-2018	04-08-2018	04-08-2018
No. of Batches	03		
Date of Submission	11-07-2019 (Dy. No. 11532)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA of Sacubitril-Valsartan (LCZ696) from M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate (Certificate#ZJ20160065) for M/s Zhejiang Tianyu pharmaceutical Co. Ltd., China issued by China Food and Drug Administration, China. It is valid till 05-12-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Sacubitril-Valsartan (1.5Kg) attested by ADC, DRAP Peshawar dated 08-05-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

PREVIOUS REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response by the applicant
1.	Justify dissolution specifications NLT 75% (Q) in 30 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min.	The firm has submitted that dissolution rate of both test and reference product submitted in phosphate buffer (pH 6.8) is more than 85% in 10min as shown in dissolution comparison. So for routine quality control test of dissolution in commercial batches we

		will adopt the innovator specifications i.e., NLT 80% (Q) in 25 minutes.
2.	Stability study data sheet shows that there is a difference of 8 months from date of manufacturing and date of initiation of stability studies. Clarification is required.	The firm has submitted that in stability reports the manufacturing 15-12-2017 and Expiry 14-12-2019 is mentioned for API mistakenly instead of the Mfg and expiry of product.We apologize for our mistake and committed to avoid such mistake in coming dossiers.

Decision:

INSPECTION REPORT VERIFICATION OF AUTHENTICITY OF STABILITY DATA
M/s Genome Pharmaceuticals Pvt Ltd plot#16/I- Phase IV, Hattar

Product:

1. Valsac 24mg/26 mg Tablets
2. Valsac 49mg/51 mg Tablets
3. Valsac 97mg/103 mg Tablets

Date of inspection 10-03-2020 in compliance to letter No.F.-2/2020-PEC dated 18-02-2020

Q. No.	QUESTION	OBSERVATION BY PANEL
1.	Whether the firm has documents confirming import of API?	The firm has imported 1.5 Kg Sacubitril - Valsartan (LCZ696 49%:51%) API complex from M/s ZHEJIANG Tianyu Pharmaceutical Co., Ltd China, vide invoice No. MT1803019C dated 26-05-2018.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation form being implemented by the firm and the rationale behind selecting the manufacturer is its GMP status.
3.	Whether documents confirm the import of Valsartan/Sacubitril reference standard and impurity standards?	The Firm Purchased reference standard of Valsartan/Sacubitril and impurities standard LCZ696 LACTAM Impurity and LCZ696 DIACID Impurity from API manufacturer with Lot of material. COA of working standard and impurity standard are available
4.	Whether the firm has certificate of Analysis of the API, reference standards and impurity standards from exporter?	COA of working standard LCZ696 Batch No 71101 and impurity standard LCZ696 LACTAM Batch No. IRS160901 and LCZ696 DIACID Batch No. IRS 160101 are available
5.	Whether the firm has any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has GMP Certificate of API manufacturer issued by regulatory authority of country of origin (China) bearing date 15/03/2018 valid till 14/03/2023.
6.	Whether firm use API manufacturer method of testing?	Firm has used manufacturer method for testing of co-crystallized API complex. Furthermore the validation data has also been provided by manufacturer.
7.	Whether firm has stability studies reports on API?	Firm has accelerated and real time stability studies reports on API co-crystal complex Valsartan + Sacubitril performed by manufacturer of API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed by manufacturer method, and manufacturer method is stability indicating (SIM). Degradation products have been quantified.
9.	Whether firm has method for quantifying the impurities in the API?	Firm has manufacturer validated method for quantifying impurities in API complex Valsartan + Sacubitril
10.	Whether firm have some remaining quantities of the API, its reference standard and impurities standards?	Firm has consumed the co-crystal API Valsartan + Sacubitril in manufacturing of Trial batches VLC50-T001, VLC50-T002, VLC50-T003, VLC100-T001, VLC100-T002, VLC100-T003, VLC200-T001, VLC200-T002 and VLC200-T003. The remaining portion of reference standards and

		impurity standards are available.
11.	Whether firm has used pharmaceutical grade excipients?	Excipients used are: Core: Magnesium Stearate BP/ USP (FACI Asia pacific Pte Ltd), Crospovidone USP (Boai NKY Pharma, China), LHPC (Shandong Head co., China), Avicel-200BP/USP (JRS Pharma Germany), Aerosil-200 BP/USP (Evonik Industries), Talcum BP, IPA BP Taiwan Coating HPMC E5 BP/USP, (Dow chemical USA), Titanium dioxide BP/USP (Kronos Titan), Polyethylene glycol 6000 BP/USP (PAN Asia Chemical Taiwan, Talcum BP, IPA BP Taiwan. All the excipients are pharmaceutical grade.
12.	Whether firm has documents confirming the import of the used excipients?	Magnesium Stearate BP/ USP (FACI Asia pacific Pte Ltd), Crospovidone USP (Boai NKY Pharma, China), LHPC (Shandong Head co., China), Avicel-200BP/USP (JRS Pharma Germany), Aerosil-200 BP/USP (Evonik Industries)Are imported While Polyethylene glycol 6000 BP/USP (PAN Asia Chemical Taiwan, Titanium dioxide BP/USP (Kronos Titan), Talcum BP and IPA BP Taiwan are purchased from local vendor.
13.	Whether firm have test reports and other records on the excipients used?	Firm provided Lab test reports and certificate of analysis for all excipients.
14.	Whether firm has written and authorized protocols for the development of Valsartan + Sacubitril tablets?	Firm has written protocol for the development of Valsartan + Sacubitril (Valsac 24mg/26 mg, Valsac 49mg/51 mg and Valsac 97mg/103 mg Tablets) The firm also developed detailed Standard manufacturing procedure and batch processing sheet for manufacturing of trial batches.
15.	Whether firm has performed Drug-excipients compatibility studies?	The firm have not performed drug-excipients compatibility studies.
16.	Whether firm has performed comparative dissolution studies?	Firm has performed In vitro comparative dissolution studies with innovator product (Entresto 50 mg, 100 mg and 200 mg) Novartis Switzerland in three different medium. The dissolution profile is comparable and similarity factor and difference factor are calculated according to FDA guidelines.
17.	Whether firm has product development (R&D) section	The firm has product development (R&D) with requisite manufacturing and testing facility.
18.	Whether firm has necessary equipment available in product development section for development of Valsartan + Sacubitril tablets?	The firm has all necessary equipment for manufacturing and testing of Valsartan + Sacubitril tablets in product development section.
19.	Are the equipment in product development section qualified?	All the equipment in R&D section are calibrated and qualified.
20.	Whether firm have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Proper external calibration and maintenance implemented and all the equipment are calibrated.
21.	Whether firm has qualified staff in product development section with proper knowledge and training in product development?	Firm has qualified staff with proper knowledge with product development in product development section.

22.	Whether firm has manufactured three stability batches for the stability studies of Valsartan + Sacubitril Tablets as required?	Firm has manufactured three stability batches for each Valsac 24mg/26 mg, Valsac 49mg/51 mg and Valsac 97mg/103 mg Tablets with batch size of 1500 tablets for Valsac 24mg/26 mg, Valsac 49mg/51 each, and 1250 for Valsac 97mg/103 mg. For each bacth.
23.	What were the criteria for fixing the batch size of stability batches?	Criteria for fixing batch size of stability batches is number of tablets per testing and number of testing frequencies according to 276th DRB meeting.
24.	Whether firm has complete record of production of stability batches?	Firm has complete record of production of stability batches.
25.	Whether firm have protocols for stability testing of stability batches?	Firm has developed protocols for stability testing of stability batches. Procedure of stability studies, Log registers with complete schedule and monthly schedule of testing available. Testing was done on monthly basis i.e. Real time stability studies: 0, 3rd, 6th, 9th, 12th, 18th and 24th months Accelerated stability studies: 0, 1st, 2nd, 3rd, 4th & 6th months as per 276 DRB meeting.
26.	Whether firm has developed and validated the method for testing of stability batches?	Firm has used In-house validated HPLC method for testing of Assay and Dissolution in stability batches.
27.	Whether firm has method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer studies are not performed Firm has used In-house validated HPLC method for testing of Assay and Dissolution in stability batches.
28.	Whether firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of Valsartan + Sacubitril API and the finished drug?	Firm has documents confirming the qualification of equipment / instruments of quality control being used in the test and analysis of Valsartan + Sacubitril API and the finished product Valsartan + Sacubitril tablets.
29.	Whether firm has stability indicating method of analysis?	Firm has used Manufacturer method for testing of API complex and finished product. The method is stability indicating and impurities in API are quantified.
30.	Whether firm has HPLC software 21CFR compliant?	The HPLC (KNAUER Azura UVD2.1L Germany) software ClarityChrome V 2.1 is 21CFR Compliant.
31.	Whether firm could you show Audit Trail reports on Valsartan + Sacubitril testing?	Complete Audit trail on the testing reports were provided by the firm and demonstrated accordingly.
32.	Whether firm have some remaining quantities of degradation products and stability batches?	Firm has remaining quantities of stability batches however there is no quantity of degradation products.
33.	Whether firm has commitment batches kept on stability testing?	Firm has three commitment batches kept on stability testing in stability chamber with accelerated and real time stability conditions.
34.	Whether firm has valid calibration status for the equipment used in Valsartan + Sacubitril tablets production and analysis?	Firm has proper calibration schedule and valid calibration status for the equipment used in Valsartan + Sacubitril tablets.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Firm possess two stability chambers for accelerated and real time stability testing. Both chambers were found qualified. The chambers have been provided with continuous power supply and digital data loggers with record of test period.
36.	Do related manufacturing area, equipment, personnel and utilities be	Firm was operating under satisfactory level of cGMP compliance.

	rated as GMP compliant?	

Conclusions:

- On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Valsac 24mg/26 mg Tablets, Valsac 49mg/51 mg Tablets and Valsac 97mg/103 mg Tablets (Valsartan + Sacubitril) is verifiable to satisfactory level.

Decision: Registration Board decided to approve registrations of "Valsac 24mg/26 mg Tablets, Valsac 49mg/51 mg Tablets and Valsac 97mg/103 mg Tablets (Valsartan + Sacubitril) by M/s Genome Pharmaceuticals Pvt Ltd plot#16/I- Phase IV, Hattar. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3355.	M/s Demont Research Laboratories., 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan	Denver Capsule 30 mg Each Capsule contains: Dexlansoprazole as Enteric Coated Pellets equivalent to Dexlansoprazole…… 30 mg Proton pump Inhibitor (Manufacturer Spec)	Form-5-D Dy. No: 76788 Dated. 29-12-17 Rs.50,000/- 29-12-2017 1x14's As per SRO	Dexilant Capsule USFDA approved Last GMP Inspection of Conducted on 23/2/2018, 26/2/2018 and report shows satisfactory cGMP level.

STABILITY STUDY DATA

Drug	Denver Capsule 30 mg		
Name of Manufacturer	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan		
Manufacturer of API	Dexlansoprazole: M/s. Vision Pharmaceuticals, Islamabad.		
API Lot No.	Dexlansoprazole: DLP252		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 months Real Time: 0,1,3,6,9,12,18, 24 months		
Batch No.	TC001	TC002	TC003
Batch Size	2300 capsules	2300 capsules	2300 capsules
Manufacturing Date	02-2018	02-2018	02-2018
Date of Initiation	30-4-2018	30-4-2018	30-4-2018
No. of Batches	03		
Date of Submission	31-12-2018 (Dy. No. 44509)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of API manufacturer dated 26-01-2018 issued by Additional Director (QA & LT), DRAP Islamabad.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of Delivery challan for the purchase of Dexlansoprazole DDR pellets 17% (quantity 3.8 kg) from M/s. Vision Pharmaceuticals, Islamabad which is a local source.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has applied Dexlansoprazole enteric coated pellets while reference formulation contains dual delayed release pellets.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3356.	M/s Demont Research Laboratories., 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan	Denver Capsule 60mg Each Capsule contains: Dexlansoprazole Enteric Coated Pellets equivalent to Dexlansoprazole…… 60 mg Proton pump Inhibitor (Manufacturer Spec)	Form-5-D Dy. No: 76789 Dated. 29-12-17 Rs.50,000/- (29-12-2017) 1x14's As per SRO	Dexilant Capsule USFDA approved Last GMP Inspection of Conducted on 23/2/2018, 26/2/2018 and report shows satisfactory cGMP level.

STABILITY STUDY DATA	
Drug	Denver Capsule 60mg
Name of Manufacturer	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
Manufacturer of API	Dexlansoprazole: M/s. Vision Pharmaceuticals, Islamabad.

API Lot No.	Dexlansoprazole: DLP252		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4, 6 months Real Time: 0,1,3,6,9,12,18, 24 months		
Batch No.	TC004	TC005	TC006
Batch Size	2300 capsules	2300 capsules	2300 capsules
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	30-4-2018	30-4-2018	30-4-2018
No. of Batches	03		
Date of Submission	31-12-2018 (Dy. No. 44509)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of API manufacturer dated 26-01-2018 issued by Additional Director (QA & LT), DRAP Islamabad.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of Delivery challan for the purchase of Dexlansoprazole DDR pellets 17% (quantity 3.8 kg) from M/s. Vision Pharmaceuticals, Islamabad which is a local source.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has applied Dexlansoprazole enteric coated pellets while reference formulation contains dual delayed release pellets.

Name of Manufacturer	M/s. DeMont Research Laboratories (Pvt.) Ltd.,
Physical Address	20 Km. Sharikpur Road, Sheikhupura.
Drug Manufacturing license No. and Validity (Date of application for DML renewal)	000844.
Contact Address	20 Km. Sharikpur Road, Sheikhupura.
Date of inspection	16-01-2020.

Purpose of inspection	Verification of Authenticity of Stability Data
Name of inspector (s)	Mr. Shaheen Iqbal, Director DTL, Lahore. Mrs. Majida Mujahid, Federal Inspector of Drugs, Lahore. Ms. Maham Misbah, Assistant Director, Lahore.
Name of Firm's Representative (s) accompanying during inspection	Mr. Bilal Ajmal, (CEO), Mr. Shahid Niazi, (Production Manager), Mr. Basit Majid, (Quality Control Manager), Ms. Tyaba Rasool, (Quality Assurance Manager).

Sr. No	Questions	Observations
1	Whether the firm has documents confirming import of API?	Not Applicable. Firm had locally purchased Dexlansoprazole DDR 17% pellets from M/s. Vision Pharmaceuticals vide invoice No. 402171 dated 20-03-2018.
2	What was the rationale behind selecting the particular manufacturer of API?	The rationale for selecting the manufacturer was the cGMP status of M/s Vision Pharmaceuticals, and compliance with the vendor qualification SOP, as informed by the firm's management.
3	Whether documents confirm the import of API reference standard and impurity standards?	Not applicable. Firm had locally purchased Working standard of API from principal manufacturer. Impurity standards were taken as a loan from M/s Dyson Research Laboratories (Pvt) Ltd..
4	Whether the firm has certificate of Analysis of the API, reference standards and impurity standards from exporter?	Firm had certificates of analysis for the APIs, working standards and impurity standards. API Batch No: DLP252, Mfg date: 02/18, Exp. date: 02/21. Working standards Batch No: 1706013, Mfg date: 04/17, Exp. date: 03/22. Impurity standards i. Sulfide. Sulfide/WS-01/17, Mfg date: 12/17, Exp. date: 11/18. ii. Sulfone. Sulfone/WS-01/17, Mfg date: 12/17, Exp. date: 11/18.
5	Whether the firm has any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Last cGMP inspection conducted on 11.02.2019 by DRAP team and the report concludes that the firm was operating at a good level of cGMP compliance.
6	Whether firm use API manufacturer method of testing?	Yes.
7	Whether firm has stability studies reports on API?	Yes.
8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes.
9	Whether firm has method for quantifying the impurities in the API?	Yes.
10	Whether firm has some remaining quantities of the API, its reference standard and impurities standards?	Firm had some remaining quantities of API, working standards and impurity standards.
11	Whether firm has used pharmaceutical grade excipients?	No excipients used in the process. Firm is only filling the pellets in capsules.
12	Whether firm has documents confirming the import of the used excipients?	Not applicable.
13	Whether firm has test reports and other records on the excipients used?	Not applicable.

14	Whether firm has written and authorized protocols for the development of tablets?	Yes.
15	Whether firm has performed Drug-excipient compatibility studies?	Not applicable.
16	Whether firm has performed comparative dissolution studies?	Firm had performed comparative dissolution studies with Dexilant capsules manufactured by M/s Takeda Pharma Co., Ltd, Japan.
17	Whether firm has product development (R&D) section?	No. Capsules were filled with pellets using semi-automatic capsule filling machine installed in the commercial production area.
18	Whether firm has necessary equipment available in product development section for development of finished product?	No.
19	Are the equipment in product development section qualified?	Equipment of commercial production was used. The equipment was qualified. Firm was advised to upgrade to automatic capsule filling machine.
20	Whether firm has proper maintenance / calibration / re- qualification program for the equipment used in PD section?	Firm had valid calibration certificates of the major equipment used in product development.
21	Whether firm has qualified staff in product development section with proper knowledge and training in product development?	No. Separate staff for product development was not available.
22	Whether firm has manufactured three stability batches for the stability studies of finished product tablets as required?	Firm had manufactured three stability batches each for the stability studies of finished products Dexlansoprazole 30mg and Dexlansoprazole 60mg. Dexlansoprazole 30mg (Batch No.s TC001, TC002, TC003) and Dexlansoprazole 60mg (Batch No.s TC004, TC005, TC006).
23	What was the criteria for fixing the batch size of stability batches?	As stated by the firm's management, criteria for fixing batch size of stability batches was the available quantity of API.
24	Whether firm has complete record of production of stability batches?	Firm had BMRs of all relevant stability batches.
25	Whether firm has protocols for stability testing of stability batches?	Yes.
26	Whether firm has developed and validated the method for testing of stability batches?	Firm had developed testing method based on API test method. However, protocols for testing method validation needed improvement.
27	Whether firm has method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable.
28	Whether firm has documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes.
29	Whether firm has stability indicating method of analysis?	Firm had included detection/quantification of impurities in its method of analysis for finished product.
30	Whether firm has HPLC software 21CFR compliant?	Firm had HPLC of Model Series 200. Audit trail option was enabled; password protection and date and time lock features were present.
31	Whether firm could you show Audit Trail reports ?	Yes.
32	Whether firm has some remaining quantities of degradation products and stability batches?	Firm had remaining quantities of stability batches. Degradation products had not been isolated.
33	Whether firm has commitment batches kept	Yes.

	on stability testing?	
34	Whether firm has valid calibration status for the equipment used in production and analysis?	Yes.
35	Do proper and continuous monitoring and control are available for stability chamber?	Firm had two stability chambers. Details are as follows: Real time stability chamber: Sanyo, DRL-QA-SC-007, 300L. Accelerated stability chamber: Supico, DRL-QA-SC-007, 200L. Firm has purchased one more stability chamber (300L capacity) on the advice of the panel (Invoice No. I-003 LHR dated 23-03-2020) as the real time stability chamber was overcrowded. Humidifier of accelerated stability study chamber was broken and required maintenance.
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Firm had valid cGMP compliance certificate from DRAP (Ref. No. 82/2019-DRAP (AD-701833-228) dated 03-04-2019; validity: three years). However, the experience of Quality Assurance manager was less than the experience required vide SRO 1460(I)/2019 dated 27-11-2019 i.e. seven years. Firm was advised to hire QA manager having the required experience.

Remarks:-

With reference to DRAP, Islamabad letter No. F.13-11/2017-PEC (Vol.I) dated 27.06.2019 the inspection of M/s DeMont Research Laboratories was conducted on 16-01-2020. Relevant sections, documents and personnel were verified by the panel and details are provided in the table above. Additional point mentioned in above-mentioned letter was also verified during the inspection and raw data for dissolution testing of dual delayed release pellets before filling was also shown by the firm.

Decision: Registration Board decided to approve registrations of "Denver Capsule 30mg and 60mg (Dexlansoprazole) by M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

3357.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar
	Brand Name +Dosage Form + Strength	SACUVAL 24/26MG TABLET
	Composition	Each film coated tablet contains: Sacubitril as Sacubitril Valsartan sodium salt complex ……...24.3mg Valsartan as Sacubitril Valsartan sodium salt complex ……...25.7mg
	Diary No. Date of R& I & fee	2930, 22-01-2019, 20,000/-, 16-01-2019
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 24/26mg by PharmEvo.
	GMP status	
	Remarks of Evaluator	•

STABILITY STUDY DATA

Drug	SACUVAL 24/26MG TABLET
Name of Manufacturer	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar

Manufacturer of API	M/s Shandong Sihuan Pharmaceuticals Co., Ltd., Address: Nanyuan Road, Economic Development Zone, Pingyuan County, Dezhou City, Shandong Province, China.		
API Lot No.	2019021101		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Real Time: 0,3,6 (06 months) Accelerated: 0,1,2,3,4,6 (06 months)		
Batch No.	T-49	T-50	T-51
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	06-06-2019	06-06-2019	06-06-2019
Date of Initiation	10-06-2019	10-06-2019	10-06-2019
No. of Batches	03		
Date of Submission	26978 (13-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Firm has submitted copy of COA of LCZ696 (Sacubitril/valsartan, batch # 2019021101) from M/s Shandong Sihuan Pharmaceutical Co., Ltd, China Firm has submitted copy of COA of working standard from API supplier.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued from Shandong Pharmaceutical Industry Association valid until 11-05-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of invoice for the import of Raw material Sacubitril/Valsartan complex attested by Assistant Director (I&E), DRAP, Peshawar.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response of the firm
1.	Clarification is required since weight of raw material (Sacubitril/Valsartan) mentioned on courier slip is 0.5 Kg while that mentioned on commercial invoice is 1.5 Kg. Moreover, submitted commercial invoice is not attested by ADC DRAP.	The firm submitted that we purchased two different consignments from same source and mistakenly that list was attached. The firm submitted copy of invoice attested by Assistant Director (I&E), DRAP, Peshawar.
2.	GMP certificate of API manufacturer from concerned regulatory authority is required to be submitted	Firm has submitted copy of GMP certificate which is not issued by relevant regulatory authority.
3.	Justify dissolution specifications NLT 80% (Q) in 45 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min.	We performed comparative dissolution which fall in limits for both our product and innovator.

Decision: Registration Board deferred the case for following:

- **Submission of GMP certificate of API manufacturer from concerned regulatory authority.**
- **Submission of dissolution limits in finished product specifications in numerical values.**

3358.		
	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar
	Brand Name +Dosage Form + Strength	SACUVAL 49/51MG TABLET
	Composition	Each film coated tablet contains: Sacubitril as Sacubitril Valsartan sodium salt complex ……...48.6mg Valsartan as Sacubitril Valsartan sodium salt complex ……...51.4mg
	Diary No. Date of R& I & fee	2931, 22-01-2019, 20,000/-, 16-01-2019
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 49/51mg by PharmEvo.
	GMP status	
	Remarks of Evaluator	•

STABILITY STUDY DATA	
Drug	SACUVAL 49/51MG TABLET
Name of Manufacturer	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar
Manufacturer of API	M/s Shandong Sihuan Pharmaceuticals Co., Ltd., Address: Nanyuan Road, Economic Development Zone, Pingyuan County, Dezhou City, Shandong Province, China.
API Lot No.	2019021101
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH
Time Period	Accelerated: 06 (months) Real Time: 06 (months)
Frequency	Real Time: 0,3,6 (06 months) Accelerated: 0,1,2,3,4,6 (06 months)

Batch No.	T-52	T-53	T-54
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	06-06-2019	06-06-2019	06-06-2019
Date of Initiation	11-06-2019	11-06-2019	11-06-2019
No. of Batches	03		
Date of Submission	26979 (13-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Firm has submitted copy of COA of LCZ696 (Sacubitril/valsartan, batch # 2019021101) from M/s Shandong Sihuan Pharmaceutical Co., Ltd, China Firm has submitted copy of COA of working standard from API supplier.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued from Shandong Pharmaceutical Industry Association valid until 11-05-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of invoice for the import of Raw material Sacubitril/Valsartan complex attested by Assistant Director (I&E), DRAP, Peshawar.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response of the firm
1.	Clarification is required since weight of raw material (Sacubitril/Valsartan) mentioned on courier slip is 0.5 Kg while that mentioned on commercial invoice is 1.5 Kg. Moreover, submitted commercial invoice is not attested by ADC DRAP.	The firm submitted that we purchased two different consignments from same source and mistakenly that list was attached. The firm submitted copy of invoice attested by Assistant Director (I&E), DRAP, Peshawar.
2.	GMP certificate of API manufacturer from concerned regulatory authority is required to be submitted	Firm has submitted copy of GMP certificate which is not issued by relevant regulatory authority.
3.	Justify dissolution specifications NLT 80% (Q) in 45 min since dissolution	We performed comparative dissolution which fall in limits for both our product and innovator.

	specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min.	

Decision: Registration Board deferred the case for following:

- **Submission of GMP certificate of API manufacturer from concerned regulatory authority.**
- **Submission of dissolution limits in finished product specifications in numerical values.**

3359.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar
	Brand Name +Dosage Form + Strength	SACUVAL 97/103MG TABLET
	Composition	Each film coated tablet contains: Sacubitril as Sacubitril Valsartan sodium salt complex ……...97.2mg Valsartan as Sacubitril Valsartan sodium salt complex ……...102.8mg
	Diary No. Date of R& I & fee	2932, 22-01-2019, 20,000/-, 16-01-2019
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 97/103mg by PharmEvo.
	GMP status	
	Remarks of Evaluator	•

STABILITY STUDY DATA			
Drug	SACUVAL 97/103MG TABLET		
Name of Manufacturer	M/s Weather Folds Pharmaceuticals, Plot No. 62/2, Phase II, Industrial area, Hattar		
Manufacturer of API	M/s Shandong Sihuan Pharmaceuticals Co., Ltd., Address: Nanyuan Road, Economic Development Zone, Pingyuan County, Dezhou City, Shandong Province, China.		
API Lot No.	2019021101		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: $40^{o}C \pm 2^{o}C/75\% \pm 5\%$ RH Real Time: $30^{o}C \pm 2^{o}C/65\% \pm 5\%$ RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Real Time: 0,3,6 (06 months) Accelerated: 0,1,2,3,4,6 (06 months)		
Batch No.	T-55	T-56	T-57
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	06-06-2019	06-06-2019	06-06-2019
Date of Initiation	12-06-2019	12-06-2019	12-06-2019
No. of Batches	03		
Date of Submission	26980 (13-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.	Documents To Be Provided	Status

No.		
1.	COA of API.	Firm has submitted copy of COA of LCZ696 (Sacubitril/valsartan, batch # 2019021101) from M/s Shandong Sihuan Pharmaceutical Co., Ltd, China Firm has submitted copy of COA of working standard from API supplier.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued from Shandong Pharmaceutical Industry Association valid until 11-05-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of invoice for the import of Raw material Sacubitril/Valsartan complex attested by Assistant Director (I&E), DRAP, Peshawar.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Sr. No.	Observations	Response of the firm
4.	Clarification is required since weight of raw material (Sacubitril/Valsartan) mentioned on courier slip is 0.5 Kg while that mentioned on commercial invoice is 1.5 Kg. Moreover, submitted commercial invoice is not attested by ADC DRAP.	The firm submitted that we purchased two different consignments from same source and mistakenly that list was attached. The firm submitted copy of invoice attested by Assistant Director (I&E), DRAP, Peshawar.
5.	GMP certificate of API manufacturer from concerned regulatory authority is required to be submitted	Firm has submitted copy of GMP certificate which is not issued by relevant regulatory authority.
6.	Justify dissolution specifications NLT 80% (Q) in 45 min since dissolution specifications of FDA approved product Entresto 24/26mg Tablet is NLT Q in 25min.	We performed comparative dissolution which fall in limits for both our product and innovator.

Decision: Registration Board deferred the case for following:

- **Submission of GMP certificate of API manufacturer from concerned regulatory authority.**
- **Submission of dissolution limits in finished product specifications in numerical values.**

3360.	Name and address of manufacturer / Applicant	M/s Pacific Pharmaceuticals Limited, 30km Multan road Lahore
	Brand Name +Dosage Form + Strength	ESMELIN TABLET 7.5mg
	Composition	Each Prolonged Release tablet contains: Darifenacin (as hydrobromide)…….. 7.5mg
	Diary No. Date of R& I & fee	Duplicate, 20,000/-, 04-12-2018, 30,000/-, 27-02-2020
	Pharmacological Group	Drug for urinary frequency and incontinence

	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Enablex 7.5 extended release tablet of APIL)
	Me-too status	N/A
	GMP status	The firm is granted GMP certificate base on evaluation conducted on 07-03-2019.
	Remarks of Evaluator	•

STABILITY STUDY DATA			
Drug	ESMELIN TABLET 7.5mg		
Name of Manufacturer	M/s Pacific Pharmaceuticals Limited, 30km Multan road Lahore		
Manufacturer of API	M/s Megafine pharma (Pvt.) Ltd, Plot No. 31 to 35 & 48 to 51, 5,26 &K/201, Lakhmapur, Tal Dindori, Dist. Nashik -422 202, Maharashtra, India		
API Lot No.	DB1804002		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Accelerated: 0,1,2,3,4,6 (06 months) Real Time: 0,3,6 (06 months)		
Batch No.	P000306O		
Batch Size	8000 Tablets		
Manufacturing Date	18-07-2019		
Date of Initiation	20-07-2019		
No. of Batches	01		
Date of Submission	(02-03-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	Copy of COA of API (batch # DLP363) from M/s Megafine Pharma, Maharashtra, India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate for M/s Megafine Pharma (P) Ltd, India issued from Food and Drug Administration, Maharashtra, India. It is valid till 12-02-2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted invoice for import of Darifenacin hydrobromide (0.5Kg) attested by Assistant Director (I & E), DRAP, Lahore dated 29-10-2018. Invoice No: NX18190203

6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data of 01 Batch only.
- Upon clarification, the firm has submitted following:

The firm has submitted that we got permission for 0.5Kg of Darifenacin to plan trial batches of both strengths. We conducted initial small trials to set the dissolution after which we are left with materials to prepare 3 batches of Esmelin 15mg tablet and **one batch of Esmelin 7.5mg Tablet** of 8000 tablets each.

We developed the product as per brand leader Enablex tablet in which average weight of both strengths was the same i.e., 190mg. The only differenc is the quantity of Calcium hydrogen phosphate which is 98mg in Esmelin 7.5mg tablet and 90mg in Esmelin 15mg tablet which is less than 5% of total average weight of tablet. That's why we prepared 3 batches of higher strength and one batch of lower strength to assess the final stability of the formulation.

Decision: Registration Board deliberated the matter in detail and decided to defer the case for submission of complete stability study for three batches of applied strength as per decision of 278th meeting of Registration Board.

3361.	Name and address of manufacturer / Applicant	M/s Pacific Pharmaceuticals Limited, 30km Multan road Lahore
	Brand Name +Dosage Form + Strength	ESMELIN TABLET 15mg
	Composition	Each Prolonged Release tablet contains: Darifenacin (as hydrobromide)…….. 15mg
	Diary No. Date of R& I & fee	Duplicate, 20,000/-, 04-12-2018, 30,000/-, 27-02-2020
	Pharmacological Group	Drug for urinary frequency and incontinence
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA (Enablex 15 extended release tablet of APIL)
	Me-too status	N/A
	GMP status	The firm is granted GMP certificate base on evaluation conducted on 07-03-2019.
	Remarks of Evaluator	•

STABILITY STUDY DATA

Drug	ESMELIN TABLET 15mg
Name of Manufacturer	M/s Pacific Pharmaceuticals Limited, 30km Multan road Lahore
Manufacturer of API	M/s Megafine pharma (Pvt.) Ltd, Plot No. 31 to 35 & 48 to 51, 5,26 &K/201, Lakhmapur, Tal Dindori, Dist. Nashik -422 202, Maharashtra, India
API Lot No.	DB1804002
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Accelerated: $40^{o}C \pm 2^{o}C/75\% \pm 5\%$ RH Real Time: $30^{o}C \pm 2^{o}C/65\% \pm 5\%$ RH
Time Period	Accelerated: 06 (months) Real Time: 06 (months)
Frequency	Accelerated: 0,1,2,3,4,6 (06 months) Real Time: 0,3,6 (06 months)

Batch No.	P000106O	P000206O	P000406O
Batch Size	8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date	18-07-2019	18-07-2019	18-07-2019
Date of Initiation	20-07-2019	20-07-2019	20-07-2019
No. of Batches	03		
Date of Submission	(02-03-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA of API (batch # DLP363) from M/s Megafine Pharma, Maharashtra, India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate for M/s Megafine Pharma (P) Ltd, India issued from Food and Drug Administration, Maharashtra, India. It is valid till 12-02-2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted invoice for import of Darifenacin hydrobromide (0.5Kg) attested by Assistant Director (I & E), DRAP, Lahore dated 29-10-2018. Invoice No: NX18190203
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Decision: Registration Board decided to consider the case after onsite inspection by the panel to be constituted by Chairman Registration Board for verification of authenticity of submitted stability study data.

b. Exemption from onsite verification of stability data

3362	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26- km Lahore Sharaqpur Road Sheikhupura.
	Brand Name +Dosage Form + Strength	JENSAC TABLETS 24/26MG
	Composition	Each Film Coated Tablet Contains: Sacubitril…….24.3 mg Valsartan……25.7 mg (as sacubitril+valsartan Trisodium Hemipentahydrate)
	Diary No. Date of R& I & fee	Dy.No. 40297, 05-12-2018, Rs.50,000/- Dated 05-12-2018
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 24/26mg by PharmEvo.
	GMP status	GMP inspection conducted on 06-11-2017 concludes that the firm is satisfactory regarding to building, equipment and functioning of HVAC.
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	JENSAC TABLETS 24/26MG		
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26- km Lahore Sharaqpur Road Sheikhupura.		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China		
API Lot No.	2400-201903001		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	JNS-PB-015001	JNS-PB-015002	JNS-PB-015003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	13-07-2019	13-07-2019	13-07-2019
No. of Batches	03		
Date of Submission	28-01-2020 (Dy. No. 31770)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
Certificate of analysis of API.	Copy of COA of Sacubitril/valsartan (batch # 2400-201903001) from M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China is submitted.
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China issued by Huaian Marketsupervision Administration, China valid upto 31-12-2020.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Sacubitril/Valsartan (1.4Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 21-03-2019 has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes

Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 28-01-2020 (Dy. No. 31770)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their products "Lansodex Capsule 60mg and 30mg, Sofopas Tablet 400/90", which were presented in 287th meeting of Registration board. Registration Board decided to approve registration of Lansodex Capsule 60mg and 30mg, Sofopas Tablet 400/90 of M/s Jenner Pharmaceuticals (Pvt) Ltd,. Sheikupura. Date of inspection : 10-12-2018 According to the report generated following points were confirmed a) The HPLC used for analysis of stability batches is Shimadzu 20 ATVP with auto sampler and gradient system and it was 21 CFR compliant. b) The firm has two separate Memmert (Germany) stability chambers for real time and accelerated stability studies which are equipped with data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Sacubitril/Valsartan (1.4Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 21-03-2019 has been submitted.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted that Sacubitril-Valsartan working standard and impurity standards were received along with shipment of API, Air way bill is attached.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China issued by Huaian Marketsupervision Administration, China valid upto 31-12-2020.
5.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for Evaluation of Vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	• Copy of COA of Sacubitril/valsartan (batch # 2400-201903001) from M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China is submitted. • Copy of COA of working standard (LCZ696) from API supplier alongwith following impurities have been submitted: Impurity A Impurity B Impurity C Impurity D Impurity E
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for the procurement of excipients used in product development
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in R&D department.

<table>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for Pharmaceutical Product Development”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Manufacturing protocols of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>JNS-PB-015001</td><td>1,000 Tabs</td><td>07-2019</td></tr>
<tr><td>JNS-PB-015002</td><td>1,000 Tabs</td><td>07-2019</td></tr>
<tr><td>JNS-PB-015003</td><td>1,000 Tabs</td><td>07-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Batch Size</th><th>Tablets used for stability testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>JNS-PB-015001</td><td>1000 Tabs</td><td>240</td><td>400</td></tr>
<tr><td>JNS-PB-015002</td><td>1000 Tabs</td><td>240</td><td>400</td></tr>
<tr><td>JNS-PB-015003</td><td>1000 Tabs</td><td>240</td><td>400</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Sacubitril-Valsartan.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Jensac Tablet 24/26” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted 12 months accelerated and 24 months real time stability study data of three batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that as the formulation of Jensac tablet 24/26mg (Sacubitril/Valsartan) is qualitatively same to that of the innovator brand ‘’Entresto Tablets 24/26mg’’ that provides reason to exclude any excipients-excipients or drug-excipients incompatibility.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>It is important to mention the medium in which comparative dissolution study has been carried. Moreover comparative dissolution study needs to be submitted in three mediums as recommended in guidelines. Clarification is required.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted audit trail reports of applied product.</td></tr>
<tr><td colspan="3">The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.
<table>
<tr><th>Sr.#</th><th>Observations</th><th>Response of the applicant</th></tr>
</table></td></tr>
</table>

1.	Label claim of applied formulation is not as per innovator. Justification / revision of formulation is required.	Label claim is taken from regulatory authority EMC i.e., Electronic Medicine compendium (EMC).
2.	GMP certificate of API manufacturer from concerned regulatory authority is required to be submitted.	GMP certificate of China Chamber of international commerce is attached. Issuing authority is Huaian Market Supervision Administration which is not verified
3.	Record of remaining quantities of stability batches i.e., Tablets used for stability testing and remaining quantities of tablets are not mentioned in submitted BPRs.	Submitted
4.	Justify dissolution specifications NLT 80% in 45 min since dissolution specifications of innovator product Entresto 24/26mg Tablet is NLT Q in 25min.	The firm has submitted that dissolution time was selected from USFDA dissolution database. Since results of both test product and innovator product are more than 90% in 20 min as per Already submitted CDP data, hence our product specifications are as per FDA chemistry review data.
5.	It is important to mention the medium in which comparative dissolution study has been carried. Moreover comparative dissolution study needs to be submitted in three mediums as recommended in guidelines. Clarification is required.	The firm has submitted that comparative dissolution profile already submitted was carried out in phosphate buffer 6.8 as per USFDA method. Now CDP data of two more mediums i.e., 0.1 N HCl and acetate buffer pH 4.5 is attached.

Decision: Decision: Registration Board decided to defer the case for following:

- **Revised label claim as per reference formulation.**
- **Submission of GMP certificate of API manufacturer from concerned regulatory authority.**

3363.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26- km Lahore Sharaqpur Road Sheikhupura.
	Brand Name +Dosage Form + Strength	JENSAC TABLETS 49/51MG
	Composition	Each Film Coated Tablet Contains: Sacubitril……48.6 mg Valsartan……51.4 mg (as sacubitril+valsartan Trisodium Hemipentahydrate)
	Diary No. Date of R& I & fee	Dy.No. 40839, 06-12-2018, Rs.50,000/- Dated 06-12-2018
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 49/51mg by PharmEvo.
	GMP status	GMP inspection conducted on 06-11-2017 concludes that the firm is satisfactory regarding to building, equipment and functioning of HVAC.
	Remarks of the Evaluator	

STABILITY STUDY DATA	
Drug	JENSAC TABLETS 49/51MG
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26- km Lahore Sharaqpur Road Sheikhupura.
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China
API Lot No.	2400-201903001
Description of Pack (Container closure system)	Alu-Alu Blister

Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	JNS-PB-016001	JNS-PB-016002	JNS-PB-016003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	13-07-2019	13-07-2019	13-07-2019
No. of Batches	03		
Date of Submission	28-01-2020 (Dy. No. 31769)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	**Status**
Certificate of analysis of API.	Copy of COA of Sacubitril/valsartan (batch # 2400-201903001) from M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China is submitted.
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China issued by Huaian Marketsupervision Administration, China valid upto 31-12-2020.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Sacubitril/Valsartan (1.4Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 21-03-2019 has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 28-01-2020 (Dy. No. 31769)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their products "Lansodex Capsule 60mg and 30mg, Sofopas Tablet 400/90", which were presented in 287th meeting of Registration board. Registration Board decided to approve registration of Lansodex Capsule 60mg and 30mg, Sofopas Tablet 400/90 of M/s Jenner

<table>
<tr><td></td><td></td><td>Pharmaceuticals (Pvt) Ltd,. Sheikupura.
Date of inspection : 10-12-2018
According to the report generated following points were confirmed
a) The HPLC used for analysis of stability batches is Shimadzu 20 ATVP with auto sampler and gradient system and it was 21 CFR compliant.
b) The firm has two separate Memmert (Germany) stability chambers for real time and accelerated stability studies which are equipped with data loggers.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of commercial invoice for the purchase of Sacubitril/Valsartan (1.4Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 21-03-2019 has been submitted.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted that Sacubitril-Valsartan working standard and impurity standards were received along with shipment of API, Air way bill is attached.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP Certificate for M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China issued by Huaian Marketsupervision Administration, China valid upto 31-12-2020.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA of Sacubitril/valsartan (batch # 2400-201903001) from M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China is submitted.
• Copy of COA of working standard (LCZ696) from API supplier alongwith following impurities have been submitted:
Impurity A
Impurity B
Impurity C
Impurity D
Impurity E</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted documents for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in R&D department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for Pharmaceutical Product Development”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Manufacturing protocols of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>JNS-PB-016001</td><td>1,000 Tabs</td><td>07-2019</td></tr>
<tr><td>JNS-PB-016002</td><td>1,000 Tabs</td><td>07-2019</td></tr>
<tr><td>JNS-PB-016003</td><td>1,000 Tabs</td><td>07-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Batch Size</th><th>Tablets used for stability</th><th>Remaining Quantities of tablets</th></tr>
</table></td></tr>
</table>

				testing	
		JNS-PB-016001	1000 Tabs	240	400
		JNS-PB-016002	1000 Tabs	240	400
		JNS-PB-016003	1000 Tabs	240	400
QA / QC DATA					
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.			
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Sacubitril-Valsartan.			
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Jensac Tablet 49/51" along with Stability Study Reports.			
15.	Reports of stability studies of API from manufacturer.	The firm has submitted 12 months accelerated and 24 months real time stability study data of three batches.			
16.	Analysis reports for excipients used.	The firm has submitted analytical reports of excipients used.			
17.	Drug-excipients compatibility studies.	The firm has submitted that as the formulation of Jensac tablet 49/51mg (Sacubitril/Valsartan) is qualitatively same to that of the innovator brand ''Entresto Tablets 24/26mg'' that provides reason to exclude any excipients-excipients or drug-excipients incompatibility.			
18.	Record of comparative dissolution data.	It is important to mention the medium in which comparative dissolution study has been carried. Moreover comparative dissolution study needs to be submitted in three mediums as recommended in guidelines. Clarification is required.			
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.			

The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.

Sr. No.	Observations	Response of the applicant
1.	Label claim of applied formulation is not as per innovator. Justification / revision of formulation is required.	Label claim is taken from regulatory authority EMC i.e., Electronic Medicine compendium (EMC).
2.	GMP certificate of API manufacturer from concerned regulatory authority is required to be submitted.	GMP certificate of China Chamber of international commerce is attached. Issuing authority is Huaian Market Supervision Administration which is not verified
3.	Record of remaining quantities of stability batches i.e., Tablets used for stability testing and remaining quantities of tablets are not mentioned in submitted BPRs.	Submitted
4.	Justify dissolution specifications NLT 80% in 45 min since dissolution specifications of innovator product Entresto 24/26mg Tablet	The firm has submitted that dissolution time was selected from USFDA dissolution database. Since results of both test product and innovator product are

	is NLT Q in 25min.	more than 90% in 20 min as per Already submitted CDP data, hence our product specifications are as per FDA chemistry review data.
5.	It is important to mention the medium in which comparative dissolution study has been carried. Moreover comparative dissolution study needs to be submitted in three mediums as recommended in guidelines. Clarification is required.	The firm has submitted that comparative dissolution profile already submitted was carried out in phosphate buffer 6.8 as per USFDA method. Now CDP data of two more mediums i.e., 0.1 N HCl and acetate buffer pH 4.5 is attached.

Decision: Registration Board decided to defer the case for following:

- **Revised label claim as per reference formulation.**
- **Submission of GMP certificate of API manufacturer from concerned regulatory authority.**

3364.	Name and address of manufacturer / Applicant	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26- km Lahore Sharaqpur Road Sheikhupura.
	Brand Name +Dosage Form + Strength	JENSAC TABLETS 97/103MG
	Composition	Each Film Coated Tablet Contains: Sacubitril…….97.2 mg Valsartan……102.8 mg (as sacubitril+valsartan Trisodium Hemipentahydrate)
	Diary No. Date of R& I & fee	Dy.No. 39904, 04-12-2018, Rs.50,000/- Dated 04-12-2018
	Pharmacological Group	Neprilysin inhibitor / Angiotensin II Receptor Blocker combination
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel tablet 97/103mg by PharmEvo.
	GMP status	GMP inspection conducted on 06-11-2017 concludes that the firm is satisfactory regarding to building, equipment and functioning of HVAC.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	JENSAC TABLETS 97/103MG		
Name of Manufacturer	M/s Jenner Pharmaceuticals (Pvt.) Ltd., 26- km Lahore Sharaqpur Road Sheikhupura.		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China		
API Lot No.	2400-201903001		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	JNS-PB-017001	JNS-PB-017002	JNS-PB-017003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	13-07-2019	13-07-2019	13-07-2019
No. of Batches	03		
Date of Submission	28-01-2020 (Dy. No. 31771)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
Certificate of analysis of API.	Copy of COA of Sacubitril/valsartan (batch # 2400-201903001) from M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China is submitted.
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China issued by Huaian Marketsupervision Administration, China valid upto 31-12-2020.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Sacubitril/Valsartan (1.4Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 21-03-2019 has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 28-01-2020 (Dy. No. 31771)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their products "Lansodex Capsule 60mg and 30mg, Sofopas Tablet 400/90", which were presented in 287th meeting of Registration board. Registration Board decided to approve registration of Lansodex Capsule 60mg and 30mg, Sofopas Tablet 400/90 of M/s Jenner Pharmaceuticals (Pvt) Ltd,. Sheikupura. Date of inspection : 10-12-2018 According to the report generated following points were confirmed a) The HPLC used for analysis of stability batches is Shimadzu 20 ATVP with auto sampler and gradient system and it was 21 CFR compliant. b) The firm has two separate Memmert (Germany) stability chambers for real time and accelerated stability studies which are equipped with data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Sacubitril/Valsartan (1.4Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 21-03-2019 has been submitted.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted that Sacubitril-Valsartan working standard and impurity standards were received along with shipment of API, Air way bill is attached.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP Certificate for M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China issued by Huaian Marketsupervision Administration, China valid upto 31-12-2020.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA of Sacubitril/valsartan (batch # 2400-201903001) from M/s Jiangsu Yongan Pharmaceutical Co., Ltd. China is submitted.
• Copy of COA of working standard (LCZ696) from API supplier alongwith following impurities have been submitted:
Impurity A
Impurity B
Impurity C
Impurity D
Impurity E</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted documents for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in R&D department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for Pharmaceutical Product Development”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Manufacturing protocols of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>JNS-PB-017001</td><td>1,000 Tabs</td><td>07-2019</td></tr>
<tr><td>JNS-PB-017002</td><td>1,000 Tabs</td><td>07-2019</td></tr>
<tr><td>JNS-PB-017003</td><td>1,000 Tabs</td><td>07-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Batch Size</th><th>Tablets used for stability testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>JNS-PB-017001</td><td>1000 Tabs</td><td>240</td><td>400</td></tr>
<tr><td>JNS-PB-017002</td><td>1000 Tabs</td><td>240</td><td>400</td></tr>
<tr><td>JNS-PB-017003</td><td>1000 Tabs</td><td>240</td><td>400</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with</td></tr>
</table>

		COAs for Sacubitril-Valsartan.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Jensac Tablet 97/103" along with Stability Study Reports.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted 12 months accelerated and 24 months real time stability study data of three batches.
16.	Analysis reports for excipients used.	The firm has submitted analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has submitted that as the formulation of Jensac tablet 97/103mg (Sacubitril/Valsartan) is qualitatively same to that of the innovator brand ''Entresto Tablets 97/103mg'' that provides reason to exclude any excipients-excipients or drug-excipients incompatibility.
18.	Record of comparative dissolution data.	It is important to mention the medium in which comparative dissolution study has been carried. Moreover comparative dissolution study needs to be submitted in three mediums as recommended in guidelines. Clarification is required.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.

The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.

Sr. No.	Observations	Response of the applicant
1.	Label claim of applied formulation is not as per innovator. Justification / revision of formulation is required.	Label claim is taken from regulatory authority EMC i.e., Electronic Medicine compendium (EMC).
2.	GMP certificate of API manufacturer from concerned regulatory authority is required to be submitted.	GMP certificate of China Chamber of international commerce is attached. Issuing authority is Huaian Market Supervision Administration which is not verified
3.	Record of remaining quantities of stability batches i.e., Tablets used for stability testing and remaining quantities of tablets are not mentioned in submitted BPRs.	Submitted
4.	Justify dissolution specifications NLT 80% in 45 min since dissolution specifications of innovator product Entresto 24/26mg Tablet is NLT Q in 25min.	The firm has submitted that dissolution time was selected from USFDA dissolution database. Since results of both test product and innovator product are more than 90% in 20 min as per Already submitted CDP data, hence our product specifications are as per FDA chemistry review data.
5.	It is important to mention the medium in which comparative dissolution study has been carried. Moreover comparative dissolution study needs to be submitted in three mediums as recommended in guidelines. Clarification is required.	The firm has submitted that comparative dissolution profile already submitted was carried out in phosphate buffer 6.8 as per USFDA method. Now CDP data of two more mediums i.e., 0.1 N HCl and acetate buffer pH 4.5 is attached.

Decision: Decision: Registration Board decided to defer the case for following:

- **Revised label claim as per reference formulation.**
- **Submission of GMP certificate of API manufacturer from concerned regulatory authority.**

3365.	Name and address of manufacturer / Applicant	M/s NovaMed Pharmaceuticals (Pvt) Ltd., 28-Km, Ferozpur Road, Lahore – Pakistan
	Brand Name +Dosage Form + Strength	TRAXART TABLET 650mg

	Composition	Each tablet contains: Tranexamic acid…….650mg
	Diary No. Date of R& I & fee	Dy.No.2901, 22-01-2019, Rs.50,000/- Dated 22-01-2019
	Pharmacological Group	Antifibrinolytic
	Type of Form	Form-5D
	Finished product Specification	BP specifications
	Pack size & Demanded Price	2 × 10's: 3 × 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	LYSTEDA Tablet 650mg of Ferring Pharms (USFDA approved)
	Me-too status	Not applicable
	GMP status	GMP inspection conducted on 5th & 27th December, 2017 concludes that the firm is found to be compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	TRAXART TABLET 650mg		
Name of Manufacturer	M/s NovaMed Pharmaceuticals (Pvt) Ltd., 28-Km, Ferozpur Road, Lahore – Pakistan		
Manufacturer of API	M/s Shilpa Medicare Limited., Address: 12-6-214/ A1, Hyderabad Road, Raichur-584 135, Karnataka, India		
API Lot No.	TXA-VIII/001/18		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,3,6 months Real Time: 0,3,6 months		
Batch No.	TP-141-T2-S1	TP-141-T2-R2	TP-141-T2-R1
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	27-03-2019	08-04-2019	08-04-2019
Date of Initiation	15-04-2019	15-04-2019	15-04-2019
No. of Batches	03		
Date of Submission	06-01-2020 (Dy. No. 29425)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	**Status**
Certificate of analysis of API.	Copy of COA of Tranexamic acid (batch # TXA-VIII/001/18) from M/s Shilpa Medicare Limited, India is submitted.
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of WHO GMP Certificate for M/s Shilpa Medicare Limited, India issued by Drugs Control Department, Government of Karnataka valid upto 27-12-2019.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

Documents confirming import of API etc.	The firm has submitted copy of invoice for the purchase of Tranexamic acid (3Kg). The invoice was attested by Assistant Director (I & E) DRAP, Lahore. Invoice No: IN1819020726 Date of Invoice : 06-02-2019
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 06-01-2020 (Dy. No. 29425)

Administrative Portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Sofonil 400mg (Sofosbuvir) Tablets, which was conducted on 06th March, 2017 and was presented in 268th meeting of Registration board held on 20-21st March, 2017. Registration Board decided to approve registration of Sofonil Tablets (Sofosbuvir 400mg) by M/s. NovaMed Pharmaceutical (Pvt.) Ltd., Lahore. Following observation regarding HPLC system was recorded in report: • The HPLC software is 21CFR compliant as per record available with the firm • Audit trail on the testing reports were shown to the panel during inspection.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase of Tranexamic acid (3Kg). The invoice was attested by Assistant Director (I & E) DRAP, Lahore. Invoice No: IN1819020726 Date of Invoice : 06-02-2019
3.	Documents for the procurement of reference standard and impurity standards.	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of WHO GMP Certificate for M/s Shilpa Medicare Limited, India issued by Drugs Control Department, Government of Karnataka valid upto 27-12-2019.
5.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for Evaluation of Vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	• Copy of COA of Tranexamic acid (batch # TXA-VIII/001/18) from M/s Shilpa Medicare Limited, India is submitted.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for the procurement of excipients used in product development
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in R&D department.
Production Data		
9.	Authorized Protocols/SOP for the	The firm has submitted photocopy of "Protocols/SOP for

<table>
<tr><td></td><td>development & stability testing of trial batches.</td><td>Pharmaceutical Product Development".</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Manufacturing protocols of following 03 Batches:<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>TP-141-T2-S1</td><td>1000 Tabs</td><td>07-2019</td></tr><tr><td>TP-141-T2-R2</td><td>1000 Tabs</td><td>07-2019</td></tr><tr><td>TP-141-T2-R1</td><td>1000 Tabs</td><td>07-2019</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td><table><tr><th>Trial No</th><th>Batch Size</th><th>Tablets used for stability testing</th><th>Remaining Quantities of tablets</th></tr><tr><td>TP-141-T2-S1</td><td>1000 Tabs</td><td>198</td><td>802</td></tr><tr><td>TP-141-T2-R2</td><td>1000 Tabs</td><td>198</td><td>802</td></tr><tr><td>TP-141-T2-R1</td><td>1000 Tabs</td><td>198</td><td>802</td></tr></table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Tranexamic acid.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for "Traxart Tablet 650mg" along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted 60 months real time stability study data of four batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>Not submitted</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Not submitted</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted audit trail reports of applied product.</td></tr>
<tr><td colspan="3">The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.
The disinitegration test limit has been set as NMT 30min for uncoated tablet.<table><tr><th>Sr. No.</th><th>Observations</th><th>Response of the applicant</th></tr><tr><td>1.</td><td>Testing time points of accelerated stability study data are not as per 278th meeting of Registration Board. Clarification is required.</td><td>Testing time point of accelerated stability study data are according to ICH Q1A R2 (i.e., minimum of three time points including the initial & final time points e.g., 0, 3, 6 months).</td></tr><tr><td>2.</td><td>Formulation approved in USFDA is modified release tablets while you have applied plain tablet. Clarification is required.</td><td>Tranexamic acid tablet 650mg by Apotex Inc. is also USFDA approved & it is not modified release tablet.</td></tr></table></td></tr>
</table>

	3.	Qualitative composition of innovator shows hypermellose in formulation which is not present in applied formulation.	The firm has submitted that the formulation is of innovator. However, innovator formulation shows Hypromellose as excipient.
	4.	The submitted GMP certificate has expired on 27-12-2019. You may submit updated copy of GMP certificate from concerned provincial or federal regulatory authority.	Submitted
	5.	Justify the non-performance of Dissolution testing in submitted stability data of Traxart Tablet since in USFDA approved formulation Lysteda®, the dissolution test has been performed in three time points 15, 45 and 90 min.	The firm has submitted we are following BP monograph of the said product and dissolution is not mentioned in the monograph. While BP monograph clearly states that *"The tablets should comply with the requirements stated under tablets and with the following requirements".* Moreover, FDA dissolution database also mentioned dissolution test for tranexamic acid tablets.
	6.	Comparative dissolution study with innovator formulation is required to be submitted.	The reference product is not available in Pakistan and is prescription product in US.

Decision: Deferred for further deliberation regarding the discussion of dissolution requirements for such cases

3366.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceutical, Plot No. 224/23 Korangi industrial Area, Karachi
	Brand Name +Dosage Form + Strength	EMPAGMET 5/500MG TABLET
	Composition	Each film coated tablet contains: Empagliflozin……..5mg Metformin hydrochloride……500mg
	Diary No. Date of R& I & fee	37, 03-11-2016, Rs.50,000/- dated 31-10-2016
	Pharmacological Group	SGLT2 inhibitor
	Type of Form	Form-5D
	Finished product Specification	Innovator specifications
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 5/500MG of Boehringer Ingelheim (USFDA Approved)
	Me-too status	N/A
	GMP status	Last GMP inspection was conducted on 10/04/18 and the report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	

STABILITY STUDY DATA	
Drug	EMPAGMET 5/500MG TABLET
Name of Manufacturer	M/s High-Q Pharmaceuticals, Plot No. 224/23 Korangi industrial Area, Karachi
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd., Zhejiang, China. **Metformin hydrochloride:** M/s Shouguang Fukang Pharmaceutical Co., Ltd, Shangdong Province, China
API Lot No.	**Empagliflozin:** 20180401 **Metformin hydrochloride:** A-81411810057
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,1,2,3,4,6 months

	Real Time: 0,3,6 months		
Batch No.	PD01/19	PD02/19	PD03/19
Batch Size	1428 Tablets	1428 Tablets	1428 Tablets
Manufacturing Date	July-2019	July-2019	July-2019
Date of Initiation	18-07-2019	18-07-2019	18-07-2019
No. of Batches	03		
Date of Submission	21-02-2020 (Dy. No.2202)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
Certificate of analysis of API.	**Empagliflozin:** Copy of COA of API (Batch # A81411810057) from M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd., Zhejiang, China has been submitted. **Metformin hydrochloride:** Copy of COA of API (Batch # 20180401) from M/s Shouguang Fukang Pharmaceutical Co., Ltd, Shangdong Province, China has been submitted.
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted copy of GMP certificate of API manufacturer issued by China Food and Drug Administration valid upto 14-03-2023. **Metformin hydrochloride:** The firm has submitted copy of GMP certificate of API manufacturer issued by Shangdong Food and Drug Administration valid upto 22-11-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Empagliflozin:** The firm has submitted copy of invoice for the purchase of Empagliflozin (2.0Kg) attested by Assistant Director (I & E) DRAP, Karachi dated 30-04-2018. **Metformin hydrochloride:** The firm has submitted copy of commercial invoice for the purchase of metformin hydrochloride (6000Kg) attested by Assistant Director (I & E) DRAP, Karachi dated 22-11-2018.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 21-02-2020 (Dy. No.2202)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last	Firm has referred to onsite inspection report of their product "Basovir 400mg Tablet and Vesoft 400/100mg Tablet", which

<table>
<tr><td></td><td>two years.</td><td>was presented in 279th and 284th meeting of Registration board.
Date of inspection : 16-02-2018 & 12-07-2018
According to the report, following points were confirmed
a) The HPLC software is 21CFR Compliant as per record available with the firm.
b) Continuous monitoring and power supply are available for stability chambers.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Empagliflozin: The firm has submitted copy of invoice for the purchase of Empagliflozin (2.0Kg) attested by Assistant Director (I & E) DRAP, Karachi dated 30-04-2018.
Metformin hydrochloride: The firm has submitted copy of commercial invoice for the purchase of metformin hydrochloride (6000Kg) attested by Assistant Director (I & E) DRAP, Karachi dated 22-11-2018.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Empagliflozin: Procured from API supplier.
Metformin hydrochloride: The firm has procured USP reference standard for metformin hydrochloride.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Empagliflozin: The firm has submitted copy of GMP certificate of API manufacturer issued by China Food and Drug Administration valid upto 14-03-2023.
Metformin hydrochloride: The firm has submitted copy of GMP certificate of API manufacturer issued by Shangdong Food and Drug Administration valid upto 22-11-2022.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted vendor pre-qualification mechanism for selection of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Empagliflozin: Copy of COA of API (Batch # A81411810057) from M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd., Zhejiang, China has been submitted.
In addition, the firm has provided following:
COA of working standard from API supplier
Empagliflozin impurity A (5mg)
Empagliflozin impurity C (5mg)
Metformin hydrochloride: Copy of COA of API (Batch # 20180401) from M/s Shouguang Fukang Pharmaceutical Co., Ltd, Shangdong Province, China has been submitted.
COA of reference standard of API submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted documents for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in R&D department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Authorized Protocols/SOP for product development and stability study”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Manufacturing protocols of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>PD01/19</td><td>1428 Tabs</td><td>07-2019</td></tr>
<tr><td>PD02/19</td><td>1428 Tabs</td><td>07-2019</td></tr>
<tr><td>PD03/19</td><td>1428 Tabs</td><td>07-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Trial No</td><td>Batch Size</td><td>Tablets used for stability</td><td>Remaining Quantities of tablets</td></tr>
</table></td></tr>
</table>

				testing	
		PD01/19	1428 Tabs	560	826
		PD02/19	1428 Tabs	560	830
		PD03/19	1428 Tabs	560	840
QA / QC DATA					
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.			
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Empagliflozin and metformin hydrochloride.			
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Empagmet 5/500mg Tablet" along with Stability Study Reports.			
15.	Reports of stability studies of API from manufacturer.	**Empagliflozin:** The firm has submitted 6 months accelerated and 6 months real time stability study data of 3 batches. **Metformin hydrochloride:** The firm has submitted 6 months accelerated and 60months real time stability study data of 3 batches.			
16.	Analysis reports for excipients used.	The firm has submitted analytical reports of excipients used.			
17.	Drug-excipients compatibility studies.	The firm has performed Drug-excipient compatibility studies by reverse phase HPLC method and studies did not reveal any incompatibility.			
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution profile of Empagmet 5/500mg Tablet with innovator product Synjardy 5/500mg Tablet (Lot # 955663) in pH 6.8 phosphate buffer, 0.1 N HCl and 4.5 pH acetate buffer. Moreover, f2 factor was calculated to compare the dissolution profiles.			
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.			

The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.

Observations	**Response of the applicant**
Evidence of procurement of reference standard and impurity standard of Empagliflozin are required.	The firm has submitted Empagliflozin working standard and impurity standards were received alongwith Empagliflozin raw material since they were FOC so not mentioned on invoice.
Justify dissolution specifications NLT 80% in 30min while dissolution specifications of innovator product (Synjardy) are NLT Q in 20min.	The firm has submitted that we have revised the dissolution specifications as per innovator and accordingly revised finished product specifications are enclosed. Furthermore we commit to follow these specifications in future testing.

Decision: Registration Board decided as follows:

- **Accept the stability study data as the dissolution specifications falls within the definition of immediate release drug product and approved registration of following drug with innovator's specification, wherein manufacturer will adopt the dissolution specifications i.e. NLT Q at 20 minutes for commercial production batches.**
    - **Empagmet 5/500mg Tablet**

Furthermore, manufacturer will place first three production batches on long term stability studies throughout

proposed shelf life and on accelerated studies for six months.		
3367.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceutical, Plot No. 224/23 Korangi industrial Area, Karachi
	Brand Name +Dosage Form + Strength	EMPAGMET 5/850MG TABLET
	Composition	Each film coated tablet contains: Empagliflozin……..5mg Metformin hydrochloride……850mg
	Diary No. Date of R& I & fee	1476, 03-04-2017, Rs.50,000/- dated 30-03-2017
	Pharmacological Group	SGLT2 inhibitor
	Type of Form	Form-5D
	Finished product Specification	Innovator specifications
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Synjardy Tablets 5/850MG (EMA Approved; EU number EU/1/15/1003/001)
	Me-too status	N/A
	GMP status	Last GMP inspection was conducted on 10/04/18 and report concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	

STABILITY STUDY DATA			
Drug	EMPAGMET 5/850MG TABLET		
Name of Manufacturer	M/s High-Q Pharmaceuticals, Plot No. 224/23 Korangi industrial Area, Karachi		
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd., Zhejiang, China. **Metformin hydrochloride:** M/s Shouguang Fukang Pharmaceutical Co., Ltd, Shangdong Province, China		
API Lot No.	**Empagliflozin:** 20180401 **Metformin hydrochloride:** A-81411810057		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,3,6 months Real Time: 0,3,6 months		
Batch No.	PD01/19	PD02/19	PD03/19
Batch Size	994 Tablets	994 Tablets	994 Tablets
Manufacturing Date	July-2019	July-2019	July-2019
Date of Initiation	23-07-2019	23-07-2019	23-07-2019
No. of Batches	03		
Date of Submission	19-03-2020 (Dy. No.4951)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
Certificate of analysis of API.	**Empagliflozin:** Copy of COA of API (Batch # A81411810057) from M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd., Zhejiang, China has been submitted. **Metformin hydrochloride:** Copy of COA of API (Batch # 20180401) from M/s Shouguang Fukang Pharmaceutical Co., Ltd, Shangdong Province, China has been submitted.

Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted copy of GMP certificate of API manufacturer issued by China Food and Drug Administration valid upto 14-03-2023. **Metformin hydrochloride:** The firm has submitted copy of GMP certificate of API manufacturer issued by Shangdong Food and Drug Administration valid upto 22-11-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	**Empagliflozin:** The firm has submitted copy of invoice for the purchase of Empagliflozin (2.0Kg) attested by Assistant Director (I & E) DRAP, Karachi dated 30-04-2018. **Metformin hydrochloride:** The firm has submitted copy of commercial invoice for the purchase of metformin hydrochloride (6000Kg) attested by Assistant Director (I & E) DRAP, Karachi dated 22-11-2018.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 19-03-2020 (Dy. No.4951)

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Basovir 400mg Tablet and Vesoft 400/100mg Tablet", which was presented in 279th and 284th meeting of Registration board. Date of inspection : 16-02-2018 & 12-07-2018 According to the report, following points were confirmed a) The HPLC software is 21CFR Compliant as per record available with the firm. b) Continuous monitoring and power supply are available for stability chambers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** The firm has submitted copy of invoice for the purchase of Empagliflozin (2.0Kg) attested by Assistant Director (I & E) DRAP, Karachi dated 30-04-2018. **Metformin hydrochloride:** The firm has submitted copy of commercial invoice for the purchase of metformin hydrochloride (6000Kg) attested by Assistant Director (I & E) DRAP, Karachi dated 22-11-2018.
3.	Documents for the procurement of reference standard and impurity standards.	**Empagliflozin:** **Metformin hydrochloride:** The firm has procured USP reference standard for metformin hydrochloride.
4.	Approval of API/ DML/GMP certificate of	**Empagliflozin:** The firm has submitted copy of GMP

<table>
<tr><td></td><td>API manufacturer issued by regulatory authority of country of origin.</td><td>certificate of API manufacturer issued by China Food and Drug Administration valid upto 14-03-2023.
Metformin hydrochloride: The firm has submitted copy of GMP certificate of API manufacturer issued by Shangdong Food and Drug Administration valid upto 22-11-2022.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted vendor pre-qualification mechanism for selection of Vendors.</td></tr>
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In addition, the firm has provided following:
COA of working standard from API supplier
Empagliflozin impurity A (5mg)
Empagliflozin impurity C (5mg)
Metformin hydrochloride: Copy of COA of API (Batch # 20180401) from M/s Shouguang Fukang Pharmaceutical Co., Ltd, Shangdong Province, China has been submitted.
COA of reference standard of API submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted documents for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in R&D department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Authorized Protocols/SOP for product development and stability study”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Manufacturing protocols of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>PD01/19</td><td>994 Tabs</td><td>07-2019</td></tr>
<tr><td>PD02/19</td><td>994 Tabs</td><td>07-2019</td></tr>
<tr><td>PD03/19</td><td>994 Tabs</td><td>07-2019</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><td>Trial No</td><td>Batch Size</td><td>Tablets used for stability testing</td><td>Remaining Quantities of tablets</td></tr>
<tr><td>PD01/19</td><td>994 Tabs</td><td>560</td><td>826</td></tr>
<tr><td>PD02/19</td><td>994 Tabs</td><td>560</td><td>830</td></tr>
<tr><td>PD03/19</td><td>994 Tabs</td><td>560</td><td>840</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Empagliflozin and metformin hydrochloride.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Empagmet 5/850mg Tablet” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from</td><td>Empagliflozin: The firm has submitted 6 months accelerated</td></tr>
</table>

	manufacturer.	and 6 months real time stability study data of 3 batches. **Metformin hydrochloride:** The firm has submitted 6 months accelerated and 60months real time stability study data of 3 batches.
16.	Analysis reports for excipients used.	The firm has submitted analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has performed Drug-excipient compatibility studies by reverse phase HPLC method and studies did not reveal any incompatibility.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution profile of Empagmet 5/850mg Tablet with innovator product Synjardy 5/850mg Tablet (Lot # 704075) in pH 6.8 phosphate buffer, 0.1 N HCl and 4.5 pH acetate buffer. Moreover, f2 factor was calculated to compare the dissolution profiles.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of applied product.

The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.

Observations	**Response of the applicant**
Evidence of procurement of reference standard and impurity standard of Empagliflozin are required.	The firm has submitted Empagliflozin working standard and impurity standards were received alongwith Empagliflozin raw material since they were FOC so not mentioned on invoice.
Justify dissolution specifications NLT 80% in 30min while dissolution specifications of innovator product (Synjardy) are NLT Q in 20min.	The firm has submitted that we have revised the dissolution specifications as per innovator and accordingly revised finished product specifications are enclosed. Furthermore we commit to follow these specifications in future testing.

Decision: Decision: Registration Board decided as follows:

- **Accept the stability study data as the dissolution specifications fall within the definition of immediate release drug product and approved registration of following drug with innovator's specification, wherein manufacturer will adopt the dissolution specifications i.e. NLT Q at 20 minutes for commercial batches.**
    - **Empagmet 5/850mg Tablet**

Furthermore, manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

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

a. New cases

3368.	Name and address of manufacturer / Applicant	M/s MTI Medical (Pvt) Ltd. 586 Sundar Industrial Estate, Lahore. Contract manufactured by Stallion Pharmaceuticals (Pvt) Ltd 581-Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Pinomer Sterile Dry Powder Injection 500mg
	Composition	Each Vial Contains: Meropenem (as trihydrate)…500mg
	Diary No. Date of R& I & fee	Dy No. 7955: 22-02-2019 PKR 50,000/-: 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meronem IV 500mg Powder for solution for injection or infusion (MHRA Approved)
	Me-too status	Meronem 500mg Injection of ICI Pakistan Ltd.
	GMP status	MTI Medical (Pvt) Ltd: Firm is granted GMP certificate based on inspection conducted on 25-9-2019. Stallion Pharmaceuticals: Certificate of GMP issued based on the inspection conducted on 22-11-2018
	Remarks of the Evaluator	• M/s stallion Pharma have Dry powder Injection vial (Carbapenem) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. MTI medical (Pvt) Ltd has 7 approved sections and no product registered on contract manufacturing. • Firm has submitted application on Form 5F (CTD) on 08-10-2019 to avail out of queue. However during the evaluation of case and submission of required documents by the firm, their normal routine queu have been attained since the initial application was received on 22-02-2019.
	Decision: Approved.	
3369.	Name and address of manufacturer / Applicant	M/s MTI Medical (Pvt) Ltd. 586 Sundar Industrial Estate, Lahore. Contract manufactured by Stallion Pharmaceuticals (Pvt) Ltd 581-Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Pinomer Sterile Dry Powder Injection 1g
	Composition	Each Vial Contains: Meropenem (as trihydrate)…1g
	Diary No. Date of R& I & fee	Dy No. 7956: 22-02-2019 PKR 50,000/-: 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meronem IV 1g Powder for solution for injection or infusion (MHRA Approved)
	Me-too status	Meronem 1g Injection of ICI Pakistan Ltd.
	GMP status	MTI Medical (Pvt) Ltd: Firm is granted GMP certificate based on inspection conducted on 25-9-2019. Stallion Pharmaceuticals: Certificate of GMP issued based on

		the inspection conducted on 22-11-2018
	Remarks of the Evaluator	• M/s stallion Pharma have Dry powder Injection vial (Carbapenem) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. MTI medical (Pvt) Ltd has 7 approved sections and no product registered on contract manufacturing. • Firm has submitted application on Form 5F (CTD) on 08-10-2019 to avail out of queue. However during the evaluation of case and submission of required documents by the firm, their normal routine queu have been attained since the initial application was received on 22-02-2019.
	Decision: Approved.	
3370.	Name and address of manufacturer / Applicant	M/s MTI Medical (Pvt) Ltd. 586 Sundar Industrial Estate, Lahore. Contract manufactured by Stallion Pharmaceuticals (Pvt) Ltd 581-Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tazopep Sterile Dry Powder Injection 2.25g
	Composition	Each Vial Contains: Piperacillin (as sodium)…2g Tazobactam (as sodium)….0.25g
	Diary No. Date of R& I & fee	Dy No. 7957: 22-02-2019 PKR 50,000/-: 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin/Tazobactam 2 g/0.25 g Powder for Solution for Infusion (MHRA Approved)
	Me-too status	Tanzo Injection by Bosch
	GMP status	MTI Medical (Pvt) Ltd: Firm is granted GMP certificate based on inspection conducted on 25-9-2019. Stallion Pharmaceuticals: Certificate of GMP issued based on the inspection conducted on 22-11-2018
	Remarks of the Evaluator	• M/s stallion Pharma have Dry powder Injection vial (Penicillin) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. MTI medical (Pvt) Ltd has 7 approved sections and no product registered on contract manufacturing. • Firm has submitted application on Form 5F (CTD) on 08-10-2019 to avail out of queue. However during the evaluation of case and submission of required documents by the firm, their normal routine queu have been attained since the initial application was received on 22-02-2019.
	Decision: Approved.	
3371.	Name and address of manufacturer / Applicant	M/s MTI Medical (Pvt) Ltd. 586 Sundar Industrial Estate, Lahore. Contract manufactured by Stallion Pharmaceuticals (Pvt) Ltd 581-Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tazopep Sterile Dry Powder Injection 4.5g
	Composition	Each Vial Contains: Piperacillin (as sodium)…4g

		Tazobactam (as sodium)….0.5g
	Diary No. Date of R& I & fee	Dy No. 7958: 22-02-2019 PKR 50,000/-: 22-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin/Tazobactam 4 g/0.5 g powder for solution for infusion (MHRA Approved)
	Me-too status	Tanzo Injection by Bosch
	GMP status	MTI Medical (Pvt) Ltd: Firm is granted GMP certificate based on inspection conducted on 25-9-2019. Stallion Pharmaceuticals: Certificate of GMP issued based on the inspection conducted on 22-11-2018
	Remarks of the Evaluator	• M/s stallion Pharma have Dry powder Injection vial (Penicillin) section. • Copy of contract manufacturing agreement is provided by the firm. • The applicant firm i.e. MTI medical (Pvt) Ltd has 7 approved sections and no product registered on contract manufacturing. • Firm has submitted application on Form 5F (CTD) on 08-10-2019 to avail out of queue. However during the evaluation of case and submission of required documents by the firm, their normal routine queu have been attained since the initial application was received on 22-02-2019.
	Decision: Approved.	

M/s Moringa Pharmaceuticals (Pvt) 35-A Sundar Industrial Estate, Raiwind Road Lahore has submitted the following applications for contract manufacturing on 01-02-2019 on Form 5.

Later the firm submitted CTD dossiers for these applications to avail out of que priority. CTD dossiers were evaluated and found deficient for which the shortcomings were communicated to the firm.

Now the firm vide its letter dated 20-02-2020, has requested to consider these applications on Form 5 instead of CTD. The firm has submitted that "The CTD version of above dossiers were submitted later in the year in order to pursue out-of-queue, early registration. However, it could not be successful since required compliance could not be met. It is therefore requested that our dossiers may please be considered on the previous format and evaluated accordingly to be put in the upcoming board meeting for registration"

3372.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Moripime 500mg Injection
	Composition	Each Vial Contains: Cefepime HCL with L-Arginine eq to Cefepime…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4607 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic-cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Feldopim 500mg Injection of M/s Wnsfeild (Reg.#046970)

	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3373.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Moripime 1g Injection
	Composition	Each Vial Contains: Cefepime HCL with L-Arginine eq to Cefepime…1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4609 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic-cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Nuxipim 1g Injection of Bosch
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3374.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Combact Injection 1g
	Composition	Each Vial Contains: Cefoperazone as Sodium…500mg Sulbactam as Sodium…500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4619 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by PMDA-Japan
	Me-too status	2Sum Injection 1g of Sami Pharma (R.#047002)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	

3375.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Combact Injection 2g
	Composition	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
	Diary No. Date of R& I & fee	Form-5 Dy.No 4617 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Cebac 2 g Injection by M/s Bosch Pharma
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3376.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Bonigen Injection 200,000IU/ml
	Composition	Each ml contains: Vitamin D-3 Cholecalciferol …200,000IU
	Diary No. Date of R& I & fee	Form-5 Dy.No 4608 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Vitamin- D
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1ml glass ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200,000 IU / 1 ml, IM solution for injection in ampoule & VITAMIN D3 GOOD 200,000 IU / 1 ml, oral solution in ampoule (**ANSM** France Approved)
	Me-too status	Drol- D injection by Regal Pharma (Reg. # 082005)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3377.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Gemton Injection 40mg/vial/IM
	Composition	Each Vial Contains:

		Esomeprazole as sodium…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4612 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for Injection vial. (**TGA** approved)
	Me-too status	Somezol Injection 40mg by Bosch (Reg# 045386)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3378.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Ferogem Injection 5ml
	Composition	Each 5ml contains: Iron Sucrose complex eq to Elemental Iron…100mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4616 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	VENOFER iron 100mg/5mL (as iron(III) hydroxide sucrose complex) injection (**TGA** Approved)
	Me-too status	Iroject Injection by Medley Pharma (Reg#070173)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3379.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Ketomor 10mg Tablet
	Composition	Each film coated tablet contains Ketorolac Tromethamine…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4611 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	USFDA approved

	Reference Regulatory Authorities.	
	Me-too status	Yukon Tablet 10mg. Reg. No. 74285
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3380.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Ketomor 20mg Tablet
	Composition	Each film coated tablet contains Ketorolac Tromethane…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4610 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Kelac 20mg Tablet by Rotex Pharma
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/- • Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed.
	Decision: Deferred for following submissions: • **Submission of differential fee of Rs. 30,000/- for contract manufacturing.** • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**	
3381.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Methicol Injection 500mcg
	Composition	Each ml contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4614 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Vitamin B-12
	Type of Form	Form 5
	Finished product Specification	Innovator's specs
	Pack size & Demanded Price	1ml ampoule x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Comezengen injection 500 µg of M/s Tatsumi Chemical (PMDA Japan Approved)
	Me-too status	Flench injection of Tabros Pharma (Reg. # 029050)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP

		certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3382.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Myriva Infusion 400mg
	Composition	Each 250ml vial contains: Moxifloxacin as HCl…400mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4613 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle by M/s Bayer Australia Ltd (TGA Approved)
	Me-too status	Izilon I.V Infusion 400mg/250ml by Bosch (Reg#030074)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	
3383.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Safpep 40mg Injection
	Composition	Each Vial Contains: Omeprazole as Sodium…40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 4604 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specification	Innovator's specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for injection of Sandoz, UK (MHRA Approved)
	Me-too status	Zegrid-40 Injection of Shaigan Pharma
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/-
	Decision: Deferred for submission of differential fee of Rs. 30,000/- for contract manufacturing.	

3384.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Zipbact 2.25g Injection
	Composition	Each Vial Contains: Piperacillin as sodium…2g Tazobactam as sodium…0.25g
	Diary No. Date of R& I & fee	Form-5 Dy.No 4606 dated 01-02-2019 Rs.20,000/- Dated 31-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin/Tazobactam 2 g/0.25 g Powder for Solution for Infusion (MHRA Approved)
	Me-too status	Tanzo Injection by Bosch
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/- • Evidence of approval of required manufacturing facility / section could not be confirmed.
	Decision: Deferred for following: • **Evidence of required manufacturing facility / section from Licensing Division.** • **Submission of differential fee of Rs. 30,000/- for contract manufacturing.**	
3385.	Name and address of manufacturer / Applicant	M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Lahore Contract manufactured by English Pharmaceutical Industries. Link Kattar Bund Road Thokar Niaz Baig, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Zipbact 4.5g Injection
	Composition	Each Vial Contains: Piperacillin as sodium…4g Tazobactam as sodium…0.5g
	Diary No. Date of R& I & fee	Form-5 Dy.No 4605 (01-02-2019) Rs.20,000/- 31-01-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin 4g / Tazobactam 500mg powder for solution for infusion vials (MHRA Approved)
	Me-too status	Tanzo Injection by Bosch (Reg# 039439)
	GMP status	Moringa Pharmaceuticals: The firm is granted GMP certificate based on inspection conducted on 30-5-2019. English Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 06-01-2018
	Remarks of the Evaluator	• Firm has not submitted complete fee for contract manufacturing. Firm has only submitted fee PKR 20,000/- • Evidence of approval of required manufacturing facility / section could not be confirmed.
	Decision: Deferred for following: • **Evidence of required manufacturing facility / section from Licensing Division.**	

	• **Submission of differential fee of Rs. 30,000/- for contract manufacturing.**	
3386.	Name and address of manufacture / Applicant	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan. Contract manufactured by M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad.
	Brand Name dosage and Strength	Acnetrac 20mg Capsule
	Composition	Each Soft Gel Capsule Contains: Isotretinoin…20mg
	Dairy No. date of R &I fee	Dy. No 22676 dated 29-06-2018 Rs. 50,000/- Dated 29-06-2018 (Duplicate dossier)
	Pharmacological Group	Anti-acne preparation
	Type of form	Form-5
	Finished product specifications	BP
	Pack size and Demand Price	3 x 10's: As per SRO
	Approval status of product in reference regulatory Authorities	Isotretinoin 20 mg Soft Capsules by Mylan (MHRA Approved)
	Me-too-status	Roaccutane capsule 20mg by Roche
	GMP Status	Medisave Pharmaceuticals: Firm has been granted GMP certificate based on inspection dated 11-12-2017 & 10-01-2018. Crystollite Pharma: Panel Inspection for renewal of DML conducted on 12-11-2018 & 02-01-2019 unanimously recommends the renewal of DML
	Remark of the Evaluator	Firm has submitted section approval letter dated 11-04-2017 specifying soft gelatin capsule (general) section.
	Decision: Approved. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	

b. Deferred cases

3387.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals (Pvt) Ltd, 158 D, Tore Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Listan AM 10/160mg Tablet
	Composition	Each film coated tablet contains: Amlodipine……10 mg Valsartan……..160 mg
	Diary No. Date of R& I & fee	Dy No 85, 26-01-2015; PKR 20,000/-
	Pharmacological Group	Angiotensin-II Receptor Antagonists
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge tablets by Novartis, (MHRA Approved)
	Me-too status	Exforge tablets by Novartis
	GMP status	Last GMP inspection report dated 23-11-2016 do not provide conclusive remarks of GMP and it concludes "the firm is employing resources for upgradation as per approved layout plan"
	Remarks of the Evaluator	Letter for shortcoming was issued on 30-03-2017 and the reply is still deficient for following documents • Method of granule preparation is still incomplete i.e. it does not elaborate which type of method is used to prepare granules. The current method of manufacturing states only 3 steps o Step-I: Preparation of granules (Pass ingredients through mesh # 16 and mix for 30 min)

		○ Step-II: Lubrication (pass ingredients through mesh # 30 and add magnesium stearate) ○ Step-III: Submit sample to QC and after release proceed for final compression and coating • The GMP inspection report do not provide conclusive remarks about GMP • Commitments as per 251st RB meeting
	Decision of 270th meeting of Registration Board	Deferred for following submissions • Detailed method of manufacturing • Commitments as per 251st meeting of Registration Board
	Evaluation by PEC	Firm has submitted following documents: • Complete outline of method of manufacturing specifying the steps for preparation of granules. • Finished product specification • Commitments as per 251st meeting of Registration Board. • Last GMP inspection report dated 24-7-2018 concluding GOOD compliance to GMP. • Master formulation having following details composition Each film coated tablet contains: Amlodipine (as besylate)…….10mg Valsartan……160mg
	Decision: Approved with following composition / label claim: **Each film coated tablet contains:** **Amlodipine (as besylate)…….10mg** **Valsartan……160mg**	
3388.	Name and address of manufacturer / Applicant	M/s. Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Spasnil Tablets
	Composition	Each coated tablet contains:- Phloroglucinol…….80 mg Trimethyl Phloroglucinol……80 mg
	Diary No. Date of R& I & fee	11-5-10
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished product Specification	Firm has claimed in house specifications.
	Pack size & Demanded Price	3x10's As Per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM France approved
	Me-too status	Anafortan Plus (AGP)
	GMP status	
	Remarks of the Evaluator	•
	Decision of previous meeting of Registration Board	• Referred to review committee for decision (M-238) • Deferred for expert opinion (M-250) • Evaluation of application as per checklist approved by 251st meeting of Registration Board. (M-268) • Deferred for submission of fee for revision of formulation.(M-293)
	Evaluation by PEC	Firm has submitted fee PKR 5,000/- dated 25-02-2020 for revision of formulation.
	Decision: Approved with following composition / label claim: **Each sugar coated tablet contains:** **Hydrated phloroglucinol…….80mg** **Trimethylphloroglucinol ……80mg**	

3389.	Name and address of manufacturer / Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tragenol tablet 37.5mg/ 325mg
	Composition	Each film-coated tablet contains: Tramadol HCl……37.5mg Paracetamol ……325mg
	Diary No. Date of R& I & fee	Dy.No.17058; 04-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Analgesic / Anti-pyretic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Ultracet tablets of Janssen Pharmaceuticals (USFDA Approved)
	Me-too status	Tonoflex P of M/s Sami Pharma (Reg. # 067163)
	GMP status	GMP report submitted does not possess any date and the report concludes : "A detailed re-inspection would be conducted in operational mode in order to assess GMP compliance as at the moment unit was completely found non- operational."
	Remarks of the Evaluator	• GMP report has no date and is not conclusive. • Firm has general tablet section.
	Decision of 285th meeting of Registration Board	Deferred for updated status of GMP of the firm form QA & LT division as the inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC	Firm has submitted recent GMP inspection conducted by panel of inspectors dated 03-02-2020 and the report concludes "The panel was of the opinion that the firm was operating at satisfactory level of cGMP compliance as of today"
	Decision: Approved.	
3390.	Name and address of manufacturer / Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Pregene capsule 50mg
	Composition	Each capsule contains: Pregabalin ……50mg
	Diary No. Date of R& I & fee	Dy.No.17059; 04-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Anti-epileptic
	Type of Form	Form- 5
	Finished product Specification	In house
	Pack size & Demanded Price	2x7's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Gabica 50mg capsule of M/s Getz (Reg. # 048725)
	GMP status	Last GMP inspection was conducted on 15-07-2016 and the report concludes: "A detailed re-inspection would be conducted in operational mode. At the time of inspection unit was found non-operational."
	Remarks of the Evaluator	• GMP status could not be confirmed by the report. • No official monograph is available in USP or BP for the applied formulation.
	Decision of 290th meeting of Registration Board	Registration Board referred the case to QA & LT Division to update GMP status of Firm on priority.
	Evaluation by PEC	Firm has submitted recent GMP inspection conducted by panel of inspectors dated 03-02-2020 and the report concludes "The panel was of the opinion that the firm was

		operating at satisfactory level of cGMP compliance as of today"
	Decision: Approved with innovator's specification.	
3391.	Name and address of manufacturer / Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Febogen tablets 40 mg
	Composition	Each film-coated tablet contains: Febuxostat……..…40mg
	Diary No. Date of R& I & fee	Dy.No.17063; 04-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Anti-gout/ preparations inhibiting uric acid production.
	Type of Form	Form- 5
	Finished product Specification	In house
	Pack size & Demanded Price	2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Zurig 40mg of M/s Getz pharma (Reg. # 067290)
	GMP status	Last GMP inspection was conducted on 15-07-2016 and the report concludes: "A detailed re-inspection would be conducted in operational mode. At the time of inspection unit was found non-operational."
	Remarks of the Evaluator	• GMP status could not be confirmed by the report. • The official monograph of the applied formulation is not available in USP or BP.
	Decision of 290th meeting of Registration Board	Registration Board referred the case to QA & LT Division to update GMP status of Firm on priority.
	Evaluation by PEC	Firm has submitted recent GMP inspection conducted by panel of inspectors dated 03-02-2020 and the report concludes "The panel was of the opinion that the firm was operating at satisfactory level of cGMP compliance as of today"
	Decision: Approved with innovator's specification.	
3392.	Name and address of manufacturer / Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Gabagene capsule 100mg
	Composition	Each capsule contains: Gabapentin ……....100mg
	Diary No. Date of R& I & fee	Dy.No.17060; 04-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Antiepileptic
	Type of Form	Form- 5
	Finished product Specification	In house
	Pack size & Demanded Price	1x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Gabix capsule 100mg of M/s Getz Pharma (Reg. # 039398)
	GMP status	Last GMP inspection was conducted on 15-07-2016 and the report concludes: "A detailed re-inspection would be conducted in operational mode. At the time of inspection unit was found non-operational."
	Remarks of the Evaluator	• The official monograph for the applied formulation is available in USP. • GMP status could not be confirmed by the report.
	Decision of 290th meeting of Registration Board	Registration Board referred the case to QA & LT Division to update GMP status of Firm on priority.

	Evaluation by PEC	Firm has submitted recent GMP inspection conducted by panel of inspectors dated 03-02-2020 and the report concludes "The panel was of the opinion that the firm was operating at satisfactory level of cGMP compliance as of today"
	Decision: Approved with innovator's specification.	
3393.	Name and address of manufacturer / Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Claragen tablets 500mg
	Composition	Each film coated tablet contains: Clarithromycin …….. 500mg
	Diary No. Date of R& I & fee	Dy.No.17062; 04-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Macrolide
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 500mg Tablet of M/s Sandoz (USFDA approved)
	Me-too status	Klaricid tablets 500mg of M/s Abbott, Karachi (Reg. # 020203)
	GMP status	Last GMP inspection was conducted on 15-07-2016 and the report concludes: "A detailed re-inspection would be conducted in operational mode. At the time of inspection unit was found non-operational."
	Remarks of the Evaluator	• Applied label claim is not complete. • GMP status could not be confirmed by the report. • Firm was issued a letter on 19th Oct, 2018 but still no reply has been received yet.
	Decision of 290th meeting of Registration Board	Registration Board referred the case to QA & LT Division to update GMP status of Firm on priority.
	Evaluation by PEC	Firm has submitted recent GMP inspection conducted by panel of inspectors dated 03-02-2020 and the report concludes "The panel was of the opinion that the firm was operating at satisfactory level of cGMP compliance as of today"
	Decision: Approved.	
3394.	Name and address of manufacturer / Applicant	M/s Genesis Pharmaceuticals, Plot # 25, Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Dulogene 30mg delayed- release capsules
	Composition	Each capsule contains: Enteric- coated pellets of Duloxetine (as HCl)…….……...30mg (Source of pellets: M/s Vision Pharma)
	Diary No. Date of R& I & fee	Dy.No.17061; 04-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	Serotonin and noradrenaline reuptake inhibitor
	Type of Form	Form- 5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	2x 7's for both & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Dulan 30 mg capsule of M/s Hilton Pharma (Reg.# 055447)
	GMP status	Last GMP inspection was conducted on 15-07-2016 and the report concludes: "A detailed re-inspection would be conducted in operational

		mode. At the time of inspection unit was found non-operational."
	Remarks of the Evaluator	• Firm has submitted GMP certificate, CoA of manufacturer and stability data of pellets. • GMP status could not be confirmed by the report.
	Decision of 290th meeting of Registration Board	Registration Board referred the case to QA & LT Division to update GMP status of Firm on priority.
	Evaluation by PEC	Firm has submitted recent GMP inspection conducted by panel of inspectors dated 03-02-2020 and the report concludes "The panel was of the opinion that the firm was operating at satisfactory level of cGMP compliance as of today"
	Decision: Approved.	
3395.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceutical Pvt. Ltd., 538- C Sundar Industrial Estate Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Doxair tablet 400mg
	Composition	Each uncoated tablet contains: Doxofylline……..400mg
	Diary No. Date of R& I & fee	Dy.No.27783; 13-08-2018; Rs.20,000 (10-08-2018)
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	Innovator's
	Pack size & Demanded Price	10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Italian Medicine Agency (AIFA) Italy approved
	Me-too status	Profylline tablet 400mg of M/s Kaizen (Reg. # 073744)
	GMP status	Last GMP inspection was conducted on 24-05-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Firm has General tablet section as mentioned in the submitted section approval letter. • Coating was mentioned in the flowchart of manufacturing method. • When asked through letter, firm replied: "*Doxair tablet 40mg are uncoated coated tablets as mentioned in Form- 5, due to some typographic mistake coating was mentioned in flowchart of manufacturing process."* • Firm has submitted Rs. 5000/- fees for revision of formulation and has submitted the master formulation according to the reference but again *uncoated coated tablets* have been mentioned in the reply.
	Decision of 293rd meeting of Registration Board	Deferred regarding the applied type of dosage form as "uncoated coated" tablets.
	Evaluation by PEC	Firm has submitted that we have applied for doxofylline uncoated tablet as per the Italy approved formulation, however due to typographic error coating step was mentioned in the method of manufacturing. In response to the letter of shortcoming we have already revised the master formulation as well as method of manufacturing to uncoated tablet along with submission of 5,000 fee for revision of formulation. However our case was again deferred for the same reason. Therefore we are requesting your kind office to consider the case.
	Decision: Approved.	

3396.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals Pvt. LTD. 538-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cvox Dry Powder Suspension 125mg
	Composition	Each 5ml contains: Ciprofloxacin as HCl…125mg
	Diary No. Date of R& I & fee	Dy. No.17972; 12-10-2017; Rs.20,000/- (12-10-2017)
	Pharmacological Group	Quinolones
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	Glass bottle, 60ml , As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not available.
	Me-too status	077456 "Ciproking 125 mg Dry powder Suspension " Medicraft Pharmaceuticals (Pvt) Ltd.,126-B, Industrial Estate, Jamrud Road, Peshawar
	GMP status	24-05-2019 Conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Firm has the relevant section. • Taste masked micropellets obtained from Vision Pharmaceuticals.(in-house specifications). • Box Warning for Quinolones. <u>Shortcomings:</u> • Clarification regarding brand name whether CVOX or CIVOX. • The innovator product is marketed with a solvent containing following ingredients o Soya lecithin, o Medium chain triglycerides, o Strawberry flavour, o Sucrose, o Purified water. Registration Board Decision (M-269). Keeping in view the following statement written in Qualitative and quantitative composition "2.5 mL suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin" and domestic conditions for difficulties in dispensing 250mg/5ml suspension for children under 2 years of age, Registration Board decided to approve the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA.
	Decision of 292nd meeting of Registration Board	Deferred the following reasons: • Clarification regarding brand name whether CVOX or CIVOX. • Revision of formulation as per innovator product i.e. "Ciprofloxacin", as the applied formulation is "Ciprofloxacin as hydrochloride". • Submission of details of solvent for oral suspension as per reference product as approved by USFDA and MHRA.
	Evaluation by PEC	Firm has submitted the following documents: • Our applied brand name is CIVOX Dry Powder suspension 125mg. However in case of any brand name

		resemblance we undertake to change the brand name. • We are submitting the revised correct master formulation with following label claim. Each 5ml of reconstituted suspension contains: Ciprofloxacin……125mg o The firm also submitted following documents o COA of micropellets of Vision Pharmaceuticals, Islamabad. o Revised master formulation containing ciprofloxacin base. • Fee PKR 5,000/- for revision of formulation. • We will use the solvent / diluent having the following composition as per the innovator product and as per the decision of Registration Board. o Soya Lecithin o Medium chain triglycerides o Flavor o Sucrose o Purified water
	Decision: Approved with USP specifications and with following composition / label claim: **Each 5ml of reconstituted suspension contains:** **Ciprofloxacin……125mg**	
3397.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals Pvt. LTD. 538-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cvox Dry Powder Suspension 250mg
	Composition	Each 5ml contains: Ciprofloxacin as HCl…250mg
	Diary No. Date of R& I & fee	Dy. No.17973; 12-10-2017; Rs.20,000/- (12-10-2017)
	Pharmacological Group	Quinolones
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	Glass bottle, 60ml , As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved Ciprofloxacin Microcapsules
	Me-too status	077457 "Ciproking 250 mg Dry powder Suspension " Medicraft Pharmaceuticals (Pvt) Ltd.,126-B, Industrial Estate, Jamrud Road, Peshawar."
	GMP status	24-05-2019 Conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has the relevant section. Taste masked micropellets obtained from Vision Pharmaceuticals.(in-house specifications). Box Warning for Quinolones. <u>Shortcomings:</u>. • Clarification regarding brand name whether CVOX or CIVOX. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Internationally the approved formulation is Ciprofloxacin whereas, the firm has applied for

		ciprofloxacin as hydrochloride.
	Decision of 292nd meeting of Registration Board	Deferred the following reasons: • Clarification regarding brand name whether CVOX or CIVOX. • Revision of formulation as per innovator product i.e. "Ciprofloxacin", as the applied formulation is "Ciprofloxacin as hydrochloride". • Submission of details of solvent for oral suspension as per reference product as approved by USFDA and MHRA.
	Evaluation by PEC	Firm has submitted the following documents: • Our applied brand name is CIVOX Dry Powder suspension 125mg. However in case of any brand name resemblance we undertake to change the brand name. • We are submitting the revised correct master formulation with following label claim. Each 5ml of reconstituted suspension contains: Ciprofloxacin……250mg o The firm also submitted following documents o COA of micropellets of Vision Pharmaceuticals, Islamabad. o Revised master formulation containing ciprofloxacin base. • Fee PKR 5,000/- for revision of formulation. • We will use the solvent / diluent having the following composition as per the innovator product and as per the decision of Registration Board. o Soya Lecithin o Medium chain triglycerides o Flavor o Sucrose o Purified water
	Decision: Approved with USP specifications and with following composition / label claim: **Each 5ml of reconstituted suspension contains:** **Ciprofloxacin……125mg**	
3398.	Name and address of manufacturer / Applicant	Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Valopine Tablet 5mg/80mg
	Composition	Each film-coated tablet contains: Amlodipine Besylate eq.to Amlodipine ……..……....5mg Valsartan…….80mg
	Diary No. Date of R& I & fee	Dy. No.2999; 19-12-2016; Rs.20,000/- (16-12-2016)
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	As per SRO & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Exforge of M/s Novartis Pharmaceuticals (UK) MHRA Approved
	Me-too status	Exforge of M/s Novartis Pharmaceuticals, Karachi
	GMP status	Last GMP inspection was conducted on 15-03-2017 which concludes an acceptable level of GMP compliance.
	Remarks of the Evaluator	• The proposed formulation is available in USP while the firm has claimed manufacturer's specifications.
	Decision of 277th meeting of Registration Board	Registration Board deferred the case for rectification of all the short coming as stated in GMP inspection report. The Board further directed to send a reference to QA & LT Division to conduct GMP inspection of Firm on priority.

	Evaluation by PEC	Three cases of the same formulation of the firm were presented in 277th meeting: 1. Valopine Tablet 5mg/80mg 2. Valopine Tablet 5mg/160mg 3. Valopine Tablet 10mg/160mg The cases of 5/160mg strength and 10/160mg strength were later approved in 291st meeting but mistakenly the case of 5/80mg strength could not be added, and the case of 10/160mg were approved twice in 291st meeting vide Sr. No 1398 and 1403. Now the firm has requested to consider the case of 5/80mg strength. • Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. • QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has clarified that current GMP status of the firm shall be considered as compliant.
	Decision: Approved.	
3399.	Name and address of manufacturer / Applicant	M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan Contract manufactured By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ncopenem 500mg IV Injection
	Composition	"Each Vial Contains: Meropenem (as trihydrate) blended with anhydrous sodium carbonate (Sterile)…500mg"
	Diary No. Date of R& I & fee	Dy. No. 33943 dated 12-10-2018 Rs.50,000/- Dated 12-10-2018
	Pharmacological Group	Beta-lactam antibacterial
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Olver Injection by Genix Pharma (Reg # 080605)
	GMP status	For M/s. Nicholas Pharmaceuticals: GMP inspection conducted on 18-06-2019 stated that the firm is operating in compliance with acceptable cGMP standard as of today.
	Remarks of the Evaluator	

Remarks	Response
Details about total number of sections & total number of products already approved on contract manufacturing of applicant.	In total number of sections applicant (M/s. Caliph Pharmaceuticals) has submitted photocopy of letter of CLB having number No. F.3-6/2005-Lic (Vol-I) dated 17th of January, 2019 verifying grant of following two additional sections & regularization of layout plan for four sections. Furthermore firm has total 19 products approved on contract.
Submit evidence of reference product packed in type II glass container.	Merem injection manufactured by Global Pharmaceuticals.
Mention quantity of sodium carbonate/vial	Sodium carbonate used as a buffering agent in the raw material as inactive in approximate

		quantity.
	Decision of 293rd meeting of Registration Board	Deferred for clarification/justification on scientific basis regarding use of type II glass container as primary packaging material for applied formulation or otherwise for evidence of reference product packed in type II glass container.
	Evaluation by PEC	• Firm has submitted that we would like to clarify that the container closure system for our applied product is 20ml type-I glass vial with rubber stopper and an aluminium cap seal, which is as per the innovator product as well as according to the recommendation of USP General chapter Containers Glass <660>.
	Decision: Approved.	
3400.	Name and address of manufacturer / Applicant	M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan Contract manufactured By M/s Nicholas Pharmaceuticals. Plot # 34, St. # SS-02, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ncopenem 1gm IV Injection
	Composition	"Each Vial Contains: Meropenem (as trihydrate) blended with anhydrous sodium carbonate (Sterile)…1000mg"
	Diary No. Date of R& I & fee	Dy.No 33944 dated 12-10-2018 Rs.50,000/- Dated 12-10-2018
	Pharmacological Group	Beta-lactam antibacterial
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Olver Injection by Genix Pharma (Reg # 080604)
	GMP status	For M/s. Nicholas Pharmaceuticals: GMP inspection conducted on 18-06-2019 stated that the firm is operating in compliance with acceptable cGMP standard as of today.

Remarks of the Evaluator

Remarks	**Response**
Details about total number of sections & total number of products already approved on contract manufacturing of applicant.	In total number of sections applicant (M/s. Caliph Pharmaceuticals) has submitted photocopy of letter of CLB having number No. F.3-6/2005-Lic (Vol-I) dated 17th of January, 2019 verifying grant of following two additional sections & regularization of layout plan for four sections. Furthermore firm has total 19 products approved on contract.
Submit evidence of reference product packed in type II glass container.	Merem injection manufactured by Global Pharmaceuticals.
Mention quantity of sodium carbonate/vial	Sodium carbonate used as a buffering agent in the raw material as inactive in approximate quantity.

Decision of 293rd meeting of Registration Board	Deferred for clarification/justification on scientific basis regarding use of type II glass container as primary packaging material for applied formulation or otherwise for evidence of reference product packed in type II glass container.
Evaluation by PEC	• Firm has submitted that we would like to clarify that the container closure system for our applied product is 30ml type-I glass vial with rubber stopper and an aluminium

		cap seal, which is as per the innovator product as well as according to the recommendation of USP General chapter Containers Glass <660>.
	Decision: Approved.	
3401.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad
	Brand Name +Dosage Form + Strength	Hairil 5% Topical Solution
	Composition	Each ml Contains: Minoxidil…50mg
	Diary No. Date of R& I & fee	Dy. No. 33004; 04-10-2018 PKR: 20,000/-; 03-10-2018
	Pharmacological Group	Other dermatologicals
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	60ml; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	MINOXIDIL EXTRA STRENGTH (FOR MEN). MINOXIDIL EXTRA STRENGTH (FOR WOMEN). USFDA approved as OTC product.
	Me-too status	Follinox 5% Solution. Reg. No. 82173
	GMP status	The firm was inspected on 22.01.2019. The panel reported good level of GMP compliance.
	Remarks of the Evaluator	•
	Decision of 293rd meeting of Registration Board	Deferred Confirmation of required manufacturing facility / section from Licensing Division.
	Evaluation by PEC	Firm has submitted the following documents: • Copy of section approval letter specifying cream/ointment/gel/lotion (General / Non-Steroidal) section and cream/ointment/gel/lotion (Steroidal) section • Copy of GMP certificate issued on the basis of inspection dated 08-10-2019
	Decision: Approved with USP specifications.	
3402.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad
	Brand Name +Dosage Form + Strength	Hairil 2% Topical Solution
	Composition	Each ml Contains: Minoxidil…20mg
	Diary No. Date of R& I & fee	Dy. No. 33003; 04-10-2018 PKR: 20,000/-; 03-10-2018
	Pharmacological Group	Other dermatologicals
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	120ml; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Men's Rogaine 2% topical solution. Women's Rogaine 2% topical solution. USFDA approved as OTC product.
	Me-too status	Follinox 2% Solution. Reg. No. 82172
	GMP status	The firm was inspected on 22.01.2019. The panel reported good level of GMP compliance.
	Remarks of the Evaluator	•
	Decision of 293rd meeting of Registration Board	Deferred Confirmation of required manufacturing facility / section from Licensing Division.
	Evaluation by PEC	Firm has submitted the following documents: • Copy of section approval letter specifying cream/ointment/gel/lotion (General / Non-Steroidal) section and cream/ointment/gel/lotion (Steroidal) section • Copy of GMP certificate issued on the basis of inspection dated 08-10-2019
	Decision: Approved with USP specifications.	

3403.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad
	Brand Name +Dosage Form + Strength	Closaf 0.1gm Tablet
	Composition	Each Tablet Contains: Clotrimazole…100mg
	Diary No. Date of R& I & fee	Dy. No. 33021; 04-10-2018 PKR: 20,000/-; 03-10-2018
	Pharmacological Group	Imidazole and triazole derivatives
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	6's; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Clotrimark 100mg Tablets. Reg. No. 84682
	GMP status	The firm was inspected on 22.01.2019. The panel reported good level of GMP compliance.
	Remarks of the Evaluator	• The firm has referred to pessary as international reference product. Proof of international availability of same formulation and same strength in reference regulatory authorities as defined in 275th meeting of the registration board is required.
	Decision of 293rd meeting of Registration Board	Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC	The applied formulation is approved by Swissmedic with following details Name: Fungotox-100 Vaginal tablets MA Holder: Mepha Pharma AG, Basel. Approval No.: 49768 (Swissmedic).
	Decision: Approved.	
3404.	Name and address of manufacturer / Applicant	M/s Don Valley Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Lowvir-C capsule 600mg
	Composition	Each capsule contains: Ribavirin…600mg
	Diary No. Date of R& I & fee	Dy. No 351; 12-8-2015 ; Rs.20,000/- (12-8-2015)
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Last inspection report 19.05.2017 panel recommended grant of GMP.
	Remarks of the Evaluator	International evidence in RRA and me-too status could not be confirmed.
	Decision of 278th meeting of Registration Board	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board
	Evaluation by PEC III	Firm has submitted a request to revise their formulation, since the applied formulation is not registered by any reference regulatory authority. Firm has also submitted fee PKR 20,000 for revision of formulation. Registration Board in its 250th meeting has decided that firms can revise the formulation of their products in line with the reference

		regulatory authorities. The details of newly applied formulation is as follows:
	REVISED FORMULATION	
	Brand Name +Dosage Form + Strength	DOVIRIN Tablet 600mg
	Composition	Each film coated tablet contains: Ribavirin…600mg
	Diary No. Date of R& I & fee	New diary and fee details: Dy No. 8573: 22-4-2020 Fee PKR 20,000/- dated 22-04-2020
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 100's" As per SRO
	Approval status of product in Reference Regulatory Authorities.	IBAVYR ribavirin 600 mg tablet bottle (TGA Australia Approved).
	Me-too status	Riba-C Tablet 600mg by Novamed (Reg#055210)
	GMP status	Inspection report dated 13-02-2020, the panel concluded good compliance to GMP.
	Decision: Approved.	
3405.	Name and address of manufacturer / Applicant	M/s Don Valley, 39, main peco road, Kot lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Lowvir-C Capsule 400mg
	Composition	Each Capsule Contains:- Ribavirin …. …400mg
	Diary No. Date of R& I & fee	Dy.No. 173, 20-8-2015, Rs.20,000/-
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's, (As per PRC)
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Virex by Atco
	GMP status	Last GMP Inspection Conducted on 19-5-17 with conclusive remarks of Fair level of cGMP compliance.
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting. • Commitments required as per decision of Registration Board taken in its 251st meeting, since the commitment pertaining to follow Drugs (Specification) Rules, 1978 is missing. • Latest GMP inspection report (which should have been conducted within the period of last one year). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.
	Decision of previous meeting of Registration Board	Deferred due to paucity of time (M-273) Deferred for evidence of approval of applied formulation by reference regulatory authorities as approved by Registration Board in its 249thmeeting. (M-274)

	Evaluation by PEC III	Firm has submitted a request to revise their formulation, since the applied formulation is not registered by any reference regulatory authority. Firm has also submitted fee PKR 20,000 for revision of formulation. Registration Board in its 250th meeting has decided that firms can revise the formulation of their products in line with the reference regulatory authorities. The details of newly applied formulation is as follows:
	REVISED FORMULATION	
	Brand Name +Dosage Form + Strength	DOVIRIN Tablet 400mg
	Composition	Each film coated tablet contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	New diary and fee details: Dy No. 8574: 22-4-2020 Fee PKR 20,000/- dated 22-04-2020
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 9 x10's As per SRO
	Approval status of product in Reference Regulatory Authorities.	IBAVYR ribavirin 400 mg tablet bottle (TGA Australia Approved).
	Me-too status	Riba-C Tablet 400mg by Novamed (Reg# 043612)
	GMP status	Inspection report dated 13-02-2020, the panel concluded good compliance to GMP.
	Decision: Approved.	
3406.	Name and address of manufacturer / Applicant	M/s Don Valley Pharmaceuticals (Pvt) Ltd., 31-Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Mont-Valley 4mg/5ml Suspension
	Composition	Dy No. 352: 12-8-2015 PKR 20,000/- 12-8-2015
	Diary No. Date of R& I & fee	Each 5ml contains: Montelukast as sodium….4mg
	Pharmacological Group	Anti-Asthma drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Available internationally as granules in Sachet
	Me-too status	Lulast dry suspension by Hygeia Pharma
	GMP status	Last inspection report 19.05.2017 panel recommended grant of GMP.
	Remarks of the Evaluator	Internationally the formulation is available in sachet. GMP inspection is older than 1 year.
	Decision of 284th meeting of Registration Board	Registration Board deferred the case for further deliberation.
	Evaluation by PEC III	Firm has submitted a request to revise their formulation, since the applied formulation is not registered by any reference regulatory authority. Firm has also submitted fee PKR 20,000 for revision of formulation. Registration Board in its 250th meeting has decided that firms can revise the formulation of their products in line with the reference regulatory authorities. The details of newly applied formulation is as follows:
	REVISED FORMULATION	
	Brand Name +Dosage Form + Strength	MONTEL Tablet 10mg
	Composition	Each film coated tablet contains: Montelukast (as sodium)…10mg

	Diary No. Date of R& I & fee	New diary and fee details: Dy No. 10379: 08-5-2020 Fee PKR 20,000/- dated 08-05-2020
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Montelukast 10 mg film-coated tablets (MHRA Approved).
	Me-too status	Montekast 10mg Tablet by Ferozesons
	GMP status	Inspection report dated 13-02-2020, the panel concluded good compliance to GMP.
	Decision: Approved.	

Case No. 02 Registration applications of remaining products of newly granted section (Human)

M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road Islamabad.
The Central Licensing Board in its 272th meeting held on 17-18th October, 2019 has considered and approved the grant of following additional Sections by way of Formulation vide section approval letter 1-22/95-Lic (Vol-II) dated 7th November 2019.

S No.	Section	No. of products Considered in 293rd Meeting of DRB	No. of Molecules Considered in 293rd Meeting of DRB	No. of products to be Considered in 295th Meeting of DRB	No. of Molecules to be Considered in 295th Meeting of DRB
1.	Dry Suspension(Cephalosporin) Section	04	03	3	2

Now the firm has requested for consideration of following applications on priority for registration. These applications were submitted in DRAP on 07-03-2019 while section approval letter was issued on 7-11-2019.

Dry Suspension(Cephalosporin) Section
3 Products/ 2 Molecules

3407.	Name and address of manufacture / Applicant	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name + Dosage Form and Strength	Distaclor 250mg/5ml Suspension
	Composition	Each 5ml of Reconstituted Suspension Contains: Cefaclor Monohydrate Eq. to Cefaclor…250mg
	Dairy No. date of R &I fee	Dy. No. 15840 dated 07-03-19, Rs. 20,000/- dated 05-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Distaclor Suspension 250mg/5ml (MHRA Approved)
	Me-too-status	Cavalor suspension 250mg by Barret Hodgson
	GMP Status	The firm was inspected on 01-10-2019 and conclusion of inspection was: Based on the areas inspected, the people met, documents reviewed and considering the findings especially the efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended: 1- Renewal of DML 2- Grant of additional sections. I- Cephalosporin (capsule)

		II- Cephalosporin (Dry suspension)
	Remark of the Evaluator	•
	Decision: Approved.	
3408.	Name and address of manufacture / Applicant	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name dosage and Strength	Distaclor 125mg/5ml Suspension
	Composition	Each 5ml of Reconstituted Suspension Contains: Cefaclor Monohydrate Eq. to Cefaclor…125mg
	Dairy No. date of R &I fee	Dy. No 15838 dated 07-03-2019 Rs. 20,000/- Dated 05-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in reference regulatory Authorities	Distaclor Suspension 125mg/5ml (MHRA Approved)
	Me-too-status	Cavalor suspension 125mg by Barret Hodgson
	GMP Status	The firm was inspected on 01-10-2019 and conclusion of inspection was: Based on the areas inspected, the people met, documents reviewed and considering the findings especially the efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended: 1- Renewal of DML 2- Grant of additional sections. I- Cephalosporin (capsule) II- Cephalosporin (Dry suspension)
	Remark of the Evaluator	
	Decision: Approved.	
3409.	Name and address of manufacture / Applicant	M/s Davis Pharmaceutical Laboratories, Plot No. 121, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name dosage and Strength	Davixime 200mg/5ml Suspension
	Composition	Each 5ml of Reconstituted Suspension Contains: Cefixime Trihydrate Eq. to Cefixime…200mg
	Dairy No. date of R &I fee	Dy. No 15841 dated 07-03-2019 Rs. 20,000/- 05-03-2019
	Pharmacological Group	Cephalosporin
	Type of form	Form-5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in reference regulatory Authorities	Suprax Suspension 200mg/ml (USFDA Approved)
	Me-too-status	Cefspan DS suspension by Barret Hodgson
	GMP Status	The firm was inspected on 01-10-2019 and conclusion of inspection was: Based on the areas inspected, the people met, documents reviewed and considering the findings especially the efforts in removal of observations noticed during the last inspection of the premises, the panel unanimously recommended: 1- Renewal of DML 2- Grant of additional sections. I- Cephalosporin (capsule) II- Cephalosporin (Dry suspension)
	Remark of the Evaluator	
	Decision: Approved.	

Case No. 03 Registration applications of import cases

a. Deferred cases

i. Human

3410.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 16/01/2019
	Name and address of manufacturer	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China
	Name and address of marketing authorization holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CALCIUM FOLINATE injection 100mg Freeze dried cake for solution for IV injection (Lyophilized Powder)
	Composition	Each vial contains: Calcium folinate…. 100mg
	Finished Product Specification	BP
	Pharmacological Group	Anti dot to folic acid antagonist/Detoxifying agent for antineoplastic treatment
	Shelf life	2 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 385 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	Calcium folinate powder for solution 100mg/vial by M/s Mylan, ANSM France Approved
	Me-too status	Calcium flogen 100mg injection by M/s Genetech (IMPORTED from China) (Reg # 059269)
	Detail of certificates attached	Original Legalized CoPP (certificate No. 20150008) issued by Shanxi Food and Drug Administration valid till 31/08/2017 confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.
	Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.
	Previous Decision(M-274): The Registration Board deferred the cases for; • Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true. • Detail of diluent to be used for reconstitution.	

- Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form.
- Submission of original, legalized and valid CoPP.

Evaluation by PEC:

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

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

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

Decision of 289th meeting of Registration Board	Deferred for following submissions: • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting • Real time stability study data of 3 batches as per zone

		IV-A for the complete shelf life.
	Evaluation by PEC	Firm has submitted following documents; 1. The firm has submitted the evidience of approval of the product in Austria but it could not be verified. Leucoverin Injection by M/s Wyeth Lederle Pharma GMBH, Austria. 2. Real Time stability studies according to the conditions of zone IV-A for 2 years signed by Director QC of following batches; Accelerated stability study data also submitted. • 170501 (Mfg date; May, 2017 & Exp. Date: May, 2020) • 170502 (Mfg date; May, 2017 & Exp. Date: May, 2020) • 170503 (Mfg date; May, 2017 & Exp. Date: May, 2020)
	Decision of 292nd meeting	Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting.
	Evaluation by PEC	The applied formulation is approved in ANSM France with following details: **Name:** CALCIUM FOLINATE AGUETTANT 100 mg powder for solution for injection **Composition:** Calcium folinate eq to folinic acid 100 mg. **MA Holder:** AGUETTANT Laboratory since 08/31/2001 The Product data sheet attached in the submitted dossier and the original CoPP contains the following composition: Calcium folinate eq to folinic acid 100mg The original, legalized CoPP present in the file confirms free sale status of the product in country of origin and the GMP status of the manufacturer. The CoPP certificate was valid till 26-02-2020.
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	

ii. Veterinary

3411.	Name and address of Applicant	M/s Geevet International First floor Naz Medicine Market Namak Mandi Peshawer
	Detail of Drug Sale License	Drug sales license by way of whole sales/distribution no. 634 valid upto 01/01/2020
	Name and address of manufacturer & marketing authorization holder	M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd. Economic Development & Experiment Zone for Economical transformation of Resource dependent city, Chifeng, Inner Mongolia, PR. China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 19736 Dated 30-05-2018
	Fee including differential fee	Rs. 100,000/- Dated 30-05-2018
	Brand Name +Dosage Form + Strength	Doxy Gold Doxycycline hydrochloride 40% + Tylosin tartrate 20% soluble powder
	Composition	Each 100g contains: Doxycycline hydrochloride….40g Tylosin tartrate ……20g
	Finished Product Specification	In-house
	Pharmacological Group	Antibiotic
	Shelf life	24Months

Demanded Price	Decontrolled
Pack size	1kg, 2.5kg
Me-too status	REOCIN-TD POWDER of M/s DELUX CHEMICAL INDUSTRIES, KARACHI.
Stability studies	Firm has submitted long term (24 months) at 30oC 65% RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
Detail of certificates attached	Original Legalized CoPP (Certificate#. 05019) Certifying Authority "veterinary Bureau of the Inner Mongolia autonomous Region" declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Inner Mongolia Huatian Pharmaceutical. Valid until 02-07-2023.
Remarks of the Evaluator.	Submitted stability data of three batches are mirror image of each other identity to assay. Firm reply as under: We get documents/data from M/s Inner Mongolia Huatian Pharmaceutical China. Unfortunately, they provide us wrong stability studies data result. That we submitted to DRAP. After reviewing the stability data we found some mistakes in provide data so we again requested to M/s Inner Mongolia Huatian Pharmaceutical China to provide us the exact/actual stability data. Latest stability studies data is submitting to your authority. We assure that his type of mistakes will not be happen in future.

Decision of 293rd meeting of Registration Board:
Registration Board deferred the case and decided that Secretary Registration Board will forward the submitted stability data of above product to M/s Inner Mongolia Huatian Pharmaceutical (Marketing Authorization Holder) via e-mail to manufacturer for confirmation of authenticity of the said data.

Evaluation by PEC:
Secretary Registration Board has sent email to the manufacturer and the following response has been received from the manufacturer:

Dear Mr Abdullah,

Glad to receive you kindly email. Hope you are fine.
1. Yes, I confirm that the veterinary drug products is manufactured by us (Inner Mongolia Huatian Pharmaceutical Co., Ltd Economic Development & Experiment Zone for Economical Transformation of Resource Dependent City, Chifeng, Inner Mongolia, P.R. China) and our best partner (Geevet International, First Floor, Naz Medicine Market, Namak Mandi, Peshawar, Pakistan) is in charge of registration and distribution of our veterinary antibiotic drugs in Pakistan.
2. The answer from our best partner (Geevet International, First Floor, Naz Medicine Market, Namak Mandi, Peshawar, Pakistan) is true. Once again sorry for the inconvenience caused by our fault.
3. Thanks for your help. We guarantee that we will not make such mistakes again
4. We confirm that the stability report of Amoxy Gold (Amoxicillin 50% Soluble Powder,Batch No: 20150204,20150205,20150206), Doxy Gold (Doxycycline hydrochloride 40% + Tylosin tartrate 20% Soluble Powder,Batch No: 20150204,20150205,20150206) and Enrocid (Enrofolxacin 20% Oral Solution,Batch No: 20150901,20150902,20150903) is true.

Best Regards
Lee
--
内蒙古华天制药有限公司

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Stability data shall be re-verified by inspecting panel during audit of manufacturer abroad.

3412.	Name and address of Applicant	M/s Geevet International First floor Naz Medicine Market Namak Mandi Peshawer
	Name and address of manufacturer	M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd. Economic Development & Experiment Zone for Economical transformation of Resource dependent city, Chifeng, Inner Mongolia, PR. China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 16850 Dated 07-05-2018
	Fee including differential fee	Rs. 100,000/- Dated 07-05-2018
	Brand Name +Dosage Form + Strength	Amoxy Gold Amoxicillin 50% soluble powder
	Composition	Each 100g contains: Amoxicillin…….50g
	Finished Product Specification	In-house
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1kg bag
	International availability	China
	Me-too status	Amosel-50 Oral Dry Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd.
	Stability studies	Firm has submitted long term (24 months) at 30oC 65% RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 05019) Certifying Authority "veterinary Bureau of the Inner Mongolia autonomous Region" declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Inner Mongolia Huatian Pharmaceutical. Valid until 02-07-2023
	Remarks of the Evaluator.	Submitted stability data of three batches are mirror image of each other identity to assay. Firm reply as under: We get documents/data from M/s Inner Mongolia Huatian Pharmaceutical China. Unfortunately, they provide us wrong stability studies data result. That we submitted to DRAP. After reviewing the stability data, we found some mistakes in provide data so we again requested to M/s Inner Mongolia Huatian Pharmaceutical China to provide us the exact/actual stability data. Latest stability studies data is submitting to your authority. We assure that his type of mistakes will not be happen in future.
	Decision of 293rd meeting of Registration Board: Registration Board deferred the case and decided that Secretary Registration Board will forward the submitted stability data of above product to M/s Inner Mongolia Huatian Pharmaceutical (Marketing Authorization Holder) via e-mail to manufacturer for confirmation of authenticity of the said data.	
	Evaluation by PEC: **Secretary Registration Board has sent email to the manufacturer and the following response has been received from the manufacturer:** Dear Mr Abdullah, Glad to receive you kindly email. Hope you are fine. 1. Yes, I confirm that the veterinary drug products is manufactured by us (Inner Mongolia Huatian Pharmaceutical Co., Ltd Economic Development & Experiment Zone for Economical Transformation of Resource Dependent City, Chifeng, Inner Mongolia, P.R. China) and our best partner (Geevet International, First Floor, Naz Medicine Market, Namak Mandi, Peshawar, Pakistan) is in charge of	

	registration and distribution of our veterinary antibiotic drugs in Pakistan. 2. The answer from our best partner (Geevet International, First Floor, Naz Medicine Market, Namak Mandi, Peshawar, Pakistan) is true. Once again sorry for the inconvenience caused by our fault. 3. Thanks for your help. We guarantee that we will not make such mistakes again 4. We confirm that the stability report of Amoxy Gold (Amoxicillin 50% Soluble Powder,Batch No: 20150204,20150205,20150206), Doxy Gold (Doxycycline hydrochloride 40% + Tylosin tartrate 20% Soluble Powder,Batch No: 20150204,20150205,20150206) and Enrocid (Enrofolxacin 20% Oral Solution,Batch No: 20150901,20150902,20150903) is true. Best Regards Lee -- 内蒙古华天制药有限公司	
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Stability data shall be re-verified by inspecting panel during audit of manufacturer abroad.	
3413.	Name and address of Applicant	M/s Geevet International First floor Naz Medicine Market Namak Mandi Peshawer
	Detail of Drug Sale License	Drug sales license by way of whole sales/distribution no. 634 valid upto 01/01/2020
	Name and address of manufacturer & marketing authorization holder	M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd. Economic Development & Experiment Zone for Economical transformation of Resource dependent city, Chifeng, Inner Mongolia, PR. China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 33533 Dated 09-10-2018
	Fee including differential fee	Rs. 100,000/- Dated 09-10-2018
	Brand Name +Dosage Form + Strength	Enrocid Gold Oral Solution Enrofloxacin 20%
	Composition	Each 100ml contains: Enrofloxacin……..20g
	Finished Product Specification	Firm claim Manufacturer specification
	Pharmacological Group	Antibiotic
	Shelf life	24 Months
	Demanded Price	Decontrolled
	Pack size	500ml,1000ml, 2.5L, 5L
	Me-too status	ENROXSEL 20 ORAL SOLUTION of M/s SELMORE PHARMACEUTICALS LAHORE.
	Stability studies	Firm has submitted long term (24 months) at 30oC 65% RH & accelerated (06 months) stability data at 40oC, 75% RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 05019) Certifying Authority "veterinary Bureau of the Inner Mongolia autonomous Region" declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Inner Mongolia Huatian Pharmaceutical. Valid until 02-07-2023. Sole Agency agreement from product License holder is provided
	Remarks of the Evaluator.	
	Decision of 293rd meeting of Registration Board: Registration Board deferred the case and decided that Secretary Registration Board will forward the submitted stability data of above product to M/s Inner Mongolia Huatian Pharmaceutical (Marketing Authorization Holder) via e-mail to manufacturer for confirmation of authenticity of the said data.	
	Evaluation by PEC: **Secretary Registration Board has sent email to the manufacturer and the following response has**	

	been received from the manufacturer: Dear Mr Abdullah, Glad to receive you kindly email. Hope you are fine. 1. Yes, I confirm that the veterinary drug products is manufactured by us (Inner Mongolia Huatian Pharmaceutical Co., Ltd Economic Development & Experiment Zone for Economical Transformation of Resource Dependent City, Chifeng, Inner Mongolia, P.R. China) and our best partner (Geevet International, First Floor, Naz Medicine Market, Namak Mandi, Peshawar, Pakistan) is in charge of registration and distribution of our veterinary antibiotic drugs in Pakistan. 2. The answer from our best partner (Geevet International, First Floor, Naz Medicine Market, Namak Mandi, Peshawar, Pakistan) is true. Once again sorry for the inconvenience caused by our fault. 3. Thanks for your help. We guarantee that we will not make such mistakes again 4. We confirm that the stability report of Amoxy Gold (Amoxicillin 50% Soluble Powder,Batch No: 20150204,20150205,20150206), Doxy Gold (Doxycycline hydrochloride 40% + Tylosin tartrate 20% Soluble Powder,Batch No: 20150204,20150205,20150206) and Enrocid (Enrofolxacin 20% Oral Solution,Batch No: 20150901,20150902,20150903) is true. Best Regards Lee -- 内蒙古华天制药有限公司
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Stability data shall be re-verified by inspecting panel during audit of manufacturer abroad.

Case no. 04 Registration applications of CTD cases

a. New cases of Import

Sr. No	Name and address of applicant		M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore
3414.	Brand name		Sunitinib AqVida 12.5mg Hard Capsule
	Detailed composition		Each capsule contains: Sunitinib Malate, 16.75mg eq. to 12.5mg Sunitinib
MODULE 1: ADMINISTRATIVE			
Section	Sub-Section		Heading
1.1			Covering Letter and Fee Deposit Slip Submitted Dy. No 3384 Dated 12-04-2019 PKR: 100,000/- dated 12-04-2019
1.2			Table of Contents (From Module 1 to Module 5) Submitted
1.3			Applicant Information Submitted
	1.3.1		Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore
	1.3.2		Name, address and contact details of Manufacturing site. **Product License Holder**: Aqvida GmbH Kaiser-Wilhelm-Strabe 89 20355 Hamburg Germany. **Manufacturer:** M/s Combino Pharm (Malta) Ltd. HF 60, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG3000, Malta.
	1.3.3		Specify whether the Applicant is: Importer
	1.3.4		**Drug Sale License** License to Sell drugs as a Distributor No: 05-352-0065-016174D valid upto 06-Feb-2022
1.4			Type of Application Submitted
	1.4.1		Application is for the registration of: Generic Drug Product
	1.4.1		Pharmaceutical product is intended for: Domestic sale
	1.4.2		For imported products, please specify one of following: Finished Pharmaceutical Product Import
1.5			Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1		Generic name with chemical name & synonyms of the applied drug. Sunitinib Malate
	1.5.2		Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit **Each capsule contains:** **Sunitinib Malate, 16.75mg eq. to 12.5mg Sunitinib**
	1.5.3		The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. **Sunitinib AqVida 12.5mg Hard Capsule**
	1.5.4		Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 30's & As per SRO
	1.5.5		Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) ATC Code: L01XE04 **OTHER ANTINEOPLASTIC AGENTS, Protein kinase inhibitors**
	1.5.6		Pharmacopoeial reference / Status of applied formulation USP
	1.5.7		Route of administration Oral
	1.5.8		For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price

		SUTENT 12.5MG CAPSULE of M/s Pfizer
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Sutent 12.5 mg hard capsules (Belgium)
	1.5.10	Dosage form of applied drug Capsule
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer.
	• **Original Legalized CoPP (Certificate#. AQV/31082018/35)** issued on 31-08-2018 by	

	Behorde fur Gesundheit und verbraucherschutz der Freien und Hansestadt Hamburg Abteilung V4 Pharmaziewesen und Medizinproduckte BillstraBe 80 20539 Hamburg Germany (*translated through google translator:* Authority for health and consumer protection of the free and Hanseatic city of Hamburg Department V4 Pharmaceuticals and Medical Devices BillstraBe 80 20539 Hamburg Germany). The certificate confirms the free sale status of the product in exporting country. The CoPP certificate does not confirm GMP status of the manufacturer. As per the CoPP the status of product license holder is (c). • Original, legalized GMP certificate (No. MT/016HM/2018) issued by Director Inspectorates and Enforcement Directorate Medicines Authority Malta dated 23-07-2018 is also submitted. • Copy of letter of authorization between the MA holder i.e. AqVida GmbH Hamburg Germany and Himmel Pharma Lahore is also submitted. The letter of authorization specifies the applied product as well.
MODULE 2: CTD SUMMARIES	
2.1 Overall CTD Table of Content Submitted	
2.2 CTD Introduction Submitted	
2.3 Quality Overall Summary (QOS)* Submitted	
2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted
MODULE 3: QUALITY	
3.1 Table of Contents of Module 3 Submitted	
3.2 Body of Data Submitted	
3.2.S DRUG SUBSTANCE (API)	

3.2.S.1	GENERAL INFORMATION	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.5	Process Validation and/or Evaluation Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted
3.2.P DRUG PRODUCT		
3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted

3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data (24 months) at 30 ± 2^0C, 75±5%RH and 6 months at 40^0C±75%RH.

Remarks of evaluator:

Shortcomings communicated	Response by the firm
Original legalized CoPP/GMP+FSC	Firm has submitted original, legalized CoPP and GMP certificate. The details of CoPP and GMP certificate are mentioned in the relevant row of the evaluation summary of the case.
Original Product Specific Sole Agency agreement.	Firm has submitted copy of product specific sole agency agreement
Firm submit against section 1.5.6 USP specification without submitting official monograph.	Firm has not submitted any document against this observation. The firm has claimed USP specifications
Commitments of module 1 are not submitted.	Firm has submitted commitments of module 1
In Module 2 only single page non-clinical overview & 5 pages clinical overview is submitted, Section 2.3 Quality Overall Summary as per WHO template is not submitted.	Firm has submitted QOS as per WHO QOS-PD template.
In Submitted Module 3, drug substance part is not submitted.	Firm has submitted drug substance part of module 3.

Decision: Approved as per Policy for inspection of Manufacturer abroad.

Sr. No	**Name and address of applicant**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore**
3415.	Brand name	Sunitinib AqVida 25mg Hard Capsule
	Detailed composition	Each capsule contains: Sunitinib Malate, 33.5mg eq. to 25mg Sunitinib

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 3385 Dated 12-04-2019 PKR: 100,000/- dated 12-04-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted

1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore
	1.3.2	Name, address and contact details of Manufacturing site. **Product License Holder**: Aqvida GmbH Kaiser-Wilhelm-Strabe 89 20355 Hamburg Germany. **Manufacturer:** M/s Combino Pharm (Malta) Ltd. HF 60, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG3000, Malta.
	1.3.3	Specify whether the Applicant is: Importer
	1.3.4	**Drug Sale License** License to Sell drugs as a Distributor No: 05-352-0065-016174D valid upto 06-Feb-2022
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: Domestic sale
	1.4.2	For imported products, please specify one of following: Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Sunitinib Malate
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit **Each capsule contains:** **Sunitinib Malate, 33.5mg eq. to 25mg Sunitinib**
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. **Sunitinib AqVida 25mg Hard Capsule**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 30's & As per SRO
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) ATC Code: L01XE04 **OTHER ANTINEOPLASTIC AGENTS, Protein kinase inhibitors**
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Oral
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price SUTENT 25MG CAPSULE of M/s Pfizer
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Sutent 25 mg hard capsules (Belgium)
	1.5.10	Dosage form of applied drug Capsule
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).

		Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer.
	• **Original Legalized CoPP (Certificate#. AQV/31082018/35)** issued on 31-08-2018 by Behorde fur Gesundheit und verbraucherschutz der Freien und Hansestadt Hamburg Abteilung V4 Pharmaziewesen und Medizinproduckte BillstraBe 80 20539 Hamburg Germany (*translated through google translator:* Authority for health and consumer protection of the free and Hanseatic city of Hamburg Department V4 Pharmaceuticals and Medical Devices BillstraBe 80 20539 Hamburg Germany). The certificate confirms the free sale status of the product in exporting country. The CoPP certificate does not confirm GMP status of the manufacturer. As per the CoPP the status of product license holder is (c). • Original, legalized GMP certificate (No. MT/016HM/2018) issued by Director Inspectorates and Enforcement Directorate Medicines Authority Malta dated 23-07-2018 is also submitted. • Copy of letter of authorization between the MA holder i.e. AqVida GmbH Hamburg Germany and Himmel Pharma Lahore is also submitted. The letter of authorization specifies the applied product as well.	
MODULE 2: CTD SUMMARIES		

2.1 Overall CTD Table of Content Submitted			
2.2 CTD Introduction Submitted			
2.3 Quality Overall Summary (QOS)* Submitted			
2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted		
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted		
2.4	Non-Clinical Overview Submitted		
2.5	Clinical Overview Submitted		
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted		
2.7	Clinical summary Submitted		
MODULE 3: QUALITY			
3.1 Table of Contents of Module 3 Submitted			
3.2 Body of Data Submitted			
3.2.S DRUG SUBSTANCE (API)			
3.2.S.1	GENERAL INFORMATION		
	3.2.S.1.1	Nomenclature Submitted	
	3.2.S.1.2	Structure Submitted	
	3.2.S.1.3	General properties Submitted	
3.2.S.2	MANUFACTURER		
	3.2.S.2.1	Manufacturer(s) Submitted	
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted	
	3.2.S.2.3	Control of Materials Not submitted	
	3.2.S.2.5	Process Validation and/or Evaluation Submitted	

3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted
3.2.P DRUG PRODUCT		
3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted

	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 75±5%RH and 6 months at 40^{0}C±75%RH.

Remarks of evaluator:

Shortcomings communicated	Response by the firm
Original legalized CoPP/GMP+FSC	Firm has submitted original, legalized CoPP and GMP certificate. The details of CoPP and GMP certificate are mentioned in the relevant row of the evaluation summary of the case.
Original Product Specific Sole Agency agreement.	Firm has submitted copy of product specific sole agency agreement
Firm submit against section 1.5.6 USP specification without submitting official monograph.	Firm has not submitted any document against this observation. The firm has claimed USP specifications
Commitments of module 1 are not submitted.	Firm has submitted commitments of module 1
In Module 2 only single page non-clinical overview & 5 pages clinical overview is submitted, Section 2.3 Quality Overall Summary as per WHO template is not submitted.	Firm has submitted QOS as per WHO QOS-PD template.
In Submitted Module 3, drug substance part is not submitted.	Firm has submitted drug substance part of module 3.

Decision: Approved as per Policy for inspection of Manufacturer abroad.

Sr. No	**Name and address of applicant**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore**
3416.	Brand name	Sunitinib AqVida 50mg Hard Capsule
	Detailed composition	Each capsule contains: Sunitinib Malate, 66.8mg eq. to 50mg Sunitinib

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 3383 Dated 12-04-2019 PKR: 100,000/- dated 12-04-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block C Faisal Town Lahore
	1.3.2	Name, address and contact details of Manufacturing site. **Product License Holder**: Aqvida GmbH Kaiser-Wilhelm-Strabe 89 20355 Hamburg Germany. **Manufacturer:** M/s Combino Pharm (Malta) Ltd. HF 60, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG3000, Malta.
	1.3.3	Specify whether the Applicant is: Importer
	1.3.4	**Drug Sale License** License to Sell drugs as a Distributor No: 05-352-0065-016174D valid upto 06-Feb-2022
1.4		Type of Application Submitted

	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: Domestic sale
	1.4.2	For imported products, please specify one of following: Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Sunitinib Malate
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit **Each capsule contains:** **Sunitinib Malate, 66.8mg eq. to 50mg Sunitinib**
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. **Sunitinib AqVida 50mg Hard Capsule**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 30's & As per SRO
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) ATC Code: L01XE04 **OTHER ANTINEOPLASTIC AGENTS, Protein kinase inhibitors**
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Oral
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price SUTENT 50MG CAPSULE of M/s Pfizer
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Sutent 50 mg hard capsules (Belgium)
	1.5.10	Dosage form of applied drug Capsule
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined.

		Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer.
	• **Original Legalized CoPP (Certificate#. AQV/31082018/35)** issued on 31-08-2018 by Behorde fur Gesundheit und verbraucherschutz der Freien und Hansestadt Hamburg Abteilung V4 Pharmaziewesen und Medizinproduckte BillstraBe 80 20539 Hamburg Germany (*translated through google translator:* Authority for health and consumer protection of the free and Hanseatic city of Hamburg Department V4 Pharmaceuticals and Medical Devices BillstraBe 80 20539 Hamburg Germany). The certificate confirms the free sale status of the product in exporting country. The CoPP certificate does not confirm GMP status of the manufacturer. As per the CoPP the status of product license holder is (c). • Original, legalized GMP certificate (No. MT/016HM/2018) issued by Director Inspectorates and Enforcement Directorate Medicines Authority Malta dated 23-07-2018 is also submitted. • Copy of letter of authorization between the MA holder i.e. AqVida GmbH Hamburg Germany and Himmel Pharma Lahore is also submitted. The letter of authorization specifies the applied product as well.	
MODULE 2: CTD SUMMARIES		
2.1 Overall CTD Table of Content Submitted		
2.2 CTD Introduction Submitted		
2.3 Quality Overall Summary (QOS)* Submitted		
2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted	

	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted		
2.4	Non-Clinical Overview Submitted		
2.5	Clinical Overview Submitted		
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted		
2.7	Clinical summary Submitted		
MODULE 3: QUALITY			
3.1 Table of Contents of Module 3 Submitted			
3.2 Body of Data Submitted			
3.2.S DRUG SUBSTANCE (API)			
3.2.S.1	GENERAL INFORMATION		
	3.2.S.1.1	Nomenclature Submitted	
	3.2.S.1.2	Structure Submitted	
	3.2.S.1.3	General properties Submitted	
3.2.S.2	MANUFACTURER		
	3.2.S.2.1	Manufacturer(s) Submitted	
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted	
	3.2.S.2.3	Control of Materials Not submitted	
	3.2.S.2.5	Process Validation and/or Evaluation Submitted	
3.2.S.3	CHARACTERIZATION		
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted	
	3.2.S.3.2	Impurities Submitted	
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)		
	3.2.S.4.1	Specification Submitted	
	3.2.S.4.2	Analytical procedures Submitted	
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers	
	3.2.S.4.5	Justification of specifications Submitted	
3.2.S.5		REFERENCE STANDARDS Submitted	

3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted
3.2.P DRUG PRODUCT		
3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data (24 months) at 30±2^{0}C, 75±5%RH and 6 months at 40^{0}C±75%RH.

Remarks of evaluator:

Shortcomings communicated	Response by the firm
Original legalized CoPP/GMP+FSC	Firm has submitted original, legalized CoPP and GMP certificate. The details of CoPP and GMP certificate are mentioned in the relevant row of the evaluation summary of the case.
Original Product Specific Sole Agency agreement.	Firm has submitted copy of product specific sole agency agreement
Firm submit against section 1.5.6 USP specification without submitting official monograph.	Firm has not submitted any document against this observation. The firm has claimed USP specifications
Commitments of module 1 are not submitted.	Firm has submitted commitments of module 1
In Module 2 only single page non-clinical overview & 5 pages clinical overview is submitted, Section 2.3 Quality Overall Summary as per WHO template is not submitted.	Firm has submitted QOS as per WHO QOS-PD template.
In Submitted Module 3, drug substance part is not submitted.	Firm has submitted drug substance part of module 3.

Decision: Approved as per Policy for inspection of Manufacturer abroad.

b. Deferred cases of import

3417. **M/s Ahsan Pharma Importer and exporter Karachi, applied for registration of Pemetrexed on Form 5-F**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 4024 Dated 18-04-2019 (Rs. 100,000/- Dated 08-03-2019) Dy. No 4025 Dated 18-04-2019 (Rs. 100,000/- Dated 08-03-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Ahsan Pharma Importer and exporter address: Zeenat Medicine market, A-5, 1st Floor Napier Road Karachi, Pakistan
	1.3.2	Name, address and contact details of Manufacturing site. Manufacturer: M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China Marketing Authorization Holder: M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	1.3.3	Specify whether the Applicant is: Importer will import from?
	1.3.4	**Drug Sale License** M/s Ahsan Pharma address: A-5, 1st Floor Zeenat Medicine market Karachi License No. 1318 valid till 30-Jul-2019
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**

	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Pemetrexed
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each injection (vial) contains: Pemetrexed (as pemetrexed disodium) ….100mg Each injection (vial) contains: Pemetrexed (as pemetrexed disodium)….500mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Pemetrexed Seacross 100mg Pemetrexed Seacross 500mg
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 10ml vial/ as per brand leader 50ml vial/ as per brand leader
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Folic acid analogues ATC code: L01BA04
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration concentrate for solution for infusion
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. ALIMTA 100MG INJECTION & ALIMTA 500MG INJECTABLE. of M/s ELI LILLY
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Pemetrexed Seacross 100 mg powder for concentrate for solution for infusion of Seacross Pharmaceuticals Limited United Kingdom Pemetrexed Seacross 500 mg powder for concentrate for solution for infusion of Seacross Pharmaceuticals Limited United Kingdom
	1.5.10	Dosage form of applied drug Powder for concentrate for solution for infusion
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. **Submitted**
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with

		detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. **Submitted**
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. **Submitted**
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance does not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. **Submitted**
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. **Submitted**
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. M/s Chongqing Pharmaceutical Research Institute (Changshou) Co. Ltd. (CPRI Changshou) Address: No. 2, The Third Branch Road, Huanan Road, Changshou Economic & Technological Development District Chongqing 401220, People's Republic of China
	• Original Legalized CoPP for Pemetrexed Seacross 100mg (Certificate#. PP10156749) dated 20-08-2018 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer. • Original Legalized CoPP for Pemetrexed Seacross 500mg (Certificate#. PP10156675) dated 20-08-2018 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer. • Firm has submitted copy of exclusive distribution ship agreement (without products list) with manufacturer (from china) and Product license holder (from UK) • <u>M/s Merixil Pharma Islamabad submit Original product specific Authorization letter by Marketing authorization holder M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom for two products, one of which is also applied by M/s Ahsan Pharma as well which has also distribution agreement with M/s Seacross Pharmaceutical Limited which is not product specific.</u>	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	**Drug substance (API)** General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Submitted
	3.2.S.2.4	Control of Critical steps and intermediates Submitted

	3.2.S.2.5	Process Validation and/or Evaluation Submitted
	3.2.S.2.6	Manufacturing process development Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.3	Validation of analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted

3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 36 months at 30 ± 2^0C,75%RH and 6 months at 40^0C±75%RH for three batches for applied strengths separately

Remarks of Evaluators:

Provided Sole agency agreement with manufacturer M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China which is not Product License Holder, and applicant submit a copy of original letter from manufacturer CEO Zhao Ding which is as under:

"M/s Sichuan Huiyu Pharmaceutical Ltd. (No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China) confirms that M/s Seacross Pharmaceutical Limited, (Bedford Business centre, 61-63 st peters street, Bedford MK40 2PR, United Kingdom) is 100% subsidiary company of M/s Sichuan Huiyu

M/s Seacross Pharmaceutical Limited is the marketing company in UK, responsible for batch release. The centeralized pharmacovigilance & risk management, and quality, safety & efficacy of pharmaceutical products: and M/s Sichuan Huiyu Pharmaceutical Ltd. is the manufacturer in China, responsible for finished product manufacturing, primary & secondary packaging and batch control testing"

Decision of 292nd meeting of Registration Board:

Registration Board deferred the case and decided to coordinate (email) M/s Seacross Pharmaceutical Limited (UK) (Marketing Authorization Holder) for declaration of their sole agent in Pakistan.

Evaluation by PEC:

Secretary Registration Board has sent email to the manufacturer and the following response has been received from the manufacturer:

Dear Mr. Abdullah

First, we would like to thank you for sending us email to confirm this, and we sincerely apologize for the inconvenience caused.

For the 2 agents, we have been agreed below recently:
Ahsan Pharma, the products shall be:
Pemetrexed (100mg, 500mg)
Azacitidine(100mg)
Paclitaxel (30mg, 100mg, 300mg)

Merixil Pharma Islamabad , the product shall be:
Bendamustine(25mg,100mg)

We apologize this again , if you have any further questions, please don't hesitate to let us know, and we will fully cooperate with you. Hope you could start the assessment of the product and approve them soon.

Your sincerely

Qin He Commercial Operation Manager
Decision: Registration Board decided to approve registration of Pemetrexed Seacross 100mg and Pemetrexed Seacross 500mg with Innovator's specifications as per Policy for inspection of Manufacturer abroad. The Board further directed that case shall be further processed after having notarized authorization letter to both firms for respective products.

3418. **M/s Merixil Pharma, Islamabad Pakistan applied for registration of Bendamustine on Form5F**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 15314 Dated 22-08-2019 (Rs. 100,000/- Dated 18-06-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Merixil Pharma, Office 28, 2nd floor rose plaza, I-8 Markaz, Islamabad Pakistan.
	1.3.2	Name, address and contact details of Manufacturing site. Manufacturer: M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China Marketing Authorization Holder: M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	1.3.3	Specify whether the Applicant is: Importer will import from UK
	1.3.4	**Drug Sale License** Copy of License to sell Drug by way of Wholesale/Distribution no. DSL-445-ICT/2013 renewed upto 02-02-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Bendamustine
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Bendamustine HCl bendamustine hydrochloride (as bendamustine hydrochloride monohydrate) ……..100mg Powder for Injection
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Bendamustine Seacross 100mg for Injection
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's Injection
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anticancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation

		In-house
	1.5.7	Route of administration IV (Bendamustine)
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Bendamustine hydrochloride 2.5 mg/ml powder for concentrate for solution for infusion (UK)
	1.5.10	Dosage form of applied drug Lyophilized Dry Powder in vial
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. **Submitted**
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. **Submitted**
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. **Submitted**
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. **Submitted**
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. **Submitted**
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.

1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer: M/s Fujian South Pharmaceutical Co. Ltd. No. 98, Dongxin Road, xuefeng town mingxi country sanming city Fujian Province China (for Azacitidine Seacross 100mg for Injection)
	• Original Legalized CoPP for BENDAMUSTINE HCl 2.5mg/ml (Certificate#. PP10161088) dated 14-05-2019 by The Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer. • GMP inspection dated 21-08-2017 of Manufacturer online verified dated 18-09-2019, link given below http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do • Original product specific Authorization letter by Marketing authorization holder M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom to Importer M/s Merixil Pharma, Office 28, 2nd floor rose plaza, I-8 Markaz, Islamabad Pakistan to register and distribute AZACITIDINE 100mg INJECTION in Pakistan. • **M/s Ahsan Pharma Karachi has submitted copy of exclusive distribution ship agreement (without products list) with manufacturer (from china) and Product license holder (from UK)**	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	**Drug substance (API)** General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted

2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Submitted
	3.2.S.2.4	Control of Critical steps and intermediates Not Submitted
	3.2.S.2.5	Process Validation and/or Evaluation Not submitted
	3.2.S.2.6	Manufacturing process development not Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.3	Validation of analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product

		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 24 months at 30 ± 2^0C,75%RH and 6 months at 40^0C±75%RH for three batches for applied strengths separately (Bendamustine Seacross 100mg for Injection)

Decision of 292nd meeting of Registration Board:

Registration Board deferred the case and decided that Secretary Registration Board will contact M/s Seacross Pharmaceutical Limited (UK) (Marketing Authorization Holder) for declaration of sole agent in Pakistan.

Evaluation by PEC:

Secretary Registration Board has sent email to the manufacturer and the following response has been received from the manufacturer:

Dear Mr. Abdullah

First ,we would like to thank you for sending us email to confirm this, and we sincerely apologize for the inconvenience caused.

For the 2 agents, we have been agreed below recently:
Ahsan Pharma, the products shall be:
Pemetrexed (100mg, 500mg)
Azacitidine(100mg)
Paclitaxel (30mg, 100mg, 300mg)

Merixil Pharma Islamabad , the product shall be:
Bendamustine(25mg,100mg)

We apologize this again , if you have any further questions, please don't hesitate to let us know, and we will fully cooperate with you. Hope you could start the assessment of the product and approve them soon.

Your sincerely
Qin He
Commercial Operation Manager

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. The Board further directed that case shall be further processed after having notarized authorization letter to both firms for respective products.

3419. **Bortezomib applied by M/s Pfizer Pakistan Limited deferred in 292nd meeting of Registration Board**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 8161 Dated 12-06-2019 PKR: 100,000/- dated 12-06-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Pfizer Pakistan Limited (Formerly Parke davis & co. Ltd.) B-2, S.I.T.E, Karachi
	1.3.2	Name, address and contact details of Manufacturing site. Bulk Filled vial: M/s Gland Pharma Limited, Unit-II, Block C, Phase I, Visakhapatnam Special Economic Zone (VSEZ), Duvvada, 530049 Visakhapatnam, India Secondary Packaging (including Pakistan specific vial labelling) & Release Site: M/s Pfizer Pakistan Limited B-2, S.I.T.E., Karachi Marketing authorization holder: M/s Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium
	1.3.3	Specify whether the Applicant is: Importer will import bulk filled vial from Belgium
	1.3.4	Drug Sale License Drug License by Way of Wholesale No. 10578 valid upto 17-Feb-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: □ Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale
	1.4.2	For imported products, please specify one of following: □ Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted

	1.5.1	Generic name with chemical name & synonyms of the applied drug. Bortezomib
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Bortezomib (As mannitol boronic ester) …….3.5mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Bortezomib
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's single use vial & As per SRO
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anticancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration Solution for injection
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price Bortezomib Pharmidea 3.5mg Powder For Solution For Iv Injection (093929)
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. BORTEZOMIB 3.5MG/VIAL (USFDA)
	1.5.10	Dosage form of applied drug Powder for solution for injection
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted

	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Approval of manufacturing facility of API by regulatory body of country and validity. M/s Laurus Labs Limited Plot No. 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam, Andhra Pradesh, India
	Original Legalized CoPP (Certificate#. 03/19/128940) dated 27-09-2018 by European Medicine Agency 30 Churchill Place, Canary Wharf, London E14 5EU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer i.e M/s Gland Pharma Limited, Unit-II, Block C, Phase I, Visakhapatnam Special Economic Zone (VSEZ), Duvvada, 530049 Visakhapatnam, India	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.5	Process Validation and/or Evaluation Submitted

3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted

	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 36 months at 30±20C, 75±5%RH and 6 months at 400C±75%RH for three batches.

Decision of 292nd meeting of Registration Board:

Deferred for following:

Clarification regarding final QC release site.

Evidence of facility for secondary packaging (including Pakistan specific vial product) & release site for anti-cancer solution for injection dosage form.

Now the firm has submitted following reply:

Grand pharma India is responsible for manufacturing of bulk, Primary packaging (vial filling) and quality testing including issuance of Certificate of Analysis (COA).

Whereas, Pfizer Pakistan Limited is responsible for secondary packaging and final batch release based on physical inspection and CoA issued by Grand Pharma. Further, we hereby resubmitting complete procedure/ activities to be perform at Pfizer Pakistan Site.

GMP inspection report issued by Area FID Karachi dated 28-01-2019 showing Bulk Packaging Area:

The area is found neat & clean. It's a spacious hall equipped with packaging lines for the packaging of bulk imported products. Packaging lines are properly segregated, and line clearance performed before start of the batch.

Further to note that as mentioned above Pfizer Pakistan Limited is responsible for Secondary Packaging and final batch releaser based on Physical inspection and CoA issued by Grand Pharma.

Decision of 293rd : Registration Board deferred the case for following:

i. **Agreement between Pfizer Pakistan DML holder & DSL holder for secondary packaging of applied product.**
ii. **Clarify about the primary packaging of the vial (either naked vial or with primary label vial will be imported).**

Evaluation by PEC:

Queries in 293rd meeting	Pfizer response
Agreement between Pfizer Pakistan DML holder & DSL holder for secondary packaging of applied product	DSL and DML holder are single legal entity having same address i.e. Pfizer Pakistan Limited at B-2 SITE, Karachi, Pakistan. Therefore agreement is not applicable
Clarify about the primary packaging of the vial (either naked vial or with primary label vial will be imported).	We will be importing vial having following information pre-printed via inject printer for identification purpose. Brand Name: Batch/Lot number Expiry Date License No. (Country of Origin) After import , Pakistan specific vials will be pasted on vials along with secondary packaging at Pfizer Pakistan limited located at B-2, SITE Karachi Pakistan.

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.

c. New cases of local manufacturing

3420.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22032: 28-10-2019
	Details of fee submitted	PKR 20,000/-: 07-10-2019
	The proposed proprietary name / brand name	**MIREXIA XR TABLETS 25MG**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet contains: Mirabegron…..25mg
	Pharmaceutical form of applied drug	Orange, Oval, coated tablet having "f" on one side and break line on other side
	Pharmacotherapeutic Group of (API)	beta-3 adrenergic agonist (G04BD12)
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MYRBETRIQ tablets **(USFDA** Approved)
	For generic drugs (me-too status)	Mibega 25mg Tablets by Getz Pharma (Reg # 089375)
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co, Ltd Jiangxi Fengxin Industrail Park, Fengxin 330700, Jiangxi Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The drug substance exhibits **stereoisomerism** due to one chiral center. The R enantiomer has been used in the manufacture of the finished product. Mirabegron free base exhibits **polymorphism** and is known to possess two crystalline forms, namely α-form and β-form crystals. The β-form crystals of Mirabegron is hygroscopic and tends to gain water content up to 3% under the relative humidity of about 20%, whereas α-form crystals did not show any increase in the water content over the entire range of relative humidity from 5% to 95% concluding that α-crystal form is stable and suitable for use as a medicine. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Myrbetriq of Astellas Pharma. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Myrbetriq Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release specially in pH 4.5 shows sustained release effect. Firm also calculated factor f2 which was above 50. The formulation was developed like innovator product using The oral-controlled absorption system (OCAS) which represents a drug delivery refinement that incorporates a matrix of gel-forming and gel-enhancing agents to promote a constant drug release independent of food and pH. The firm has used Polyethylene Oxide (Polyox WSR N6OK LEO) and Polyethylene Glycol 8000 as XR polymer (gel forming).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA	
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co, Ltd Jiangxi Fengxin Industrail Park, Fengxin 330700, Jiangxi Province, China.
API Lot No.	20180105V
Description of Pack (Container closure system)	Alu-Alu Blister

Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MBXR-001	MBXR-002	MBXR-003
Batch Size	1000 tablet	1000 tablet	1000 tablet
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	08-02-2019	08-02-2019	08-02-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of Drug Manufacturing License (GAN 20160125) of M/s Jiangxi Synergy Pharmaceutical Co, Ltd Jiangxi Fengxin Industrail Park, Fengxin 330700, Jiangxi Province, China. The certificate is valid till 15-02-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to Import drugs for clinical trial, examination, test or analysis" specifying import of 0.6kg Mirabegron. The license is issued by AD (I&E) DRAP Peshawar office. Firm has submitted copy of commercial invoice dated 19-03-2018 specifying import of 0.6Kg Mirabegron. The commercial invoice is not attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Justify the time difference in manufacturing of batches in 12-2018 and initiation of stability studies on 08-02-2019.	Firm has submitted that all batches of Mirexia XR 25mg Tablet were manufactured in December 2018 and the final coating was performed on 9-01-2019, 10-01-2019 and 11-01-2019 for all the three batches respectively.

	The packing was performed on 16-01-2019 and the stability was initiated on 08-02-2019, wherein there was only difference and delay of 11 working days between the packing and initiation date. Firm further submitted that during every step of manufacturing and even after packing all the batches were placed under controlled temperature conditions.
Justify why the Butylated hydroxytoluene (BHT) contents were not analysed for stability batches as recommended in the EMA public assessment report for the product Betmiga.	Firm has submitted that BHT is used as an antioxidant in the formulation. The finished product release specifications vide assessment report # EMA/706651/2012) does not include content of BHT. Firm has submitted the chemistry review report of FDA which states that "*BHT specification limit was defined only for release. It is expected that during storage of the drug product level of BHT will decrease"*

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

3421.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozesons Laboratories Limited, P.O. Ferozesons Amangarh, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted GMP certificate based on the inspection conducted dated 25-01-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 08-04-2015 specifying Tablet General section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22031: 28-10-2019
	Details of fee submitted	PKR 20,000/-: 07-10-2019
	The proposed proprietary name / brand name	**MIREXIA XR TABLETS 50MG**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet contains: Mirabegron…..50mg
	Pharmaceutical form of applied drug	Yellow color, oval shaped coated tablets having "f" on one side and break line on other side
	Pharmacotherapeutic Group of (API)	beta-3 adrenergic agonist (G04BD12)
	Reference to Finished product specifications	Innovators specs
	Proposed Pack size	10's, 14's, 20's, 28's and 30's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MYRBETRIQ tablets **(USFDA** Approved)
	For generic drugs (me-too status)	Mibega 50mg Tablets by Getz Pharma (Reg # 089378)
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co, Ltd Jiangxi Fengxin Industrail Park, Fengxin 330700, Jiangxi Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The drug substance exhibits **stereoisomerism** due to one chiral center. The R enantiomer has been used in the manufacture of the finished product. Mirabegron free base exhibits **polymorphism** and is known to possess two crystalline forms, namely α-form and β-form crystals. The β-form crystals of Mirabegron is hygroscopic and tends to gain water content up to 3% under the relative humidity of about 20%, whereas α-form crystals did not show any increase in the water content over the entire range of relative humidity from 5% to 95% concluding that α-crystal form is stable and suitable for use as a medicine. Firm has submitted verification studies of analytical method for the testing of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Myrbetriq of Astellas Pharma. Firm has also submitted results of comparative dissolution profile of their product with the innovator product i.e. Myrbetriq Tablet. Firm has performed CDP in 0.1 N HCl, acetate buffer pH 4.5 and phosphate buffer pH 6.8. The results of drug release specially in pH 4.5 shows sustained release effect. Firm also calculated factor f2 which

		was above 50. The formulation was developed like innovator product using The oral-controlled absorption system (OCAS) which represents a drug delivery refinement that incorporates a matrix of gel-forming and gel-enhancing agents to promote a constant drug release independent of food and pH. The firm has used Polyethylene Oxide (Polyox WSR N6OK LEO) and Polyethylene Glycol 8000 as XR polymer (gel forming).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Jiangxi Synergy Pharmaceutical Co, Ltd Jiangxi Fengxin Industrail Park, Fengxin 330700, Jiangxi Province, China.		
API Lot No.	20180105V		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MBXR-004	MBXR-005	MBXR-006
Batch Size	1000 tablet	1000 tablet	1000 tablet
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	18-02-2019	18-02-2019	18-02-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "INVICTA (Sofosbuvir 400mg+ Velpatasvir 100 mg) Tablets" which was presented in 281st meeting of Registration Board wherein the Board decided to approve registration of INVICTA Tablet. Date of inspection: 16th March 2018. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of Drug Manufacturing License (GAN 20160125) of M/s Jiangxi Synergy Pharmaceutical Co, Ltd Jiangxi Fengxin Industrail Park, Fengxin 330700, Jiangxi Province, China. The certificate is valid till 15-02-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to Import drugs for clinical trial, examination, test or analysis" specifying import of 19-02-2018. The license is issued by AD (I&E) DRAP Peshawar office. Firm has submitted copy of commercial invoice dated 19-03-2018 specifying import of 0.6Kg Mirabegron. The commercial invoice is not attested by AD (I&E) DRAP field office.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance along with audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Justify why the Butylated hydroxytoluene (BHT) contents were not analysed for stability batches as recommended in the EMA public assessment report for the product Betmiga.	Firm has submitted that BHT is used as an antioxidant in the formulation. The finished product release specifications vide assessment report # EMA/706651/2012) does not include content of BHT. Firm has submitted the chemistry review report of FDA which states that "*BHT specification limit was defined only for release. It is expected that during storage of the drug product level of BHT will decrease"*

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

3422.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms is provided)
	GMP status of the firm	**Moringa Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 30-5-2019. **Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No 4603 dated 01-02-2019 (Form 5) Dy No. 10254 dated 07-05-2020 (Form 5-F)
	Details of fee submitted	Rs.20,000/- Dated 31-01-2019 Rs. 30,000/- dated 06-05-2020
	The proposed proprietary name / brand name	**AXONE Injection 250mg IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone 250mg powder for solution for injection **(MHRA** Approved)
	For generic drugs (me-too status)	Droncef injection 250mg by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and	Firm has submitted results of pharmaceutical equivalence for

	Comparative Dissolution Profile	all the quality tests for their product against the innovator i.e. Rocephin Injection 250mg. The results of all the tests of both products falls within the specifications and are comparable. The firm has also performed compatibility studies of the product with recommended diluent i.e. lignocaine. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies also demonstrate comparable results with the innovator product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.		
API Lot No.	Q011812004		
Description of Pack (Container closure system)	Vials containing powder for reconstitution, packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	8389 vials	8389 vials	8389 vials
Manufacturing Date	01-2019	01-2019	02-2019
Date of Initiation	12-02-2019	14-02-2019	10-03-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of	Firm has submitted copy of invoice specifying import of 100Kg ceftriaxone sodium dated 08-01-2019. The invoice is

	import).	signed by AD (I&E) DRAP Islamabad office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that their stability chambers are supplied with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- Firm has initially applied for these product for contract manufacturing from English Pharmaceuticals on Form 5 with 20,000/- fee, later the firm has requested to change the manufacturer and submitted Form 5F (CTD) along with balance fee 30,000/-

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed".	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Rocephin Injection 250mg. The results of all the tests of both products falls within the specifications and are comparable. Firm has performed all the tests as per USP monograph.
Submit results of compatibility of your product with the diluent as recommended in the label	The firm has also performed compatibility studies of the product with recommended diluent i.e. lignocaine. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies also demonstrate comparable results with the innovator product.
Submit the results of in-use stability studies in line with the storage conditions mentioned in the label of innovator product.	Firm has submitted the results of in use stability studies conducted at 2-8^{o}C for 24 hours. The in-use stability results are also in line with the innovator product. The stability study recommends the label "Reconstituted injection can be stored at 2-8^{o}C for 24 hours"
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted protocols and results of verification of analytical method of drug substance based on recommendations of USP.

Decision: Deferred for capacity assessment of M/s Seraph Pharmaceuticals and evaluation of product development data of Form5F.		
3423.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms is provided)
	GMP status of the firm	**Moringa Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 30-5-2019. **Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4615 dated 01-02-2019 (Form 5) Dy No. 10255 dated 07-05-2020 (Form 5-F)
	Details of fee submitted	Rs.20,000/- Dated 31-01-2019 Rs. 30,000/- dated 06-05-2020
	The proposed proprietary name / brand name	**AXONE Injection 500mg IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……500mg
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone 500mg powder for solution for injection **(MHRA** Approved)
	For generic drugs (me-too status)	Droncef injection 500mg by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Rocephin Injection 500mg. The results of all the tests of both products falls within the specifications and are comparable. The firm has also performed compatibility studies of the product with recommended diluent i.e. lignocaine. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies also demonstrate comparable results with the innovator product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.		
API Lot No.	Q011812004		
Description of Pack (Container closure system)	Vials containing powder for reconstitution, packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	8389 vials	8389 vials	8389 vials

Manufacturing Date	01-2019	01-2019	02-2019
Date of Initiation	12-02-2019	14-02-2019	10-03-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 100Kg ceftriaxone sodium dated 08-01-2019. The invoice is signed by AD (I&E) DRAP Islamabad office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that their stability chambers are supplied with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- Firm has initially applied for these product for contract manufacturing from English Pharmaceuticals on Form 5 with 20,000/- fee, later the firm has requested to change the manufacturer and submitted Form 5F (CTD) along with balance fee 30,000/-

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator /	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Rocephin Injection 500mg. The results of all the tests of both products falls within the specifications and are comparable. Firm has performed all the tests as per USP monograph.

reference / comparator product should be submitted and discussed".	
Submit results of compatibility of your product with the diluent as recommended in the label	The firm has also performed compatibility studies of the product with recommended diluent i.e. lignocaine. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies also demonstrate comparable results with the innovator product.
Submit the results of in-use stability studies in line with the storage conditions mentioned in the label of innovator product.	Firm has submitted the results of in use stability studies conducted at 2-8^{o}C for 24 hours. The in-use stability results are also in line with the innovator product. The stability study recommends the label "Reconstituted injection can be stored at 2-8^{o}C for 24 hours"
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted protocols and results of verification of analytical method of drug substance based on recommendations of USP.

Decision: Deferred for capacity assessment of M/s Seraph Pharmaceuticals and evaluation of product development data of Form5F.

3424.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms is provided)
	GMP status of the firm	**Moringa Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 30-5-2019. **Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4618 dated 01-02-2019 (Form 5) Dy No. 10256 dated 07-05-2020 (Form 5-F)
	Details of fee submitted	Rs.20,000/- Dated 31-01-2019 Rs. 30,000/- dated 06-05-2020
	The proposed proprietary name / brand name	**AXONE Injection 1g IV**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone (as sodium)……1g
	Pharmaceutical form of applied drug	Sterilized white to off white crystalline dry powder contained in a glass vial with sterilized rubber stopper & aluminium flip seal on it.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone 500mg powder for solution for injection **(MHRA** Approved)
	For generic drugs (me-too status)	Droncef injection 500mg by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Rocephin Injection 1g. The results of all the tests of both products falls within the specifications and are comparable. The firm has also performed compatibility studies of the product with recommended diluent i.e. water for injection. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies

		also demonstrate comparable results with the innovator product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical zone, Economic & technological development zone, Datong Shanxi China.		
API Lot No.	Q011812004		
Description of Pack (Container closure system)	Vials containing powder for reconstitution, packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	8389 vials	8389 vials	8389 vials
Manufacturing Date	01-2019	01-2019	02-2019
Date of Initiation	12-02-2019	14-02-2019	10-03-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 100Kg ceftriaxone sodium dated 08-01-2019. The invoice is signed by AD (I&E) DRAP Islamabad office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software	Firm has submitted that since the stability study of this product

	21CFR & audit trail reports on product testing	was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that their stability chambers are supplied with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- Firm has initially applied for these product for contract manufacturing from English Pharmaceuticals on Form 5 with 20,000/- fee, later the firm has requested to change the manufacturer and submitted Form 5F (CTD) along with balance fee 30,000/-

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed".	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the innovator i.e. Rocephin Injection 1g. The results of all the tests of both products falls within the specifications and are comparable. Firm has performed all the tests as per USP monograph.
Submit results of compatibility of your product with the diluent as recommended in the label	The firm has also performed compatibility studies of the product with recommended diluent i.e. sterile water for injection. Firm has performed comparative analysis with innovator product after reconstitution as well. The reconstitution studies also demonstrate comparable results with the innovator product.
Submit the results of in-use stability studies in line with the storage conditions mentioned in the label of innovator product.	Firm has submitted the results of in use stability studies conducted at 2-8^{o}C for 24 hours. The in-use stability results are also in line with the innovator product. The stability study recommends the label "Reconstituted injection can be stored at 2-8^{o}C for 24 hours"
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted protocols and results of verification of analytical method of drug substance based on recommendations of USP.

Decision: Deferred for capacity assessment of M/s Seraph Pharmaceuticals and evaluation of product development data of Form5F.

3425.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms is provided)
	GMP status of the firm	**Moringa Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 30-5-2019. **Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4602 dated 01-02-2019 (Form 5) Dy No. 10259 dated 07-05-2020 (Form 5-F)
	Details of fee submitted	Rs.20,000/- Dated 31-01-2019 Rs. 30,000/- dated 06-05-2020
	The proposed proprietary name / brand name	**Saf-Xime 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Capsule contained in Alu Alu blister
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size	1x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Suprax Capsule 400mg **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 400mg capsule by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification

		of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Capsule 400mg". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The analysis of all quality tests were performed according to JP monograph. The results depicts that the developed formulation is comparable to the comparator product. Firm has further performed comparative dissolution profile (CDP) testing as per the WHO guidelines in three dissolution mediums. The results of CDP also demonstrates similarity of the developed formulation in terms of release profile from the comparator product.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA			
Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.		
API Lot No.	17CF10172		
Description of Pack (Container closure system)	1 x 5's capsule in alu-alu blister packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	55,500 capsule	55,500 capsule	55,500 capsule
Manufacturing Date	01-2018	03-2018	05-2018
Date of Initiation	19-01-2018	16-03-2018	10-05-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of	Firm has referred to following product specific inspection reports

	the firm (if any)	• Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML of M/s Saakh Pharma is submitted by the firm. Copy of GMP certificate of M/s Saakh Pharma dated 15-01-2018 issued on the basis of inspection dated 16-10-2017 is submitted by the firm. The certificate is issued by Additional Director DRAP Karachi.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 12-01-2018 specifying purchase of 50Kg cefixime from Saakh Pharma (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that their stability chambers are supplied with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- Firm has initially applied for these product for contract manufacturing from English Pharmaceuticals on Form 5 with 20,000/- fee, later the firm has requested to change the manufacturer and submitted Form 5F (CTD) along with balance fee 30,000/-

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed".	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Capsule 400mg". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The analysis of all quality tests were performed according to JP monograph. The results depicts that the developed formulation is comparable to the comparator product. Firm has further performed comparative dissolution profile (CDP) testing as per the WHO guidelines in three dissolution mediums. The

	results of CDP also demonstrates similarity of the developed formulation in terms of release profile from the comparator product.
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted protocols and results of verification of analytical method of drug substance based on recommendations of USP.

Decision: Deferred for capacity assessment of M/s Seraph Pharmaceuticals and evaluation of product development data of Form5F.

3426.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms is provided)
	GMP status of the firm	**Moringa Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 30-5-2019. **Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4601 dated 01-02-2019 (Form 5) Dy No. 10257 dated 07-05-2020 (Form 5-F)
	Details of fee submitted	Rs.20,000/- Dated 31-01-2019 Rs. 30,000/- dated 06-05-2020
	The proposed proprietary name / brand name	**Saf-Xime 100mg/5ml Dry suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate)……100mg
	Pharmaceutical form of applied drug	Amber colored glass bottle containing white to off white powder for reconstitution volume 30ml (after reconstitution)
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	30ml bottle

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Suprax suspension 100mg/5ml **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 100mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Dry powder for suspension 100mg/5ml". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The analysis of all quality tests were performed according to USP monograph. The results depicts that the developed formulation is comparable to the comparator product. The firm has also performed compatibility studies of the product with diluent i.e. purified (boiled and cooled water). Firm has performed testing of assay pH and other parameters for 7 days at room temperature and 14 days at 2 – 8 ^{o}C and the results after reconstitution were within the acceptable range specified by the firm.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.
STABILITY STUDY DATA		
Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim	

	Karachi.			
API Lot No.	17CF10172			
Description of Pack (Container closure system)	1's bottle of powder for suspension packed in unit carton			
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)			
Batch No.	001	002	003	
Batch Size	10,000 bottles	10,000 bottles	10,000 bottles	
Manufacturing Date	01-2018	01-2018	03-2018	
Date of Initiation	18-01-2018	19-01-2018	26-03-2018	
No. of Batches	03			

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML of M/s Saakh Pharma is submitted by the firm. Copy of GMP certificate of M/s Saakh Pharma dated 15-01-2018 issued on the basis of inspection dated 16-10-2017 is submitted by the firm. The certificate is issued by Additional Director DRAP Karachi.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 12-01-2018 specifying purchase of 50Kg cefixime from Saakh Pharma (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for	Firm has submitted that their stability chambers are supplied

	temperature and humidity monitoring of stability chambers (real time and accelerated)	with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- Firm has initially applied for these product for contract manufacturing from English Pharmaceuticals on Form 5 with 20,000/- fee, later the firm has requested to change the manufacturer and submitted Form 5F (CTD) along with balance fee 30,000/-

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed".	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Dry powder for suspension 100mg/5ml". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The analysis of all quality tests were performed according to USP monograph. The results depicts that the developed formulation is comparable to the comparator product.
Submit results of compatibility of your product with the diluent as recommended in the label and also submit the results of in-use stability studies in line with the storage conditions mentioned in the label of innovator product.	The firm has also performed compatibility studies of the product with diluent i.e. purified (boiled and cooled water). Firm has performed testing of assay pH and other parameters for 7 days at room temperature and 14 days at 2 – 8^{o}C and the results after reconstitution were within the acceptable range specified by the firm.
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	Firm has submitted protocols and results of verification of analytical method of drug substance based on recommendations of USP.

Decision: Deferred for capacity assessment of M/s Seraph Pharmaceuticals and evaluation of product development data of Form5F.

3427.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Moringa Pharmaceuticals 35-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms is provided)
	GMP status of the firm	**Moringa Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 30-5-2019. **Seraph Pharmaceuticals:** GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial

		Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4600 dated 01-02-2019 (Form 5) Dy No. 10258 dated 07-05-2020 (Form 5-F)
	Details of fee submitted	Rs.20,000/- Dated 31-01-2019 Rs. 30,000/- dated 06-05-2020
	The proposed proprietary name / brand name	**Saf-Xime 200mg/5ml Dry suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate)……100mg
	Pharmaceutical form of applied drug	Amber colored glass bottle containing white to off white powder for reconstitution volume 30ml (after reconstitution)
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP specs
	Proposed Pack size	30ml bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Suprax suspension 200mg/5ml **(USFDA** Approved)
	For generic drugs (me-too status)	Tripsan 200mg/5ml dry suspension by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions till 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation

		of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted process validation report
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Dry powder for suspension 200mg/5ml". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The analysis of all quality tests were performed according to USP monograph. The results depicts that the developed formulation is comparable to the comparator product. The firm has also performed compatibility studies of the product with diluent i.e. purified (boiled and cooled water). Firm has performed testing of assay pH and other parameters for 7 days at room temperature and 14 days at 2 – 8 ^{o}C and the results after reconstitution were within the acceptable range specified by the firm.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.		
API Lot No.	17CF10172		
Description of Pack (Container closure system)	1's bottle of powder for suspension packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	10,000 bottles	10,000 bottles	10,000 bottles
Manufacturing Date	01-2018	01-2018	03-2018
Date of Initiation	18-01-2018	19-01-2018	26-03-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board.

		Firm has further submitted that their product Neogene 2g Injection was approved in 293th meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML of M/s Saakh Pharma is submitted by the firm. Copy of GMP certificate of M/s Saakh Pharma dated 15-01-2018 issued on the basis of inspection dated 16-10-2017 is submitted by the firm. The certificate is issued by Additional Director DRAP Karachi.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice dated 12-01-2018 specifying purchase of 50Kg cefixime from Saakh Pharma (Pvt) Ltd.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that their stability chambers are supplied with uninterrupted power supply and have digital data logger for monitoring temperature and humidity. The digital data logger have been verified by the panel during our onsite inspection as well.

Evaluation by PEC:

- Firm has initially applied for these product for contract manufacturing from English Pharmaceuticals on Form 5 with 20,000/- fee, later the firm has requested to change the manufacturer and submitted Form 5F (CTD) along with balance fee 30,000/-

Shortcomings communicated	Response by the firm
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed".	Firm has performed comparative analysis of their developed formulation against the comparator product i.e. "Cefspan Dry powder for suspension 200mg/5ml". Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator product. The analysis of all quality tests were performed according to USP monograph. The results depicts that the developed formulation is comparable to the comparator product.
Submit results of compatibility of your product with the diluent as recommended in the label and also submit the results of in-use stability studies in line with the storage conditions mentioned in the label of innovator product.	The firm has also performed compatibility studies of the product with diluent i.e. purified (boiled and cooled water). Firm has performed testing of assay pH and other parameters for 7 days at room temperature and 14 days at 2 – 8^{o}C and the results after reconstitution were within the acceptable range specified by the firm.
Submit the data of verification of analytical method for drug substances in section 3.2.S.4.3 to comply the decision of 293rd meeting of	Firm has submitted protocols and results of verification of analytical method of drug substance based on recommendations of USP.

Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted".	
Justify the significant difference (i.e. more than 5% from initial assay values) in Batch 001 and 002 during accelerated conditions.	Firm has submitted that there was a difference of assay values greater than 5% from initial value in Batch 001 and 002 in accelerated study, but we have completed the real time stability studies till 24 months and there is no difference in the results at real time conditions and the product falls within specifications throughout the shelf life of 24 months. This is also justified in the light of ICH guidelines.

Decision: Deferred for capacity assessment of M/s Seraph Pharmaceuticals and evaluation of product development data of Form5F.

3428.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E., Karachi**
	Name, address of Manufacturing site.	M/s Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E., Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	04-09-2018
	Details of fee submitted	PKR 20,000/-: 04-09-2018
	The proposed proprietary name / brand name	**Lanzol-X 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Dual delayed release pellet of dexlansoprazole eq. to dexlansoprazole……30mg
	Pharmaceutical form of applied drug	White and green coloured, dual delayed release pellets filled into hard gelatin capsule size '3' blue cap and body.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	In house
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant Capsule by Takeda (**USFDA** Approved)
	For generic drugs (me-too status)	Razodex 30mg Capsule by Getz Pharma (Reg# 086976)

	Name and address of API manufacturer.	**Pellets manufacturer:** Vision Pharmaceutical Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad-Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data sheets of pellets as per zone IV-A for 36 months.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted CDP data with innovator product Dexilant along with calculation of f2 and f1 factor. The value of f2 was 91 and the value of f1 was 01.
	Process validation data of product	Firm has submitted that since they have manufactured lab scale batches therefore process validation is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies of product	Firm has submitted 6 months real time and accelerated stability study data of 3 batches.

Summary of Evaluation: Firm has filed section wise data for module 2 & 3 of Form5-F. The submitted data has been reviewed **(Assessment document available as reference)** and following observations have been communicated to the firm for which is response is yet awaited.

STABILITY STUDY DATA

API Lot No.	DLP255		
Description of Pack (Container closure system)	Alu-Alu blister containing blue colored opaque capsule size "3" containing white and green colored delayed release pellets		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18PD097DEXT01	18PD107DEXT02	18PD108DEXT03
Batch Size	0.335Kg (1800 capsule)	1500 Tablet (1800 capsule)	1500 Tablet (1800 capsule)
Manufacturing Date	09-2018	11-2018	11-2018
Date of Initiation	04-10-2018	15-11-2018	17-11-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data	Yes

	sheets etc.	
5.	Documents confirming import of API etc.	Firm has submitted invoice for purchase of 5 Kg pellets dated 20-03-2018 from Vision Pharmaceuticals, Islamabad.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcoming communicated	Response by the firm
Process validation and /or evaluation data (3.2.P.3.5) including summary of validation studies and the proposed protocol that will be used for the validation of three commercial batches needs to be submitted.	Firm has submitted process validation protocol issued on July 2019. The protocols contains methodology, critical process control parameters, specifications, acceptance criteria and proposed validation results sheet for filled capsules at various critical steps. The summary of validation results are not submitted
Submit the evidence of procurement of pellets.	Firm has submitted invoice for purchase of 5 Kg pellets dated 20-03-2018 by Vision Pharmaceuticals, Islamabad.

- Stability initiation date for batch 18PD097DEXT01mentioned in stability summary sheets is 22-10-2018 while that mentioned in covering letter is 04-10-2018. Clarify

3429.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E., Karachi**
	Name, address of Manufacturing site.	M/s Pharmatec Pakistan (Private) Limited D-86/A, S.I.T.E., Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	04-09-2018
	Details of fee submitted	PKR 20,000/-: 04-09-2018
	The proposed proprietary name / brand name	**Lanzol-X 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Dual delayed release pellet of dexlansoprazole eq. to dexlansoprazole……60mg
	Pharmaceutical form of applied drug	White and green coloured, dual delayed release pellets filled into hard gelatin capsule size ‘2’ red cap and body.

	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	In house
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant Capsule by Takeda (**USFDA** Approved)
	For generic drugs (me-too status)	Razodex 60mg Capsule by Getz Pharma (Reg# 086977)
	Name and address of API manufacturer.	**Pellets manufacturer:** Vision Pharmaceutical Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad-Pakistan.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data sheets of pellets as per zone IV-A for 36 months.
	Comparative Dissolution Profile Data (Details of reference product & study)	Firm has submitted CDP data with innovator product Dexilant along with calculation of f2 and f1 factor. The value of f2 was 91 and the value of f1 was 01.
	Process validation data of product	Firm has submitted that since they have manufactured lab scale batches therefore process validation is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies of product	Firm has submitted 6 months real time and accelerated stability study data of 3 batches.

Summary of Evaluation: Firm has filed section wise data for module 2 & 3 of Form5-F. The submitted data has been reviewed **(Assessment document available as reference)** and following observations have been communicated to the firm for which is response is yet awaited.

STABILITY STUDY DATA

API Lot No.	DLP255		
Description of Pack (Container closure system)	Alu-Alu blister containing blue colored opaque capsule size "3" containing white and green colored delayed release pellets		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18PD098DEX60T01	18PD102DEX60T02	18PD102DEX60T02(B)
Batch Size	0.668Kg (capsule)	0.668Kg (1800 capsule)	0.668Kg (1800 capsule)
Manufacturing Date	09-2018	10-2018	11-2018
Date of Initiation	04-10-2018	22-10-2018	15-11-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted invoice for purchase of 5 Kg pellets dated 20-03-2018 from Vision Pharmaceuticals, Islamabad.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcoming communicated	Response by the firm
Process validation and /or evaluation data (3.2.P.3.5) including summary of validation studies and the proposed protocol that will be used for the validation of three commercial batches needs to be submitted.	Firm has submitted process validation protocol issued on July 2019. The protocols contains methodology, critical process control parameters, specifications, acceptance criteria and proposed validation results sheet for filled capsules at various critical steps. The summary of validation results are not submitted
Submit the evidence of procurement of pellets.	Firm has submitted invoice for purchase of 5 Kg pellets dated 20-03-2018 by Vision Pharmaceuticals, Islamabad.

- Stability initiation date for batch 18PD097DEXT01mentioned in stability summary sheets is 22-10-2018 while that mentioned in covering letter is 04-10-2018. Clarify

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Lanzol-X 30mg and Lanzol-X 60mg (Dexlansoprazole) Capsules by M/S. Pharmatec Pakistan (Private) Limited, D-86/A, S.I.T.E, Karachi.

Reference No: F.13-11/2017-PEC (Pt) : Dated 14th November, 2019.

Investigation Date and Time: 20-03-2020 (Morning).

Investigation Site: Factory premises of M/S. Pharmatec Pakistan (Private) Limited, D-86/A, S.I.T.E, Karachi.

Background:

Registration Board meeting considered the applications of M/S. Pharmatec Pakistan (Private) Limited, D-86/A, S.I.T.E, Karachi for registration of Lanzol-X 30mg and Lanzol-X 60mg (Dexlansoprazole) Capsules. Registration Board considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm as per decision of Registration Board and to submit report for further consideration.

Composition of Panel:

7. Dr. Aslam Shah, Ex-Member Registration Board, Senior Manager Pharmacy & Supply Chain, Indus Hospital, Karachi.
8. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.

9. Dr. Mahrukh Mughal, Assistant Director, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

Q. NO.	QUESTION	OBSERVATION BY PANEL
1.	Do you have documents confirming the import of API including approval from DRAP?	The firm has procured 17% and 22.5% Dexlansoprazole pellets each of 5kg from M/S. Vision Pharmaceuticals (Pvt.) Limited, Islamabad, dated: 20-03-2018.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm has selected the vendor on the basis of authorization for manufacturing of Dexlansoprazole pellets and GMP certificate issued by DRAP.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has obtained working standard of the API from API manufacturer. Impurities standards have been procured 12 months later than starting stability studies on the stability batches.
4.	Do you have certificate of analysis of API, reference standards and impurity standards?	The firm has certificate of analysis for Dexlansoprazole Pellets, Dexlansoprazole working standard and impurity standards.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has provided the copy of GMP certificate issued by DRAP.
6.	Do you use APIs manufacturer method of the testing?	The firm has used API Manufacturer's method for testing the pellets.
7.	Do you have stability studies report on APIs?	The firm has stability studies report of API (Dexlansoprazole pellets) conducted by API manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM and degradation products have been quantified?	The manufacturer of API has performed the stability studies on API as per SIM Method and the Related Substance/ impurities have been quantified.
9.	Do you have method for quantifying the impurities in API?	The API manufacturer has developed method for quantifying impurities in the API. The method is available with M/S. Pharmatec Pakistan.
10.	Do you have some remaining quantities of API, the reference standards and impurities?	The firm has remaining quantity of API pellets, Dexlansoprazole working standard and impurity standards.
11.	Have you used pharmaceutical grade excipients?	The firm has used cap shell size no 3 for 30mg and cap shell size no 2 for 60mg capsules.
12.	Do you have documents confirming the import of used excipients?	The firm has documents confirming the import of capsule shells.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports on empty capsules shell sizes no. 3 and 2.

<table>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of products?</td><td>The firm has protocol for the development of Lanzol-X Capsules 30mg/60mg.</td></tr>
<tr><td>15.</td><td>Have you performed drug-excipient compatibility studies?</td><td>The API manufacturer performed specificity by placebo method in analytical method validation.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>Firm has performed comparative dissolution studies with Dexilant Capsules in three recommended dissolution media, however, the analytical method being used is developed by the manufacture but the method has not been validated till date. The same analytical method is used for routine dissolution testing at different time intervals. Analysis with non-validated method especially when developed by the firm itself is a critical negligence rendering the whole study questionable and non-acceptable.</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section?</td><td>The firm has product development section with some equipment for manufacturing tablets dosage form only. The area, equipment and environmental conditions need gross changes and upgradation.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of product?</td><td>• The firm has used commercial equipment for development of Lanzol-X Capsules 30mg/60mg as PD area does not have any facility for manufacturing capsules dosage form.
• For analysis routine QC analytical instruments have been used. As per record all the relevant commercial manufacturing equipment and QC instruments are qualified.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>Not Applicable</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance/ calibration/ requalification program for the equipment used in PD section?</td><td>The firm has maintenance / calibration / requalification program for the equipments in the PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff for Product Development including 02 Pharmacists and 02 Chemists.</td></tr>
<tr><td>22.</td><td>Have you manufactured stability batches for the stability studies of the product as required?</td><td>The firm has manufactured three stability batches each for Lanzol-X 30mg and Lanzol-X 60mg capsules with batch size 2500 capsules each.
<table>
<tr><td colspan="3">Lanzol-X 30mg Capsule</td></tr>
<tr><td></td><td>Mfg: date</td><td>Exp: date</td></tr>
<tr><td>18PD097DEXT01</td><td>Sep-2018</td><td></td></tr>
<tr><td>18PD107DEXT02</td><td>Nov-2018</td><td></td></tr>
<tr><td>18PD108DEXT03</td><td>Nov-2018</td><td></td></tr>
<tr><td colspan="3">Lanzol-X 60mg Capsule</td></tr>
<tr><td></td><td>Mfg: date</td><td>Exp: date</td></tr>
<tr><td>18PD098DEX60T01</td><td>Sep-2018</td><td></td></tr>
<tr><td>18PD102DEX60T02</td><td>Oct-2018</td><td></td></tr>
<tr><td>18PD102DEX60T02 (B)</td><td>Nov-2018</td><td></td></tr>
</table>
The capsules are packed in blisters.</td></tr>
<tr><td>23.</td><td>Do you have criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is based on testing frequencies and number of capsules required per testing frequency and DRAP guidelines.</td></tr>
</table>

24.	Do you have complete record of production of stability batches?	The firm has detailed record of the stability batches of Lanzol-X Capsules 30mg & 60mg.
25.	Do you have protocols for stability testing of stability products?	The firm has protocol for testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	Firm has used a testing method derived from literature for testing their product upto 12 months. This method was used without any validation activity. After 12 months, the firm has used the API manufacturer method of testing after proper validation. However, chromatograms with both methods show significant variation from one testing point to another and within the same testing point. This behavior reflects the whole testing questionable and unacceptable.
27.	Do you have method transfer studies in case when the method of testing used by your firm is given by another firm?	Not done.
28.	Do you have documents confirming the qualification of equipment/instruments being used in the test and analysis of API and the finished products?	The firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of the Lanzol-X Capsules 30mg & 60mg.
29.	Do your method of analysis stability indicating?	Firm has used two methods of testing, one without validation and another with validation, but chromatograms with both the methods show significant variation in Rt i.e. from 2.1 – 8.99 for Dexlansoprazole peak at both intra & inter testing points, therefore, the method is used on HPLC systems which are probably not qualified properly, hence making the method non validated and not stability indicating. This scenario raise fingers on the whole validation / qualification program of the firm.
30.	Do your HPLC software 21 CFR compliant?	The firm has HPLC software which is 21CFR Compliant.
31.	Can you show audit trail reports on product testing?	The firm has audit trail Reports on their testing.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has some remaining quantities of stability batches.
33.	Do you have stability batches kept on stability testing?	The firm has three stability batches of each strength kept on stability for Real time stability testing.
34.	Do you have valid calibration status for the equipment used in production and analysis?	The firm has valid calibration status for the equipment used in Lanzol-X Capsules 30mg & 60mg production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has online monitoring software available for stability chamber.
36.	Do related manufacturing area, equipment, personnel, and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities can be rated as GMP compliant.
37.	<u>Any Query raised by PEC:</u> Stability initiation date for batch 18PD097DEXT01 / 18PD098DEX60T01 mentioned in stability summary sheets is verifying	04-10-2018 is the manufacturing date whereas 22-10-2018 is the date of initiation of stability studies.

	date 22-10-2018 while that mentioned in covering letter is manufacturing date 04-10-2018.	

Conclusions:

6. Record related to testing method development, validation and testing at various time points in stability studies program show that there are significant negligencies and variations, hence the overall stability studies are technically questionable and inappropriate.
7. Qualification of related HPLC systems and facilities and conditions of product development area are also gray areas, requiring immediate attention of the management.
8. Keeping in view the above, Lanzol-X 30mg and 60mg (Dexlansoprazole) Capsules is NOT VERIFIABLE.

Recommendations:

1. Firm must redesign the whole study and conduct proper testing as per proper validated stability indicating method.
2. Firm must also reassess their whole qualification program especially including the QC equipment / instruments.
3. Firm must also upgrade their product development area for future development work as per proper guidelines.

Decision: Registration Board deliberated the matter and discussed the observations raised by inspection panel. The Board determined that the firm has performed stability studies and the same is also verified by inspection panel; however the firm has used non-validated method of analysis for testing of the product which makes the whole testing and stability studies questionable. On the basis of the observations of the inspection panel, Registration Board decided to reject the application of Lanzol-X 30mg and Lanzol-X 60mg of M/s Pharmatec Pakistan (Private) Limited, D-86/A, S.I.T.E, Karachi due to following reasons:

- **Use of non-validated method of analysis for performing dissolution testing and comparative dissolution profile**
- **Firm has used testing method derived from literature for testing their product upto 12 months stability time point without performing validation studies. After 12 months, the firm has used the API manufacturer method of testing after proper validation. However, chromatograms with both methods show significant variation from one testing point to another and within the same testing point.**
- **Firm has used two methods of testing, one without validation and another with validation, but chromatograms with both the methods show significant variation in Retention time Rt i.e. from 2.1 – 8.99 for Dexlansoprazole peak at both intra & inter testing points, therefore, making the method non validated and not stability indicating.**

Case No. 05 Registration applications of drugs for which stability study data is submitted

a. New cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3430.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.	Byflanz Capsule 6/50mg Each capsule contains: Olanzapine ….6mg Fluoxetine HCl……50mg (Antipsychotic in combination with SSRI)	Form 5-D 16-12-2012 PKR 8,000/- (16-02-2012) + PKR 12,000/- (13-11-2013) +	Symbyax Capsule (**USFDA** Approved) 29-01-2018. GMP rated as GOOD.

			PKR 30,000/- (14-06-2019) PKR 8000 and 12000 chalan is duplicate	

Evaluation by PEC:

- Firm has initially applied the product with brand name "Lanco capsule" but later the firm has requested to change the brand name to Byflanz Capsule while submitting balance fee 30,000/-. Already 3 other strengths of the same drug has been registered with brand name Byflanz
- Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.

STABILITY STUDY DATA

Drug	Byflanz Capsule 6/50mg		
Name of Manufacturer	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.		
Manufacturer of API	**Olanzapine**: Cadila Pharmaceuticals Limited, Ankleshwar Gujrat India		
	Fluoxetine HCl: Divis Pharmaceuticals Pvt Ltd. Survey No. 10, Gaddapotaram (V), Jinnaram (M) Khazipally I.D.A Sanga eddy District		
API Lot No.	**Olanzapine**: 18OLZ006		
	Fluoxetine HCl: 0790618		
Description of Pack (Container closure system)	Blue cap and white body, hard gelatin capsule size #2 containing yellow color powder in Alu Alu blister pack		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-C-383-P	NPD-C-363-L	NPD-C-384-P
Batch Size	2500 Capsule	2500 Capsule	2500 Capsule
Manufacturing Date	24-10-2018	17-10-2018	24-10-2018
Date of Initiation	01-11-2018		01-11-2018
No. of Batches	03		
Date of Submission	Dy.# 6507 dated 20-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Olanzapine**: Copy of GMP certificate issued by Food and Drug control administration Gujrat state India dated 31-8-2018 is submitted
		Fluoxetine HCl: Copy of GMP certificate dated 18-6-2018 issued by Drugs control administration government of Telangana has been submitted.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by	Yes

	attested respective documents like chromatograms, laboratory reports, data sheets etc.	
5.	Documents confirming import of API etc.	**Olanzapine**: Copy of commercial invoice attested by ADC dated 29/08/2018 for import of 1.2 Kg Olanzapine by Divis Pharma
		Fluoxetine HCl: Copy of commercial invoice attested by ADC dated 07/2018 for import of 4.18 Kg Fluoxetine HCl by Divis Pharma is submitted
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The panel may be advised to verify the following:

- Verify the ADC attested invoice for import of both API along with date of clearance, since the invoices submitted along with stability data are not clear.
- Verify whether the firm has performed testing as per USP method.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3431.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.	Byflanz Capsule 12/50mg Each capsule contains: Olanzapine ….12mg Fluoxetine HCl……50mg (Antipsychotic in combination with SSRI)	Form 5-D 16-12-2012 PKR 8,000/- (16-02-2012) + PKR 12,000/- (13-11-2013) + PKR 30,000/- (14-06-2019) PKR 8000 and 12000 chalan is duplicate	Symbyax Capsule (**USFDA** Approved) 29-01-2018. GMP rated as GOOD.
	Evaluation by PEC: • Firm has initially applied the product with brand name "Lanco capsule" but later the firm has requested to change the brand name to Byflanz Capsule while submitting balance fee 30,000/-. Already 3 other strengths of the same drug has been registered with brand name Byflanz • Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Byflanz Capsule 12/50mg
Name of Manufacturer	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area

	Karachi.		
Manufacturer of API	**Olanzapine**: Cadila Pharmaceuticals Limited, Ankleshwar Gujrat India		
	Fluoxetine HCl: Divis Pharmaceuticals Pvt Ltd. Survey No. 10, Gaddapotaram (V), Jinnaram (M) Khazipally I.D.A Sanga eddy District		
API Lot No.	**Olanzapine**: 18OLZ006		
	Fluoxetine HCl: 0790618		
Description of Pack (Container closure system)	Blue cap and white body, hard gelatin capsule size #2 containing yellow color powder in Alu Alu blister pack		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-C-386-P	NPD-C-385-P	NPD-C-365-L
Batch Size	2500 Capsule	2500 Capsule	2500 Capsule
Manufacturing Date	24-10-2018	24-10-2018	17-10-2018
Date of Initiation	01-11-2018	01-11-2018	01-11-2018
No. of Batches	03		
Date of Submission	Dy.# 7198 dated 27-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Olanzapine**: Copy of GMP certificate issued by Food and Drug control administration Gujrat state India dated 31-8-2018 is submitted
		Fluoxetine HCl: Copy of GMP certificate dated 18-6-2018 issued by Drugs control administration government of Telangana has been submitted.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Olanzapine**: Copy of commercial invoice attested by ADC dated 29/08/2018 for import of 1.2 Kg Olanzapine by Divis Pharma
		Fluoxetine HCl: Copy of commercial invoice attested by ADC dated 07/2018 for import of 4.18 Kg Fluoxetine HCl by Divis Pharma is submitted
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes

8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The panel may be advised to verify the following:

- Verify the ADC attested invoice for import of both API along with date of clearance, since the invoices submitted along with stability data are not clear.
- Verify whether the firm has performed testing as per USP method.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Byflanz 6/50mg and 12/50mg (Olanzapine / Fluxetine HCl) Capsules by M/S. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (Pt) : Dated 28th August, 2019.

Investigation Date and Time: 15-04-2020 (Morning).

Investigation Site: Factory premises of M/S. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.

Background:

Registration Board meeting considered the applications of M/S. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi for registration of Byflanz 6/50mg and 12/50mg (Olanzapine / Fluxetine HCl) Capsules. Registration Board considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm as per decision of Registration Board and to submit report for further consideration.

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi, Member Registration Board, Islamabad.
2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
3. Ms. Sanam Kausar, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

Sr. No	Question	Observation by panel
38.	Do you have documents confirming the import of APIs?	The firm has imported 1.2kg API of Olanzapine from Cadila Pharmaceutical Limited India, batch No. 18OLZ006 and 4.18kg API of Fluoxetine HCl from Divis Pharmaceuticals Pvt, Ltd India Batch No. 0790618 for manufacturing of stability batches of Byflanz 6/50mg and 12/50mg capsules. They have taken approval from DRAP-Karachi for import.
39.	What was the rationale behind selecting the particular manufacturer of APIs?	There is proper vendor qualification program being implemented by the firm which include an audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF, provision of reference standard, impurity standards etc. The firm was evaluated on above mentioned criteria and selected.
40.	Do you have documents confirming the import of APIs reference standard of APIs and impurity	The firm has documents confirming the import of APIs working standards of APIs and their impurities.

	standards?	
41.	Do you have certificate of Analysis of the API, reference standards of the APIs and impurity standards?	The firm has certificates of analysis for both APIs, reference standards of both APIs and their impurity standards.
42.	Do you have any approval of APIs or GMP certificate of APIs manufacturers issued by regulatory authorities of countries of origin?	The firm has GMP certificate no. (1809989) valid till 31/08/2021 for Olanzapine manufacturer issued by Food and Drug Control Administration Gujrat, India. and GMP certificate no. (2810/E(G)/TS/2018) valid till 31/12/2021 for Fluoxetine HCl manufacturer issued by Drug Control Administration Telangana, India.
43.	Do you use API manufacturer method of testing	The firm has used USP methods of testing for APIs.
44.	Do you have stability studies reports on APIs?	The firm has stability studies reports on both APIs.
45.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM methods and degradation products have been quantified.
46.	Do you have method for quantifying the impurities in the APIs?	The firm has methods for quantifying the impurities in both APIs.
47.	Do you have some remaining quantities of the APIs, their reference standards and impurities standards?	The firm has remaining quantities of both APIs, reference standard of APIs and their impurities.
48.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Olanzapine, Fluoxetine HCl, Sodium Lauryl Sulfate, Starch STA-RX 1500 and Megnesium Stearate.
49.	Do you have documents confirming the import of the used excipients?	The firm has documents confirming the import/purchase of all excipients used.
50.	Do you have test reports and other records on the excipients used	The firm has test reports and other records on the excipients used.
51.	Do you have written and authorized protocols for the development of Byflanz 6/50mg and 12/50mg capsules?	The firm has written and authorized protocols for the development of Byflanz 6/50mg and 12/50mg capsules.
52.	Have you performed Drug excipient compatibility studies?	Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.
53.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies of their products against innovator products (Symbyax by M/s Lilly, USA) and their products have shown comparable dissolution profiles.
54.	Do you have product development (R&D) section.	The firm has product development (R&D) section with equipment for manufacturing of capsule dosage form. The analytical part is performed on equipment dedicated for R&D activities.
55.	Do you have necessary equipment available in product development section for development of API Capsules?	The firm has necessary equipment for product development of Byflanz 6/50mg and 12/50mg capsules. The product in question has been packed using packing machine of commercial packaging. Furthermore, the analytical part has been performed via the dedicated quality control equipment & laboratory established for R&D activities.
56.	Are the equipment in product development section qualified?	The available equipment in product development section are qualified.

57.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has SOP for the maintenance / calibration / requalification of equipment used on PD section. All the equipment are qualified as per above SOP.
58.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff which include One PhD Chemistry and six Pharmacists in product development section with relevant work experience.
59.	Have you manufactured three stability batches for the stability studies of API Capsules as required?	The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of • Byflanz (Olanzapine 6mg+Fluoxetine HCl 50mg) Capsules having batch No. NPD-C-384-P,NPD-C-363-L,NPD-C-383-P with batch size of 2500 capsules each. The capsules are packed in Alu-Alu blisters of pack size 1x 10's. • Byflanz (Olanzapine 12mg+Fluoxetine HCl 50mg) Capsules having batch No. NPD-C-365-L, NPD-C-385-P, NPD-C-386-P with batch size of 2500 capsules each. The capsules are packed in Alu-Alu blisters of pack size 1x 10's.
60.	What was the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of capsules per testing and the number of capsules required for whole stability testing.
61.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. Necessary logbooks of equipment used has been available with the firm.
62.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocol for stability testing of stability batches.
63.	Do you have developed and validated the method for testing of stability batches?	The firm has pharmacopeial and verified method for testing of stability batches.
64.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
65.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.
66.	Do your method of analysis stability indicating?	The firm's method of analytical testing has stability indicating parameters.
67.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
68.	Can you show Audit Trail reports on API testing?	The firm showed the audit trail reports on API testing.
69.	Do you have some remaining quantities of degradation products and stability batches?	The firm does not have remaining quantities of stability batches for accelerated studies but has remaining quantities for real time stability studies.
70.	Do you have commitment batches kept on stability testing?	The firm has completed accelerated stability testing on the three stability batches. The real time stability testing is in progress on all the three stability batches. Currently 06 months studies have been completed with satisfactory results.
71.	Do you have valid calibration status for the equipment used in API	The firm has valid calibration status for the equipment used in production and analysis.

	capsules production in analysis?	
72.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
73.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities be rated as GMP compliant.
74.	Any Query raised by PEC: • Verify the ADC attested invoice for import of both APIs along with date of clearance, since the invoices submitted along with stability data are not clear. • Verify whether the firm has performed testing as per USP method.	The following invoices were verified. 1 Olanzapine 1.2 kg 32018500029 25-07-2018 2 Fluoxetine 4.18 kg FLU/EXP/051/2018-19 07-07-0218 • The use of USP method for testing was also verified.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Byflanz 6/50mg and 12/50mg (Olanzapine + Fluxetine HCl) Capsules is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Byflanz 6/50mg and 12/50mg (Olanzapine + Fluxetine HCl) Capsules.

Recommendations:

The firm may kindly be granted necessary registration of Byflanz 6/50mg and 12/50mg (Olanzapine + Fluxetine HCl) Capsules.

Decision: Registration Board decided to approve registration of Byflanz 6/50mg and 12/50mg (Olanzapine + Fluxetine HCl) Capsules with Innovator's specifications by M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3432.	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.	Igrelor Tablet 90mg Each Film Coated Tablet Contains: Ticagrelor…90mg	Form-5 Dy.No 5084 (06-02-2019) Rs.20,000/- (04-02-2019) 10's, 14's, 20's, 28's, 30's	Brilinta Tablets (**USFDA** Approved) 29-01-2018. GMP rated as GOOD.
	(Stability Dy. # 22421 dated 30-10-2019)			

STABILITY STUDY DATA

Drug	Igrelor Tablet 90mg
Name of Manufacturer	M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd., Jiangsu Province China.
API Lot No.	RD-TG-201810081

Description of Pack (Container closure system)	Alu-Alu Blister (2x10's packed in unit carton)		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-573-P	NPD-T-567-L	NPD-T-574-P
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	19-03-2019	08-03-2019	20-03-2019
Date of Initiation	27-03-2019	27-03-2019	27-03-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin	Firm has submitted copy of "License for Drug production" issued by the Jiangsu Food and Drug Administration in the name of M/s Nantong Chanyoo Pharmatech Co., Ltd., China with License number "S. 20160512" and valid up to 31-12-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice specifying import of 1.4 Kg Ticagrelor, the invoice is attested by AD, DRAP dated 12-01-2019.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978	Yes

REMARKS OF EVALUATOR

- The firm has adopted acceptance criteria for dissolution testing as NLT 85% (Q+5, where Q=80%) in 60 minutes, while the USFDA approved reference product has defined a two point dissolution test at 45 and 60 minutes time.
- The panel may be requested to verify the exact polymorphic form of ticagrelor used.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Igrelor 90mg (Ticagrelor) Tablets by M/S. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.

Reference No: F.1-2/2020-PEC : Dated 18th February, 2020.

Investigation Date and Time: 08-04-2020 (Morning).

Investigation Site: Factory premises of M/S. Martin Dow Limited, Plot No. 37, Sector 19, Korangi

Industrial Area, Karachi.

Background:

Registration Board meeting considered the applications of M/S. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi for registration of Igrelor 90mg (Ticagrelor) Tablets. Registration Board considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm as per decision of Registration Board and to submit report for further consideration.

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi, Member Registration Board, Islamabad.
2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
3. Ms. Sanam Kausar, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

Sr. No	Question	Observation by panel
1.	Do you have documents confirming the import of API?	The firm has imported 1.4kg Ticagrelor API from Nantong Chanyoo pharmatech Co. Ltd, China Batch No. RD-TG-201810081 and has taken approval from DRAP-Karachi for import.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor qualification being implemented by the firm which include an audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF, reference standard, impurity standards etc. The firm was evaluated on above mentioned criteria and selected
3.	Do you have documents confirming the import of API reference standard and impurity standards	The firm has documents confirming the import of API of said batches and working standards of API and major mpurities.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API and working standards of API and major impurities.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate (No.2017006 valid up to 07-09-2020) of Ticagrelor manufacturer issued by Nantong Food and Drug Administration, China.
6.	Do you use API manufacturer method of testing	The firm has used API manufacturer method of testing for API.
7.	Do you have stability studies reports on API?	The firm has accelerated stability studies reports of six months and two years on real time on API stability studies reports.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying the impurities in the API. The testing method has been obtained from the API manufacturer.

10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of API, reference standard of API and impurities.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including, Ticagrelor, Mannitol, Di-calcium phosphate dihydrous DC grade, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate.
12.	Do you have documents confirming the import of the used excipients?	The firm has documents confirming the import/purchase of all excipients used.
13.	Do you have test reports and other records on the excipients used	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Igrelor 90mg tablets?	The firm has written and authorized protocols for the development.
15.	Have you performed Drug excipient compatibility studies?	Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies of their product against innovator product (Brilique by M/s AstraZeneca AB Sweden) and their product have shown comparable dissolution profile.
17.	Do you have product development (R&D) section	The firm has product development (R&D) section with equipment for manufacturing of tablet dosage form. The analytical part is performed on equipment dedicated for R&D activities.
18.	Do you have necessary equipment available in product development section for development of Igrelor 90mg tablets?	The firm has necessary equipment for product development of Igrelor 90mg tablets. The product in question has been packed using packing machine of commercial packaging. Furthermore, the analytical part has been performed via the dedicated quality control equipment & lab.
19.	Are the equipment in product development section qualified?	The available equipment in product development section are qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has SOP for the maintenance / calibration / requalification of equipment used in PD section. The program is properly implemented.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff which include One PhD Chemistry and six Pharmacists in product development section with relevant work experience.
22.	Have you manufactured three stability batches for the stability studies of Igrelor 90mg tablets as required?	The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of Igrelor (Ticagrelor 90mg) Tablet (NPD-T-573-P, NPD-T-574-P, NPD-T-567-L) with batch size 2500 tablets each. The tablets are packed in Alu-Alu blisters of pack size 2 x 10's.
23.	What was the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of tablets per testing and the number of tablets required for whole stability testing.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. Necessary logbooks of equipment used has been available with the firm.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocol for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated their own method for testing of stability batches based upon the API testing method.
27.	Do you have method transfer studies	Not Applicable

	in case when the method of testing being used by your firm is given by any other lab?	
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of analytical testing has stability indicating parameters. The stability indicating nature of the method has been supported by forced degradation and spiking studies.
30.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit Trail reports on API testing and product testing?	The firm showed the audit trail reports on API and product testing.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm does not have remaining quantities of stability batches for accelerated studies but has remaining quantities for real time stability studies. Some quantities of impurities standards are also available.
33.	Do you have commitment batches kept on stability testing?	The firm has completed accelerated stability testing on the three stability batches. The real time stability testing is in progress on all the three stability batches. Currently 06 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment used in Igrelor 90mg tablets production in analysis?	The firm has valid calibration status for the equipment used in production and analysis of Igrelor 90mg tablets.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities are rated as GMP compliant.
37.	<u>Any query of PEC:</u> • The firms has adopted acceptance criteria for dissolution testing as NLT 85% (Q+5, where Q=80%) in 60 minutes, while the USFDA approved reference product has defined a two point dissolution test at 45 and 60 minutes time? • Verification of the exact polymorphic from of ticagrelor use in the stability studies?	• The firm has performed the testing of their product (test) as well as innovators product (reference) at 45 minutes during comparative dissolution profile (CDP) analysis and found that the results of both test and reference product are comparable at 45 minutes in all 03 dissolution media. However, the will incorporate the testing specification of 45 minutes for dissolution in finished product specifications and will perform this test in scale-up batches. • The firm has used polymorphic form-II as evidenced by the documents they provided to the inspection team.

Conclusions:

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

Recommendations:

1. The firm may kindly be granted necessary registration of Igrelor (Ticagrelor 90mg) Tablet.
2. Since Ticagrelor falls in class-IV API as per BCS classification therefore, post-registration bioequivalence studies are also recommended. The product has also efficacy and safety problems in the real world data therefore PMS, as requirement, is also recommended.

Note: The firm has submitted written commitment for post-registration bioequivalence and PMS studies which is attached herewith for consideration.
Decision: Registration Board decided to approve registration of Igrelor (Ticagrelor 90mg) Tablet with Innovator's specifications by M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3433.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.	Amlidy Tablet 25mg Each film coated tablet contains: Tenofovir alfenamide (as fumarate) ….25mg (Anti-viral)	Form 5D 03-09-2018 PKR 50,000/- (31-08-2018)	Vemlidy Tablet by Gilead Sciences (**USFDA** Approved) 29-01-2018. GMP rated as GOOD.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Amlidy Tablet 25mg		
Name of Manufacturer	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.		
Manufacturer of API	Shanghai Desano Chemical Pharmaceutical Co. Ltd. No. 417 Binhai Road, Laogang Town Pudong New Area Shanghai China.		
API Lot No.	DBH251-B15A-180702		
Description of Pack (Container closure system)	Yellow color round biconvex film coated tablet plain on both sides in Alu-Alu blister pack		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-374-P	NPD-T-359-L	NPD-T-388-P
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	23-10-2018	12-10-2018	25-10-2018
Date of Initiation	30-10-2018	30-10-2018	30-10-2018
No. of Batches	03		
Date of Submission	Dy.# 6507 dated 20-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Shanghai Food and Drug Administration
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice which is not clear
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcomings	Response by the firm
GMP certificate of the API manufacturer issued by relevant (i.e. provincial or federal) regulatory authority of China, since the submitted GMP has been issued by Shanghai Food and Drug Administration which is a district authority and does not have mandate to issue GMP certificate as per Chapter I General Provisions; Article 5 of Regulations for Implementation of the Drug Administration Law of the People's Republic of China.	Firm has submitted GMP certificate No. SH20170046 issued by China Food and Drug Administration which is valid till 03-12-2022.
Submit clear invoice attested by ADC in which the date of clearance along with signature / stamp is readable, since the submitted invoice is not clear.	Firm has submitted copy of commercial invoice which is cleared by ADC on 17-8-2018 specifying import of 0.47Kg tenofovir
Provide detailed method of testing / analysis of finished product.	Firm has submitted copy of testing method and analysis of finished drug.
Justify the acceptance criteria of dissolution test i.e. NLT 80% in 30 minutes without defining the time and value of "Q" since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. The FDA guidance "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" specifies under the heading **DISSOLUTION ACCEPTANCE CRITERIA** that *for immediate release solid oral drug products containing a high solubility drug substance, the dissolution criterion is Q=80% in 30 minutes*. Furthermore, USFDA chemistry review for the innovator product "Vemlidy Tablet" specifies that the acceptance criteria for dissolution test is NLT (Q+5) in 15 minutes.	Firm has submitted commitment to revise the specification to NLT 80% (Q=75%) in 15 minutes. Firm has further submitted that they have tested the product at 9th month stability time point and the results are satisfactory in 15 minutes. • **The dissolution results as per revised specification (i.e. NLT 80% in 15 minutes) at 9th month time point cannot be applied on 6 months real time and accelerated stability study data as per previous specifications i.e. NLT 80% in 30 minutes.** • **Firm has initiated stability studies on 10-2018 and the letter of shortcoming for difference in specifications was issued on 19-08-2019 (10 months after initiation of stability studies) and the firm has in its reply dated 28-08-2019 submitted that they have tested dissolution at 9th**

	month time point.
Specify the exact storage conditions at which the API was kept after import in August 2018 till the manufacturing of batches in October 2018.	Firm has submitted that the storage condition recommended by its manufacturer is 2-8 degree and the firm has kept the material under the same conditions at MDL warehouse with continuous temperature monitoring.

Decision of 292nd meeting:

Deferred for following:

- Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 80% in 15 minutes] with values close to acceptance criteria can be representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from innovator product [i.e. NLT 80% in 30 minutes].

Response by the firm:

The firm has responded as follows:

Tenofovir alafenamide belongs to **BCS Class III**, having solubility of 4.7mg/mL in water at 20°C, which is considered as a rapidly dissolving API, posing no intrinsic risk to dissolution of the developed product. Due to this characteristic of API (high solubility), it is expected that dissolution profile at accelerated conditions at 15 minutes will also meet its acceptance criteria. Further, it is also depicted by long term stability studies at 9 & 12 months (15 minutes), which was also confirmed by stability studies conducted by innovator as there was no impact on dissolution at different stability conditions. The limit of dissolution test for the said product was derived from FDA *1074043 FNL*, dated *08/09/18*, titled "Dissolution testing and acceptance criteria for Immediate-release solid oral dosage form drug products containing high solubility drug substances", where the dissolution time point is given as 30 minutes. Also, the results of CDP of both formulations (MDL as well as Innovator's) are similar at 15 minutes and 30 minutes time points in all (03) dissolution media.

Root cause:

- Since the analytical data of innovator's formulation is not available publicly in most cases, therefore, Q value of dissolution at 15 minutes was missed in literature survey for this product.

Justification of selection of dissolution time:

- Tenofovir alafenamide belongs to BCS Class III, having solubility of 4.7mg/mL in water at 20°C, which is considered as a rapidly dissolving API, posing no intrinsic risk to dissolution of the developed product.
- The FDA method available for dissolution testing of the said product has the maximum time point of 30 minutes.
- As per USP Chapter <701>, the general criteria for disintegration test (DT) for coated tablets is NMT 30 minutes. Based on this consideration, it was inferred that since the produced tablet (Amlidy) is coated tablet, its DT should be achieved in 30 minutes, so the same time was adopted by MDL for Amlidy tablets as the dissolution time while setting the testing parameters.

Impact Assessment

- The said product is developed qualitatively according to the innovator (Vemlidy) formulation, which is mentioned as follows:

Excipients used by Innovator	**Excipients used by MDL**
Core:	**Core:**
Lactose Monohydrate	Lactose Monohydrate
Microcrystalline Cellulose	Microcrystalline Cellulose
Croscarmellose Sodium	Croscarmellose Sodium
Magnesium Stearate	Magnesium Stearate
Film Coating:	**Film Coating:**
Polyvinyl alcohol	Sheffcoat PVA White 5Y00079 (It contains Polyvinyl alcohol, Titanium Dioxide, Macrogol and Talc)
Titanium dioxide	
Macrogol	
Talc	
Iron Oxide Yellow	Iron Oxide Yellow

- As per the EMEA assessment report of Vemlidy (Procedure No. EMEA/H/C/004169/0000), following were

the evaluations by the innovator during stability studies of the product:

- **Under Long term:** There were no significant changes to any of the measured parameters except for a small increase in degradation products. All parameters including dissolution remained within specification limits.
- **Under intermediate conditions:** More degradation was observed, along with a decrease in assay although levels remained within specification. The other parameters including dissolution remained unchanged.
- **Under accelerated conditions:** Significant degradation was observed after 6 months coupled with a decrease in assay but remained within specification limits, the other parameters including dissolution remained unchanged.

- The results of CDP of both formulations (MDL as well as Innovator's) are similar at 15 minutes and 30 minutes time points in all (03) dissolution media.
- 9th month and 12th month stability analysis of Amlidy tablet has been performed and the results of dissolution are as under, which are more than 80% at 15 minutes. Further, according to ICH Q1A (R2), 30°C / 65% RH is defined as the intermediate conditions for stability studies, for which, 12 months study data should be minimally covered for submission.

Batch #	**Storage Conditions**	**9 months**	**12 months**
		% release at 15 min (Avg. of 6 units)	**% release at 15 min (Avg. of 6 units)**
NPD-T-359-L	30°C / 65% RH	105	101
NPD-T-374-P		105	98
NPD-T-388-P		101	99

- The dissolution results of same batches at following stability time points, performed at 30 minutes are also given below:

Storage Conditions	30°C / 65% RH			40°C / 75% RH		
Batch #	**0 Month**	**3rd Month**	**6th Month**	**0 Month**	**3rd Month**	**6th Month**
	% release at 30 min (Avg. of 6 units)	% release at 30 min (Avg. of 6 units)	% release at 30 min (Avg. of 6 units)	% release at 30 min (Avg. of 6 units)	% release at 30 min (Avg. of 6 units)	% release at 30 min (Avg. of 6 units)
NPD-T-359-L	106	108	106	106	100	106
NPD-T-374-P	98	100	109	98	100	95
NPD-T-388-P	100	105	102	100	99	101

- Based on the above data, it is visible that the variance of dissolution results at different time points during stability studies is minimal and poses no impact on product quality.

Conclusion:

Based on above discussion, it is observed that the variation in dissolution results at 15 minutes & at 30 minutes in Amlidy tablets is insignificant up to 12-months of intermediate stability conditions. Furthermore, the developed product also gave similar results in CDP as that of the innovator. EMEA assessment report of Vemlidy (Procedure No. EMEA/H/C/004169/0000) also indicates that there is no impact on dissolution during stability till expiry of the product. Therefore, it can be inferred that the product will produce the desired results for dissolution as per the set specifications till product shelf life. QC specifications for dissolution of the said product has been revised to NLT 80% in 15 minutes.

Commitment:

The dissolution testing will be continued at 15 minutes' time point on the developed batches till 24 months and the same will also be conducted for the validation batches as well.

Decision of 293rd meeting of Registration Board:

Registration Board decided to defer the case and directed the firm to submit dissolution testing data at 15 minutes at initial and one month time point at both accelerated and real time stability conditions for 2 batches.

Evaluation by PEC:
Firm has submitted stability real time and accelerated study data for following 2 new Batches at 0 and 1 month interval in which dissolution acceptance criteria was "NLT 80% Q in 15 minutes."
1. NPD-931-P (Mfg date: 21-01-2020, initial testing date: 22-01-2020)
2. NPD-932-P (Mfg date: 21-01-2020, initial testing date: 22-01-2020)

The panel was requested to verify the development of two new batches and performance of dissolution test with revised acceptance criteria.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Amlidy (Tenofovir Alafenamide fumarate) 25mg Tablets by M/s Martin Dow Limited, Karachi.

Reference No: F.1-2/2020 dated 22nd April, 2020
Investigation Date and Time: 12th May, 2020
Investigation Site: Factory premises of M/s Martin Dow Ltd. Karachi.

Background:
Registration Board in its 293rd meeting considered the applications of M/s. Martin Dow Limited, Karachi for registration of Amlidy (Tenofovir Alafenamide fumarate) 25mg Tablets and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration. The panel was also advised to verify:
"The development of two new batches and performance of dissolution test with revised acceptance criteria"
Composition of Panel:
1. Dr. Rafeeq Alam, Meritorious Professor and Dean Faculty of Pharmacy Ziauddin University, Karachi.
2. Dr. Hira Bhutto, Assistant Director, CDL, DRAP, Karachi.
3. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:
Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:
The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Details of Investigation:

S.No	Description	Observation by panel
1	Do you have documents confirming the import of API including approval from DRAP?	The firm has imported 470.0g Tenofovir Alafenamide fumarate raw material from M/S Shanghai Desano Pharma, China, and taken proper approval from DRAP, Karachi dated 17-08-2018. Batch No. | Quantity Imported DBH251-B15A-180702 | 470.0 g
2	Do you have any rationale behind selecting the particular manufacturer	There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through: • Postal Audit checklist • GMP approval by competent authority
3	Do you have documents confirming the Import of Reference standard and Impurities standards?	The firm has imported 65.0gm of working standard, 10mg of impurity 1, and impurity 2 each and 13.5mg 251-4 Isomer 6&7 from Shanghai Desano Pharma, China through indenter.
4	Do you have certificate of analysis of the API reference standard and impurities standards?	The firm has Certificate of Analysis for API, working standards and impurities.
5	Do you have any approval of API or GMP certificate of manufacturer	The firm has provided copy of GMP certificate and written confirmation of API Tenofovir Alafenamide fumarate by

<table>
<tr><td></td><td>issued by regulatory authority of country of origin?</td><td>Shanghai Food and Drug Administration.</td></tr>
<tr><td>6</td><td>Do you use API manufacturer method of Testing for testing of API?</td><td>The firm has used API Manufacturer’s method of testing</td></tr>
<tr><td>7</td><td>Do you have stability Studies Report on API?</td><td>The firm has stability studies report of API Tenofovir Alafenamide Fumarate conducted by API manufacturer.</td></tr>
<tr><td>8</td><td>If Yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified.?</td><td>The manufacturer of API has performed the stability studies of API as per SIM Method and impurities have been quantified by the API manufacturer</td></tr>
<tr><td>9</td><td>Do you have method for quantifying the impurities in the API?</td><td>The firm has methods for quantifying the impurities in API.</td></tr>
<tr><td>10</td><td>Do you have some remaining quantities of the API, Its reference standard and impurities standard?</td><td>The firm has remaining 48.0g of Tenofovir Alafenamide Fumarate API but no quantity of initially imported impurity and working standard, however the firm has also imported more working standard and impurity standards.</td></tr>
<tr><td>11</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm has used pharmaceutical grade excipients.
Lactose Monohydrate, Microcrystalline cellulose, Croscarmellose Sodium and Magnesium Stearate.</td></tr>
<tr><td>12</td><td>Do you have documents confirming the import of the used excipients</td><td>The firm has documents confirming the import of the used excipients.</td></tr>
<tr><td>13</td><td>Do you have test reports and other records on the excipients?</td><td>The firm has test reports and other records on the excipients.</td></tr>
<tr><td>14</td><td>Do you have written and authorized protocols for the development of Amlidy 25mg tablets?</td><td>The firm has written and authorized protocol for the development of Amlidy 25mg Tablets.</td></tr>
<tr><td>15</td><td>Have you performed Drug-Excipient compatibility studies?</td><td>Since firm has used same excipients as used by the innovator. Therefore, compatibility studies were not performed.</td></tr>
<tr><td>16</td><td>Have you performed comparative studies?</td><td>Firm has performed comparative studies with Gilead’s licensed product Tafnat 25mg tablets manufactured byMylan Laboratories Limited, India.</td></tr>
<tr><td>17</td><td>Do you have Product Development / R&D Section?</td><td>The firm has dedicated product development (R&D) Section with the facility of manufacturing and a separate analytical laboratory for testing of new products</td></tr>
<tr><td>18</td><td>Do you have necessary equipment’s available in product development section for development of Amlidy 25mg tablets?</td><td>The firm has necessary equipment available in product development section for development and test/analysis of Amlidy Tablets 25mg.</td></tr>
<tr><td>19</td><td>Are the equipment’s in product development qualified?</td><td>The available equipment in Product Development are qualified.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD?</td><td>There is proper maintenance / calibration program for the equipment used in PD.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has 06 Pharmacists and 01 PhD Chemistry for Product Development and 01 Pharmacist and 06 Chemist in Analytical section of New Product Development.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of Amlidy 25mg tablets as required?</td><td>The firm has manufactured three stability batches of each 2500 tablets.
<table>
<tr><td colspan="3">Amlidy 25mg tablets</td></tr>
<tr><td>Batch No</td><td>Date of Mfg.</td><td>Expiry Date</td></tr>
<tr><td>NPD-T-359-L</td><td>Oct-2018</td><td>Oct-2020</td></tr>
<tr><td>NPD-T-374-P</td><td>Oct-2018</td><td>Oct-2020</td></tr>
<tr><td>NPD-T-388-P</td><td>Oct-2018</td><td>Oct-2020</td></tr>
</table></td></tr>
</table>

23	Do you have any criteria for fixing the batch size of stability of batches?	The criteria for fixing the batch size of stability batches is the number of Tablets per testing frequencies.
24	Do you have complete record of production of stability batches?	The firm has complete record for the stability batches of Amlidy 25mg tablets.
25	Do you have protocols for stability testing of stability batches	The firm has protocols for testing of stability batches.
26	Do you have developed and validated the method for testing of stability batches	The firm has developed and validated method of testing of finish product Amlidy 25mg Tablets, based on method of testing of API.
27	Do you have method transfer studies in case when the method of testing being used by your firm is by any other lab.	Method transfer studies is not applicable as the firm developed and validated their own method.
28	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of the product's API and product Amlidy 25mg tablets?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the Amlidy 25mg tablets.
29	Do your method of analysis Stability indicating?	The firm's Method of analysis is Stability indicating.
30	Do your HPLC software 21CFR compliant?	The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA
31	Can you show audit trail reports on Amlidy 25mg Tablets testing?	The firm has complete audit trail Reports on testing.
32	Do you have some remaining quantities of degradation products and stability batches?	The firm has some remaining quantities of stability batches only.
33	Do you have batches kept on stability testing?	The firm has three stability batches kept on stability for Real time stability testing. 12 Months Real Time and 6 months Accelerated stability studies has been completed.
34	Do you have valid calibration status for the equipment's used in Amlidy 25mg tablets production and analysis?	The firm has valid calibration status for the equipment used in Amlidy 25mg tablets production and analysis.
35	Do Proper and Continuous monitoring and control are available for stability chamber?	Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software 21CFR compliance.
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities can be rated as compliant to minimum GMP standards.
37	Any other query raised by Registration Board: Verify the development of two new batches and performance of dissolution test with revised acceptance criteria	The firm has developed following two batches and performed complete stability testing at 0, 1 and 3 months including dissolution tests with revised specifications: NPD-T-931-P Mfg Date: Jan-2020 NPD-T-932-P Mfg Date: Jan-2020

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Amlidy 25mg Tablets (Tenofovir alafenamide) is verifiable to highly satisfactory level.

2. The related manufacturing area, equipments, personnel and utilities are GMP compliant and are well suited for the manufacturing of Amlidy 25mg Tablets.

Decision: Registration Board decided to approve registration of Amlidy (Tenofovir alafenamide) 25mg Tablets with Innovator's specifications by M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3434.	Brookes Pharma (Pvt) Ltd., 58 & 59, Sector 15, Korangi Industrial Area, Karachi.	Brofex IV Infusion Each 100ml contains: Ibuprofen…….400mg (Antipyretic, analgesic)	Form 5D 13-04-2017 PKR 50,000/- (Duplicate) (13-04-2017)	Ibuprofen 400 mg Solution for Infusion (**MHRA** Approved) Last GMP inspection was conducted on 30-01-2017 and the report concludes good level of GMP compliance.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Brofex IV Infusion		
Name of Manufacturer	Brookes Pharma (Pvt) Ltd., 58 & 59, Sector 15, Korangi Industrial Area, Karachi.		
Manufacturer of API	Hubei Biocause Phamaceutical Co., Ltd. 122-132 Yangwan Road,Jingmen, Hubei, China		
API Lot No.	C100-1509229M		
Description of Pack (Container closure system)	100ml clear glass USP type-II vial, sealed with rubber stopper and flip off seal, further packed in bleach board carton.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 1, 2, 3, 6 (Months)		
Batch No.	PD-PS-006G8	PD-PS-009G8	PD-PS-002H8
Batch Size	10L	10L	10L
Manufacturing Date	07-2018	07-2018	10-2018
Date of Initiation	21-07-2018	26-07-2018	17-10-2018
No. of Batches	03		
Date of Submission	Dy.# 7295 dated 27-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority	Firm has submitted copy of GMP certificate (No. HB20170363) issued by China Food and Drug Administration valid till 28-08-2022

	of country of origin.	
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of ADC attested invoice and Form-6 dated 26-7-2017 specifying import of 300g Ibuprofen
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The panel may be requested to verify the following:

- Justification of the pH of finished product 7.2 to 8.5 while the pH of MHRA approved reference product is 6.5 to 7.8.
- Sterilization process of the ibuprofen injection since the submitted Certificate of Analysis (COA) specifies that the API is non-sterile. Furthermore, to confirm where the sterilization and filling was carried out.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Brofex (Ibuprofen 400mg) IV Infusion by M/s. Brooks Pharma, (Pvt) Ltd., Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (pt) dated 14th November, 2019.

Investigation Date and Time: 13th February, 2020 (Morning).

Investigation Site: Factory premises of M/S. Brooks Pharma, (Pvt.) Ltd., Korangi Industrial Area, Karachi.

Background:

Registration Board meeting considered the applications of M/s. Brooks Pharma, (Pvt.) Ltd., Korangi Industrial Area, Karachi for registration of Brofex (Ibuprofen 400mg) IV Infusion. Registration Board considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm as per decision of Registration Board and to submit report for further consideration.

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi, Member Registration Board, Islamabad.
2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
3. Dr. Asfandyar Ajab Khan, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Detail of Investigation:

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the	The firm has Approval from DRAP for the import of

	import of API, Ibuprofen including approval from DRAP?	300g, China, Ibuprofen Raw material from M/S HUBEI BRANULES-BIOCAUSE PHARMACEUTICAL, China having invoice number W170613-130.
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the manufacture of API was firm's established criteria including: 1. GMP Certificate 2. Availability of Stability data 3. DMF Availability, free availability etc.
3.	Do you have documents confirming the import of Ibuprofen reference standard and impurity standards?	Firm has imported Ibuprofen Reference Standard and Impurity standard from USP.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Firm has certificates of Analysis of API from API manufacturer M/S HUBEI BRANULES-BIOCAUSE PHARMACEUTICAL, and Reference standard of API and Impurity standard from USP.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has valid GMP certificate " HB20170363' of API manufacturer M/S HUBEI BRANULES-BIOCAUSE PHARMACEUTICAL issued by China Food and Drug Administration is available
6.	Do you use API manufacturer method of testing for testing API?	The firm has used USP method for API testing.
7.	Do you have stability studies reports on API?	The firm has satisfactory stability studies record of API, performed by manufacturer on following condition. Long term stability at 30±2ºC and 65%±5% RH for 72 months & Accelerated stability study, at 40±2ºC and 75%±5% RH for 6 months.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability studies have been performed as per SIM method and degradation products have been quantified by API manufacturer.
9.	Do you have method for quantifying the impurities in the API?	USP Method has been used for the testing of API for impurities.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of API, reference standard of API and impurities.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including NaCl, HCl and Tris (hydroxy methyl aminomethane) from Merck (Pvt.) Ltd. & L-Arginine from Shanghai Kyowa Aminio acid Co Limited.
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the Local purchase of Excipient from Merck (Pvt.) Ltd. & Import documents from Shanghai Kyowa Aminio acid Co Limited for L-Arginine.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other record on excipients used.
14.	Do you have written and authorized protocols for the development of product Ibuprofen Infusion 100ml?	The firm has written and authorized protocols (Manufacturing direction) for the development of Ibuprofen Infusion 100ml.
15.	Have you performed Drug-excipient compatibility studies?	As the composition is qualitatively similar to that of the Patent "caldolor" Injection therefore the firm has not performed Drug-Excipients compatibility studies.
16.	Have you performed comparative studies?	Not done
17.	Do you have product development (R&D) section?	The firm has product development (PD) section, however, the product in question has been developed in

<table>
<tr><td></td><td></td><td>commercial manufacturing area.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in the product development section for development of Ibuprofen Infusion?</td><td>All the stability batches for the stability studies have been manufactured in sterile production area.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The equipment in production development department are qualified, however Ibuprofen infusion 100ml batches have been manufactured in production sterile area, where all equipment are qualified</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>All the batches for stability studies manufactured in sterile area, where equipment are properly maintained /calibrated and qualified.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified and trained staff in product development section with proper knowledge and training in product development. For the said product technical assistance has been obtained from staff of commercial product manufacturing area.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of the product Ibuprofen Infusion as required?</td><td>The firm has manufactured three stability batches for the stability studies of the product Ibuprofen Infusion with details as below:
<table>
<tr><th>Sr. No.</th><th>Batch No.</th><th>Mfg. date</th></tr>
<tr><td>1.</td><td>PD/PS-006G8</td><td>18-07-2018</td></tr>
<tr><td>2.</td><td>PD/PS-009G8</td><td>24-07-2018</td></tr>
<tr><td>3.</td><td>PD/PS-002H8</td><td>11-10-2018</td></tr>
</table>
having batch size 10 liter each. The product is packed in 100ml glass vials.</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing batch size of the stability batches is as per DRAP and ICH guidelines.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record of production of stability batches. All the batch documents are properly maintained.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocols for stability testing of stability batches.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has used USP method for testing the product. Complete record of the method validation is also available with the firm.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>Not Applicable at this stage.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Ibuprofen and Brofex Infusion?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Ibuprofen API and finished product.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>Method of analysis is stability indicating as supported by forced degradation & spiking studies.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21 CFR Compliant?</td><td>Firm has 21CFR part 11compliant HPLC system as evidenced by the record presented by the firm.</td></tr>
<tr><td>31.</td><td>Can you show Audit trial reports on Ibuprofen Infusion testing?</td><td>Related audit trail was checked and found ok.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm has some remaining quantities of stability batches.</td></tr>
</table>

33.	Do you have stability batches kept on stability testing?	The firm has stability batches kept on real time (30±2°C, 65±5% RH) stability condition, 12 month stability testing is completed with satisfactory results.
34.	Do you have valid calibration status for the equipment used in Ibuprofen Infusion production and analysis?	The firm has valid calibration status for the equipment used in Ibuprofen Infusion production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has monitoring and control available for stability chambers.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities be rated GMP compliant.
37	Any observation by the PEC 1. Justification of pH of finished product 7.2 to 8.5 while the pH of MHRA approved reference product is 6.5 to 7.8	Justification: Ibuprofen intravenous infusion solution is internationally available in polyolefin bags or glass vials with different pH ranges. The design specifications (Composition, container / Closure system and Controls) of M/s. Brookes Pharmaceuticals, Karachi are based on the Ibuprofen Intravenous Infusion of M/s. Pharmaceutical Solution Industry Ltd., Jeddah (SA) having US patent No. 9,351,926B2, dated May 31, 2016 and European patent No. EP 2636 406 A1 dated 11-09-2013 wherein the pH ranges from 7.2 to 8.5 and the containers in both cases are glass vials. Furthermore, two ibuprofen infusion formulations with UK marketing authorization No. PL 033551/0152 (B. Braun, Germany) and PL 08553/0619 (Dr. Reddy's Laboratories, UK) have pH 6.8 – 7.8 and 7.8 – 8.4 respectively, whereas the container in both the cases is polyolefin bags. In order to get strong scientific evidence in the issue, M/s. Brooks, was directed to conduct pH rate profile within pH range of 6.0 – 8.5. The firm submitted the pH rate profile (copy attached) within the above pH range with the following observations and conclusions. Observations: a. There is no significant impact on Assay observed throughout the pH range i.e. 6.0 to 8.5 when sample kept for 12 days o 80 ^{o}C. Following is the study outcome. b. The Samples shows very stable behavior with respect to Assay between pH range 7.5 to 8.5 with only 1.5% degradation after 12 days at 80 ^{o}C. c. Where as there is comparatively high rate of degradation between pH 6.0 to 7.0 with about 3.18% to 3.66% degradation after 12 days at 80 ^{o}C, although well within the specification
	2. Sterilization process of the ibuprofen injection since the submitted certificate of analysis (COA) specifies that the API is non-sterile. Furthermore, to confirm where the sterilization and filling was carried out.	Conclusion: On the basis of above data it is evident that ibuprofen shows very stable trend in "Infusion" between pH 7.5 to 8.5 and there is no significant change, where as slightly higher comparative degradation trend between pH 6.0 to 6.5. Therefore it is concluded that ibuprofen is very stable compound throughout pH range of 6.0 to 8.5, but more stable between pH range 7.2 to 8.5. (Brookes pH Range) *Keeping in view the above the pH range of 7.2 – 8.5 as*

		mentioned by M/S. Brooks Pharma, Karachi can be considered justified scientifically in our opinion. Justification: The product solution is first sterilized through filtration and then terminally sterilized after being filled in the glass vials. The whole process of manufacturing and sterilization for all the three stability batches has been performed in commercial manufacturing and sterilization areas of liquid injectable section.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Brofex (Ibuprofen 400mg) IV Infusion is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Brofex (Ibuprofen 400mg) IV Infusion.

Recommendations:

The firm may kindly be granted necessary registration of Brofex (Ibuprofen 400mg) IV Infusion.

Note: Copy of pH rate studies conducted by the firm are attached.

Brookes
Quality Control Department
Brookes Pharma Private Limited.

pH profiling effect on Assay of Brofex Infusion 400mg/100ml

Objective : To determine the effect of pH on Assay of Ibuprofen Infusion with respect to pH range established for Brofex Infusion.

Background of the study: This study was designed with relation to the "pH profiling study" to determine the effect of proposed pH range on Assay.
Study was performed on entire pH range i.e. from pH 6.0 to pH 8.5, sample was kept on 80°C for 12days and Assay testing was performed on three different time points i.e. initial, after 6 days & after 12 days.
Assay Results & graphical presentation are as follow;

S.No.	Batch	Time Days	Assay Limit		pH Points					
			Lower Limit	Upper Limit	pH 8.5	pH 8	pH 7.5	pH 7	pH 6.5	pH 6
1	PD-PT-003C0	0	90	110	101.16	98.21	99.65	98.99	100.83	101.83
2		6	90	110	101.35	97.24	98.08	98.14	99.23	100.64
3		12	90	110	99.63	96.55	98.15	95.34	97.22	98.59
Percent Degradation from Initial					-1.61%	-1.69%	-1.61%	-3.66%	-3.88%	-3.18%

(Graphic Presentation is given on Page # 02)

Observation
1 There is no significant impact on Assay observed throughout the pH range i.e. 6.0 to 8.5 when sample kept for 12 days on 80°C. Following is the study outcome.

a. The Samples show very stable behavior with respect to Assay between pH range 7.5 to 8.5 with only 1.5 % degradation after 12 days at 80°C

b. Where as there is comparatively high rate of degradation between pH 6.0 to 7.0 with about 3.18% to 3.66% degradation after 12 days at 80°C, although well within the specification

Conclusion: On the basis of above data it is evident that Ibuprofen shows very stable trend in "Infusion" between pH 7.5 to 8.5 and there is no significant change, where as slightly higher comparative degradation trend between pH 6.0 to 6.5.
Therefore it is concluded that Ibuprofen is very stable compound throughout pH range of 6.0 To 8.5, but more stable between pH range 7.2 to 8.5. (Brookes pH Range)

Performed By Recommended By Approved By

Decision: Registration Board decided to approve registration of Brofex (Ibuprofen 400mg) IV Infusion with Innovator's specifications by M/s Brookes Pharma (Pvt) Ltd., 58 & 59, Sector 15, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3435.	M/s Genome Pharmaceuticals (Pvt) Ltd. 16/1, Phase IV, Industrial Estate Hattar.	IPF-267mg Capsule Each capsule contains: Pirfenidone…….267mg	Form 5-D 09-03-2015 50,000/- 09-03-2015 (**DUPLICATE)**	Esbriet Capsule **(USFDA** Approved) Inspection report dated 29.03.2019, panel concluded that the firm is operating at satisfactory level of GMP compliance

	(Stability Dy. # 21783 dated 24-11-2019)		
STABILITY STUDY DATA			
Drug	IPF-267mg Capsule		
Name of Manufacturer	M/s Genome Pharmaceuticals (Pvt) Ltd. 16/1, Phase IV, Industrial Estate Hattar.		
Manufacturer of API	ZCL chemicals Limited, Plot No. 3102/B, GIDC Ankleshwar€, Gujrat, India.		
API Lot No.	FEN3300118		
Description of Pack (Container closure system)	Alu-Alu blister (3x10's)		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IPF267-T001	IPF267-T002	IPF267-T003
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	16-03-2019	19-03-2019	19-03-2019
No. of Batches	03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Documents To Be Provided	**Status**		
COA of API	Yes		
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin	Firm has submitted copy of GMP certificate (No. 1808977) issued by Food and Drugs Control Administration Gujrat State India and valid till 12-08-2021		
Protocols followed for conduction of stability study and details of tests.	Yes		
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes		
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice (No. 2218177) dated 31-12-2018 specifying import of 4Kg Pirfenidone, which is signed by AD, DRAP Peshawar.		
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes		
Commitment to continue real time stability study till assigned shelf life of the product.	Yes		
Commitment to follow Drug Specification Rules, 1978	Yes		
REMARKS OF EVALUATOR			
The dissolution acceptance criteria of the firm is NLT (Q=80%) in 30 minutes, as per the innovator product. The panel may be requested to verify the following:			

- Validation of analytical method of assay and dissolution, since firm has used HPLC method for assay and UV method for dissolution testing.
- Confirmation that the firm has performed dissolution testing using USP apparatus-II (paddle) along with sinkers.

INSPECTION REPORT VERIFICATION OF AUTHENTICITY OF STABILITY DATA
M/s Genome Pharmaceuticals Pvt Ltd plot#16/I- Phase IV Hattar

Product: IPF Capsule 267 mg
Active ingredient: Pirfenidone..... 267mg
Date of inspection: 27-02-2020 in compliance to letter No.F.-2/2020-PEC dated 18-02-2020

Inspection panel:
- Director DTL Peshawar
- Atiq ul Bari AD/ FID-I & II DRAP Peshawar
- Adnan shahidullah Assistant Director DRAP Peshawar

Q. No.	QUESTION	OBSERVATION BY PANEL
1.	Whether the firm has documents confirming import of API?	ADC attested invoice, Form 6 available.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation form being implemented by the firm and the rationale behind selecting the manufacturer is its GMP status.
3.	Whether documents confirm the import of Pirfenidone Reference Standard and impurity standards?	The firm purchased 100mg working standard of Pirfenidone from API manufacturer and details are mentioned on Invoice of API. Reference Standard of Pirfenidone from British pharmacopeia also purchased. The import documents from EDQM were available. Impurities standards are not available.
4.	Whether the firm has certificate of Analysis of the API, reference standards and impurity standards from exporter?	Firm has certificates of analysis of API (Pirfenidone) and working standards of manufacturer. Reference standard of Pirfenidone from British pharmacopeia was also available. Characterization data of impurities were provided by manufacturer.
5.	Whether the firm has any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has GMP Certificate of API manufacturer issued by regulatory authority of country of origin (India) bearing date 13/08/2018 valid until 12/08/2021.
6.	Whether firm use API manufacturer method of testing?	Firm has Used BP method for testing of API. Furthermore the manufacturer method and validation data also provided by API manufacturer.
7.	Whether firm has stability studies reports on API?	Firm has accelerated and real time stability studies reports on API (Pirfenidone) performed by manufacturer of API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	yes
9.	Whether firm has method for quantifying the impurities in the API?	Firm has BP method for quantifying impurities in API (Pirfenidone).
10.	Whether firm have some remaining quantities of the API, its reference standard and impurities standards?	Firm has consumed the Pirfenidone in manufacturing of Trial batches IPF267-T001, IPF267-T002 and IPF267-T003. The remaining portion of API reference standards is available.
11.	Whether firm has used pharmaceutical grade excipients?	Excipients used are: Povidone K30 (KoVidone k30) (Boai NKY Pharmaceuticals,

		China), Magnesium Stearate BP/ USP (FACI Asia pacific Pte Ltd). Croscarmellose sodium (Maple Bio-tech) Microcrystalline cellulose BP/USP (JRS Pharma Germany), EHGC Shells Size "0" purple cap and white body (Pharmacap) All the excipients are pharmaceutical grade as per documents provided
12.	Whether firm has documents confirming the import of the used excipients?	Excipients Magnesium stearate BP/ USP (FACI Asia pacific Pte Ltd), Povidone K30 (KoVidone k30)((Boai NKY Pharmaceuticals, China), Croscarmellose sodium (Maple Bio-tech) Microcrystalline cellulose BP/USP (JRS Pharma Germany), are directly imported from manufacturer. While EHGC Shells are purchased from local vendor.
13.	Whether firm have test reports and other records on the excipients used?	Firm provided Lab test reports and certificate of analysis for all excipients.
14.	Whether firm has written and authorized protocols for the development of Pirfenidone tablets?	Firm has written protocol for the development of Pirfenidone Capsules 267 mg. the firm also developed detailed Standard manufacturing procedure and batch processing sheet for manufacturing of trial batches.
15.	Whether firm has performed Drug-excipient compatibility studies?	The firm have not performed drug-excipient compatibility studies.
16.	Whether firm has performed comparative dissolution studies?	Firm has performed In vitro comparative dissolution studies with innovator product (Esbriet 267 mg hard capsules) Roche Pharma AG Germany, in three different medium using FDA methods Apparatus II, with Sinker at 50RPM. The dissolution profile is comparable and similarity factor and difference factor are calculated according to FDA guidelines. Furthermore the dissolution testing in stability studies were performed using FDA method i.e. 1000 ml deionized water, USP Apparatus II, with Sinker at 50RPM.
17.	Whether firm has product development (R&D) section	The firm has product development (R&D) with requisite manufacturing and testing facility.
18.	Whether firm has necessary equipment available in product development section for development of Pirfenidone tablets?	The firm has all necessary equipment for manufacturing and testing of IPF-267 mg Capsules in product development section.
19.	Are the equipment in product development section qualified?	All the equipment in R&D section were calibrated and qualified.
20.	Whether firm have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Proper external calibration and maintenance implemented and all the equipment are calibrated.
21.	Whether firm has qualified staff in product development section with proper knowledge and training in product development?	Firm has qualified staff with proper knowledge with product development in product development section.
22.	Whether firm has manufactured three stability batches for the stability studies of Pirfenidone Capsules as required?	Firm has manufactured three stability batches for the stability studies of IPF-267 mg with batch No IPF267-T001, IPF267-T002 and IPF267-T003. Having batch size of 1200Capsules each.
23.	What were the criteria for fixing the batch size of stability batches?	Criteria for fixing batch size of stability batches is number of Capsules required per testing and number of testing frequencies according to 276th DRB meeting.
24.	Whether firm has complete record of	Firm has complete record of production of stability batches.

	production of stability batches?	
25.	Whether firm have protocols for stability testing of stability batches?	Firm has developed protocols for stability testing of stability batches. Procedure of stability studies, Log registers with complete schedule and monthly schedule of testing available. Testing was done on monthly basis i.e. Real time stability studies: 0, 3rd, 6th, 9th, 12th, 18th and 24th months Accelerated stability studies: 0, 1st, 2nd, 3rd, 4th & 6th months as per 276 DRB meeting.
26.	Whether firm has developed and validated the method for testing of stability batches?	Firm has used in-house HPLC method for Assay determination and dissolution testing are performed on UV method. Both methods were validated and record was available.
27.	Whether firm has method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Firm has developed and validated analytical method for testing of finished product. Method transfer studies not performed
28.	Whether firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of Pirfenidone API and the finished drug?	Firm has documents confirming the qualification of equipment / instruments of quality control being used in the test and analysis of Pirfenidone API and the finished product IPF 267 mg Capsules
29.	Whether firm has stability indicating method of analysis?	Firm has used Manufacturer method for testing of API and finished product. The method is stability indicating and impurities in API are quantified.
30.	Whether firm has HPLC software 21CFR compliant?	The HPLC (KNAUER Azura UVD2.1L Germany) software ClarityChrome V 2.1 is 21CFR Compliant.
31.	Whether firm could you show Audit Trail reports on Pirfenidone testing?	Complete Audit trail on the testing reports were provided by the firm and demonstrated accordingly.
32.	Whether firm have some remaining quantities of degradation products and stability batches?	Firm has remaining quantities of stability batches however there is no quantity of degradation products.
33.	Whether firm has commitment batches kept on stability testing?	Firm has three commitment batches kept on stability testing in stability chamber with accelerated and real time stability conditions.
34.	Whether firm has valid calibration status for the equipment used in Pirfenidone Capsules production and analysis?	Firm has proper calibration schedule and valid calibration status for the equipment used in IPF-267 mg Capsules
35.	Do proper and continuous monitoring and control are available for stability chamber?	Firm possess two stability chambers for accelerated and real time stability testing. Both chambers were found qualified. The chambers have been provided with continuous power supply and digital data loggers with record of test period.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Yes, firm is GMP compliant as per date of inspection.

- Firm has used In-house HPLC method for Assay determination and dissolution testing are performed on UV method. Both methods are validated and record was available.

- The dissolution testing in stability studies were performed using FDA method i.e. 1000 ml de-ionized water, USP Apparatus-II, with sinker at 50RPM. (sinkers available in QC)

Conclusions:

On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of IPF-267 mg Capsules (Pirfenidone-267 mg) is verifiable to satisfactory level.

Decision: Registration Board decided to approve registration of IPF-267 mg Capsules (Pirfenidone-267 mg) with Innovator's specifications by M/s Genome Pharmaceuticals (Pvt) Ltd. 16/1, Phase IV, Industrial Estate Hattar. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3436.	M/s Genome Pharmaceuticals (Pvt) Ltd. 16/1, Phase IV, Industrial Estate Hattar.	CHB-25mg Tablets Each film coated tablet contains: Tenofovir alafenamide (as fumarate)…….25mg	Form 5-D Dy No. 2331 06-04-2017 50,000/-	Vemlidy Tablets **(USFDA** Approved) Inspection report dated 29.03.2019, panel concluded that the firm is operating at satisfactory level of GMP compliance
	(Stability Dy. # 21783 dated 24-10-2019)			

STABILITY STUDY DATA			
Drug	CHB-25mg Tablets		
Name of Manufacturer	M/s Genome Pharmaceuticals (Pvt) Ltd. 16/1, Phase IV, Industrial Estate Hattar.		
Manufacturer of API	Zhejiang Warrant Pharmaceutical Co. Ltd., China		
API Lot No.	20180620		
Description of Pack (Container closure system)	Alu-Alu blister (3x10's / packed in cardboard unit carton)		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CHB-T001	CHB-T002	CHB-T003
Batch Size	2072 Tablet	2072 Tablet	2072 Tablet
Manufacturing Date	17-12-2018	17-12-2018	17-12-2018
Date of Initiation	27-12-2018	27-12-2018	28-12-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin	Firm has submitted copy of GMP certificate (No. ZJ20160046) issued by CFDA China and valid till 28-02-2021

Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice (No. MT1809013C) dated 17-09-2018 specifying import of 0.2Kg Tenofovir alafenamide hemifumarate. **The invoice is not attested by ADC, DRAP.**
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978	Yes

REMARKS OF EVALUATOR

The dissolution acceptance criteria of the firm is NLT (Q=80%) in 15 minutes, as per the innovator product.
The panel may be requested to verify the following:

- Evidence of import of API from Zhejiang Warrant Pharmaceutical Co. Ltd., China since the firm has not provided copy of commercial invoice attested by DRAP field office.
- Validation of method of assay and dissolution, since firm has used HPLC method for assay while UV method for dissolution testing.

INSPECTION REPORT ON VERIFICATION OF AUTHENTICITY OF STABILITY DATA
M/s Genome Pharmaceuticals Pvt Ltd plot#16/I- Phase IV
Hattar
Product name: CHB-25 mg tablets
Active ingredient: Tenofovir Alafenamide… 25mg
Inspection date: 27-02-2020 in compliance to letter No.F.-2/2020-PEC dated 18-02-2020.

Inspection panel:

- Director DTL Peshawar
- Atiq ul Bari AD/ FID-I & II DRAP Peshawar
- Adnan shahidullah Assistant Director DRAP Peshawar

Q. No.	QUESTION	OBSERVATION BY PANEL
1.	Whether the firm has documents confirming import of API?	Firm has used Tenofovir Alafenamide 0.2 Kg imported from M/s ZHEJIANG Warrant Pharmaceutical Co., Ltd China, Vide invoice No.MT 1809013C and has clearance from DRAP office, Peshawar date 05/10/2018. from M/s ZHEJIANG Warrant Pharmaceutical Co., Ltd
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation form being implemented by the firm and the rationale behind selecting the manufacturer is its GMP status.
3.	Whether documents confirm the import of Tenofovir Alafenamide reference standard and impurity standards?	The Firm Purchased reference standard of Tenofovir Alafenamide and impurities standard TAF-Impurity A, TAF-Impurity B, TAF-Impurity C, TAF-Impurity D, TAF-Impurity E, from API manufacturer with Lot of material. The details are mentioned on invoice of material.
4.	Whether the firm has certificate of Analysis of the API, reference standards and impurity standards from	Firm has certificates of analysis for the API (Tenofovir Alafenamide), reference standards and impurities standards i.e. (TAF-Impurity A, TAF-Impurity B, TAF-Impurity C, TAF-

	exporter?	Impurity D, TAF-Impurity E)
5.	Whether the firm has any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has GMP Certificate of API manufacturer issued by Regulatory authority of country of origin (China) bearing date 29/02/2016 valid until 28/02/2021.
6.	Whether firm use API manufacturer method of testing?	Firm has used manufacturer method for testing of API. Furthermore the validation data has also been provided by manufacturer.
7.	Whether firm has stability studies reports on API?	Firm has accelerated and real time stability studies reports on API (Tenofovir Alafenamide) performed by manufacturer of API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed by manufacturer method, and manufacturer method is stability indicating (SIM). Degradation products have been quantified.
9.	Whether firm has method for quantifying the impurities in the API?	Firm has manufacturer validated method for quantifying impurities in API (Tenofovir Alafenamide).
10.	Whether firm have some remaining quantities of the API, its reference standard and impurities standards?	Firm has consumed the Tenofovir Alafenamide in manufacturing of Trial batches CHB-T001, CHB-T002 and CHB-T003. The remaining portion of reference standards and impurity standards are available.
11.	Whether firm has used pharmaceutical grade excipients?	Excipients used are: Core: Magnesium STEARATE BP/ USP (FACI Asia pacific Pte Ltd), Crospovidone USP (Boay Nky Pharma china), Avicel-200BP/USP (JRS Pharma Germany), Lactose MH USP/BP (Malkara Birliksutvesut Mamulleri AS) Coating Polyvinyl alcohol, (Shandoong Xinhua China), Titanium dioxide BP/USP (Kronos Titan),Polyethylene glycol 6000 BP/USP (PAN Asia Chemical Taiwan), Talcum BP,Iron Oxide Yellow HZ, and IPA BP LCY Taiwan. All the excipients are pharmaceutical grade as per record shown.
12.	Whether firm has documents confirming the import of the used excipients?	Excipients Magnesium Stearate BP/ USP (FACI Asia pacific Pte Ltd), Crospovidone USP (Boay Nky Pharma china), Avicel-200BP/USP (JRS Pharma Germany), Lactose MH USP/BP (Malkara Birliksutvesut Mamulleri AS), Croscarmellose sodium USP Maple Biotechare directly imported from manufacturer as per record. While Polyvinyl alcohol, (Shandoong Xinhua China), Titanium dioxide BP/USP (Kronos Titan),Polyethylene glycol 6000 BP/USP (PAN Asia Chemical Taiwan), Talcum BP, Iron Oxide Yellow HZ, and IPA BP LCY Taiwan are purchased from local vendor.
13.	Whether firm have test reports and other records on the excipients used?	Firm provided Lab test reports and certificate of analysis for all excipients.
14.	Whether firm has written and authorized protocols for the development of Tenofovir Alafenamide tablets?	Firm has written protocol for the development of CHB-25 mg. the firm also developed detailed Standard manufacturing procedure and batch processing sheet for manufacturing of trial batches.
15.	Whether firm has performed Drug-	All excipients are according to Innovator product (Tafnat 25 mg)

	excipients compatibility studies?	Mylan Laboratories Ltd.(as per online data available) The firm have not performed drug-excipients compatibility studies.
16.	Whether firm has performed comparative dissolution studies?	Firm has performed In vitro comparative dissolution studies with innovator product (Tafnat tablets) Mylan Laboratories Ltd. in three different medium. The dissolution profile is comparable and similarity factor and difference factor are calculated according to FDA guidelines.
17.	Whether firm has product development (R&D) section	The firm has product development (R&D) with requisite manufacturing and testing facility.
18.	Whether firm has necessary equipment available in product development section for development of Tenofovir Alafenamide tablets?	The firm has all necessary equipment for manufacturing and testing of CHB-25 mg tablets in product development section.
19.	Are the equipment in product development section qualified?	All the equipment in R&D section were calibrated and qualified.
20.	Whether firm have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Proper external calibration and maintenance implemented and all the equipment were calibrated.
21.	Whether firm has qualified staff in product development section with proper knowledge and training in product development?	Firm has qualified staff with proper knowledge with product development in product development section.
22.	Whether firm has manufactured three stability batches for the stability studies of Tenofovir Alafenamide Tablets as required?	Firm has manufactured three stability batches for the stability studies of CHB-25with batch No. CHB-T001, CHB-T002 and CHB-T003 with batch size of 2072 tablets each.
23.	What were the criteria for fixing the batch size of stability batches?	Criteria for fixing batch size of stability batches is number of tablets per testing and number of testing frequencies according to 276th DRB meeting.
24.	Whether firm has complete record of production of stability batches?	Firm has complete record of production of stability batches.
25.	Whether firm have protocols for stability testing of stability batches?	Firm has developed protocols for stability testing of stability batches. Procedure of stability studies, Log registers with complete schedule and monthly schedule of testing available. Testing was done on monthly basisi.e. Real time stability studies: 0, 3rd, 6th, 9th, 12th, 18th and 24th months Accelerated stability studies: 0, 1st, 2nd, 3rd, 4th & 6th months as per 276 DRB meeting.
26.	Whether firm has developed and validated the method for testing of stability batches?	Firm has used HPLC method for Assay and dissolution testing are performed on UV method. Both methods are validated and record was available.
27.	Whether firm has method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer studies not performed. Firm has developed their own analytical method for assay and dissolution testing. Both methods are validated accordingly.
28.	Whether firm has documents confirming the qualification of equipment / instruments being used in the test and analysis of Tenofovir Alafenamide API and the finished drug?	Firm has documents confirming the qualification of equipment / instruments of quality control being used in the test and analysis of Tenofovir Alafenamide API and the finished productCHB-25 mg tablets.

29.	Whether firm has stability indicating method of analysis?	Firm has used Manufacturer method for testing of API and finished product. The method is stability indicating and impurities in API are quantified.
30.	Whether firm has HPLC software 21CFR compliant?	The HPLC (CECIL-Adept-CE-4200) software PowerStream version 4.2 (Build 20255) is 21CFR Compliant.
31.	Whether firm could you show Audit Trail reports on Tenofovir Alafenamide testing?	Complete Audit trail on the testing reports were provided by the firm and demonstrated accordingly.
32.	Whether firm have some remaining quantities of degradation products and stability batches?	Firm has remaining quantities of stability batches however there is no quantity of degradation products.
33.	Whether firm has commitment batches kept on stability testing?	Firm has three commitment batches kept on stability testing in stability chamber with accelerated and real time stability conditions.
34.	Whether firm has valid calibration status for the equipment used in Tenofovir Alafenamide tablets production and analysis?	Firm has proper calibration schedule and valid calibration status for the equipment used in CHB-25 mg tablets.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Firm possess two stability chambers for accelerated and real time stability testing. Both chambers were found qualified. The chambers have been provided with continuous power supply and digital data loggers with record of test period.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Firm has valid GMP status, manufacturing area provided with necessary qualified equipment and utilities. HVAC system and its control were adequate.

- The Firm has imported 0.2Kg Tenofovir Alafenamide from M/s ZHEJIANG Warrant Pharmaceutical Co., Ltd China, Vide invoice No.MT 1809013C and has clearance from DRAP office, Peshawar date 05/10/2018. Other Import Documents i.e. form-6, Form-7, from -3 from M/s ZHEJIANG Warrant Pharmaceutical Co., Ltd and Airwaybill were also seen during inspection.
- Firm has used HPLC method for Assay and dissolution testing are performed on UV method. Both methods are validated and record is available.

Conclusions:

On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of CHB-25mgTablets (Tenofovir Alafenamide 25 mg) is verifiable to satisfactory level.

Decision: Registration Board decided to approve registration of CHB-25mgTablets (Tenofovir Alafenamide 25 mg) with Innovator's specifications by M/s Genome Pharmaceuticals (Pvt) Ltd. 16/1, Phase IV, Industrial Estate Hattar. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

b. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3437.	Ameer & Adnan Pharmaceuticals (Pvt) Ltd. Plot No. 47, Sundar Industrial Estate, Raiwind Road Lahore.	Omdexo 30mg Capsule Each capsule contains: Dexlansoprazole (as dual delayed release pellets)….30mg PPI	Form 5 Dy No. 8689 27-02-2019 PKR 20,000/- (26-02-2019)	Dexilant Capsule (**USFDA** Approved) Last GMP inspection was conducted on 29-11-2018 and the report concludes satisfactory level of GMP compliance.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Omdexo 30mg Capsule		
Name of Manufacturer	Ameer & Adnan Pharmaceuticals (Pvt) Ltd. Plot No. 47, Sundar Industrial Estate, Raiwind Road Lahore.		
Manufacturer of API	Vision Pharmaceuticals, Islamabad		
API Lot No.	DLP420		
Description of Pack (Container closure system)	Alu-Alu foil blister sealed with aluminium foil. The blister are introduced into unit carton.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CZ-001	CZ-002	CZ-003
Batch Size	1900 capsule	1900 capsule	1900 capsule
Manufacturing Date	20-02-2019	20-02-2019	20-02-2019
Date of Initiation	22-02-2019	23-02-2019	25-02-2019
No. of Batches	03		
Date of Submission	Dy.# 16453 dated 02-09-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by	Yes

	attested respective documents like chromatograms, laboratory reports, data sheets etc.	
5.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 11-02-2019 specifying purchase of 2 Kg of pellets.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Panel may be requested to verify the following

- Testing of pellets at pH 1.2, 5.5 and 6.75/7 to confirm dual delayed release profile as per the decision of 276th meeting of Registration Board.
- Dissolution testing at buffer stage at pH 7.0 with 5mM SLS as per the FDA dissolution database.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3438.	Ameer & Adnan Pharmaceuticals (Pvt) Ltd. Plot No. 47, Sundar Industrial Estate, Raiwind Road Lahore.	Omdexo 60mg Capsule Each capsule contains: Dexlansoprazole (as dual delayed release pellets)….60mg PPI	Form 5 Dy No. 8688 27-02-2019 PKR 20,000/- (26-02-2019)	Dexilant Capsule (**USFDA** Approved) Last GMP inspection was conducted on 29-11-2018 and the report concludes satisfactory level of GMP compliance.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Omdexo 60mg Capsule		
Name of Manufacturer	Ameer & Adnan Pharmaceuticals (Pvt) Ltd. Plot No. 47, Sundar Industrial Estate, Raiwind Road Lahore.		
Manufacturer of API	Vision Pharmaceuticals, Islamabad		
API Lot No.	DLP420		
Description of Pack (Container closure system)	Alu-Alu foil blister sealed with aluminium foil. The blister are introduced into unit carton.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CZ-001	CZ-002	CZ-003

Batch Size	961 capsule	961 capsule	1900 capsule
Manufacturing Date	21-02-2019	21-02-2019	21-02-2019
Date of Initiation	26-02-2019	27-02-2019	27-02-2019
No. of Batches	03		
Date of Submission	Dy.# 16454 dated 02-09-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 11-02-2019 specifying purchase of 2 Kg of pellets.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Panel may be requested to verify the following

- Testing of pellets at pH 1.2, 5.5 and 6.75/7 to confirm dual delayed release profile as per the decision of 276th meeting of Registration Board.
- Dissolution testing at buffer stage at pH 7.0 with 5mM SLS as per the FDA dissolution database.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Omdexo 30mg and 60mg capsules by M/s Ameer & Adnan, 47-Sunder industrial Estate, Lahore.

The panel inspection of Ameer & Adnan, 47-Sunder industrial Estate, Lahore for verification of authenticity of stability data of Omdexo 30mg and 60mg capsules was conducted on 07-11-2019 and 23-01-2020.

The panel comprised of

a) Shaheen Iqbal, Director, Drug Testing Laboratory, Lahore
b) Ufaq Tanveer Federal Inspector of Drugs, DRAP, Lahore
c) Anam Saeed Assistant Director, DRAP, Lahore

S. No.	Question	Observation by Panel
1	Do you have documents confirming the import of API including approval from DRAP?	The firm purchased API from M/s. Vision Pharmaceuticals (Pvt) Ltd,
2	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular manufacturer was its GMP compliant status and good well in the market.
3	Do you have documents confirming the import of reference standard and	Working standards and impurities standards were given to the firm by M/s. Vision Pharmaceuticals

	impurity standards?	(Pvt) Ltd,
4	No you have certificate of Analysis of the API, reference standards and impurity standards	Yes
5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes
6	Do you use API manufacturer method of testing for testing API?	No. The firm developed its own method for testing of API.
7	Do you have stability studies report of API?	Yes. M/s. Vision Pharmaceuticals (Pvt) Ltd, Provided stability studies on two batches of API.
8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	No.
9	Do you have method for quantifying the impurities in the API?	Yes-HPLC was used for this purpose. In house method was used.
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	No API was left Some quantity of working standard and impurities standards were left.
11	Have you used pharmaceutical grade excipients?	N/A
12	Do you have documents confirming the import of the used excipients?	N/A
13	Do you have test reports and other records on the excipients used?	N/A
14	Do you have written and authorized protocols for the development of applied product?	SOP for product development was provided but product development protocol was not developed.
15	Have you performed Drug-excipients compatibility studies?	N/A
16	Have you performed comparative dissolution studies?	Yes. However, the firm purchased reference product from M/s. Sami Pharmaceuticals (Delanzo) not from the innovator. The innovator comparative dissolution profile was incomplete. Testing at buffer PH 5.5 was missing for accelerated study stability batches. It was advised to do dissolution at PH 5.5 for the remaining quantities of stability hatches.
17	Do you have product development (R&D) section	Yes.
18	Do you have necessary equipments available in product development section for development of applied product?	No. Firm utilized production area of capsules section for manufacturing their product.
19	Are the equipments in product development section qualified?	Yes
20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Yes
21	Do you have qualified staff in product development section with proper knowledge and training in product development?	Yes. List attached.
22	Have you manufactured three stability batches for the stability studies of applied product as required.	Yes. Omdexo 30mg Omdexo 60mg CZ-001 1900 CZ-001 961 CZ-002 1900 CZ-002 961

		CZ-003 1900 CZ-003 961
23	Do you have any criteria for fixing the batch size of stability batches?	As per stability protocol.
24	Do you have complete record of production of stability batches?	Yes
25	Do you have protocols for stability testing of stability batches?	Yes
26	Do you have developed and validated the method for testing of stability batches.	Firm had developed its own method but the method was not stability indicating.
27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	N/A
28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drugs?	Yes.
29	Is your method of analysis stability indicating?	No.
	Is your HPLC software is 21CFR compliant?	No.
30	(Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported).	No.
31	Can you show Audit Trail reports on stability studies testing?	No.
32	Do you have some remaining quantities of degradation products and stability batches?	Yes. Stability batches are still in stability chamber.
33	Do you have stability batches kept on stability testing?	Yes. For long term stability.
34	Do you have valid calibration status for the equipments used in production and analysis?	Yes.
35	Do proper and continuous monitoring and control are available for stability chamber? (Number and utilized/available capacity of stability chambers shall also be reported).	Yes.
36	Do related manufacturing area, equipment, personnel and utilities berated as GMP compliant?	Yes.

Conclusion:

The panel inspection of Ameer & Adnan, 47-Sunder industrial Estate, Lahore for verification of authenticity of stability data of Omdexo 30mg and 60mg capsules was conducted on 07-11-2019 and 23-01-2020 and the details are as given above. The panel also verified the following.

i) Testing of pellets at pH 1.2,5.5 and 6.75/7 to confirm dual delayed release profile as per the decision of 276th meeting of Registration Board.

ii) Dissolution testing at buffer stage at pH 7.0 with 5mM SLS as per the FDA dissolution database.

However it seems from the data that the firm did not perform accelerated salability studies testing at PH 5.5.

Also the firm developed its own method for testing of raw material and stability batches. The detailed report is being submitted to the competent authority for further consideration.
Discussion: Registration Board deliberated on the analytical method adopted by the firm and reiterated that the firm can either adopt the API manufacturer's method of testing (since it is a validated method) or develop and validate analytical method based on ICH guidelines. The Board further deliberated that in any case the analytical method should be properly validated. **Decision of 294th meeting:** Registration Board decided to defer the case of Omdexo 30mg and 60mg capsules for submission of data of validation of analytical method since the firm has not used API manufacturer's method of testing.
Evaluation by PEC: Firm has submitted protocols as well as report of analytical method validation along with chromatograms and signed raw data sheets.
Decision: Registration Board decided to approve registration of Omdexo (Dexlansoprazole) 30mg and 60mg capsules with Innovator's specifications by M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd. Plot No. 47, Sundar Industrial Estate, Raiwind Road Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

c. Exemption from onsite verification of stability data

i. New cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
3439.	M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad.	Dapaduo XR Tablets 5/1000mg Each bi-layered film coated tablet contains: Dapagliflozin (as propanediol monohydrate) (immediate release)……..5mg Metformin hydrochloride (Extended release)…..…1000mg (Anti-diabetic)	Form 5-D Dy No. 16125 07-03-2019 PKR 50,000/- 07-03-2019 As per SRO	XIGDUO XR Tablet (**USFDA** Approved) GMP Inspection conducted on 10-10-2018 & 17-10-2018 concluded that the panel unanimously recommended for the grant of cGMP certificate.

STABILITY STUDY DATA

Drug	Dapaduo XR Tablets 5/1000mg
Name of Manufacturer	M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad.
Manufacturer of API	**Dapagliflozin:** Hangzhou Huadong Medicine group Zhejiang Huayi Pharmaceutical Co. Ltd.
	Metformin: Abhilasha Pharma Pvt. Ltd. Plot No. 1408,1409 GIDC Ankleshwar Gujrat India
API Lot No.	**Dapagliflozin:** C017-51710001
	Metformin: MET123/17
Description of Pack (Container closure system)	Alu Alu Blister Pack in Unit carton
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH

Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated:0,1,2,3,4,6 (months) Real Time: 0,3,6 (months)		
Batch No.	T #01	T #02	T #03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	08-2018	08-2018	08-2018
Date of Initiation	25-08-2018	25-08-2018	25-08-2018
No. of Batches	03		
Date of Submission	32249 (30-01-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate (No. ZJ20170047) issued by CFDA, valid till 02-07-2022.
		Metformin: Copy of GMP certificate (No. 19101625) issued by Food and Drugs Control Administration Gujrat state India, valid till 02-10-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin:** Firm has submitted copy of commercial invoice dated 16-03-2018 specifying import of 300g dapagliflozin propanediol monohydrate. The invoice is attested by AD (I&E) DRAP Islamabad.
		Metformin: Firm has submitted copy of commercial invoice dated 6-09-2017 specifying import of 1000Kg metformin hydrochloride. The invoice is attested by AD (I&E) DRAP Islamabad.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board decided to approve registration of "DASCOT 30 mg Tablets (Daclatasvir 30 mg)" & "DASCOT 60 mg Tablets (Daclatasvir 60 mg)" as well as

		VELSCOT 400mg/100mg Tablet by M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Date of Inspection: 26-01-2018. • The HPLC software is 21 CFR compliant. • The firm has demonstrated all audit trail reports for DASCOT 30 & 60mg tablet.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** Firm has submitted copy of commercial invoice dated 16-03-2018 specifying import of 300g dapagliflozin propanediol monohydrate. The invoice is attested by AD (I&E) DRAP Islamabad.
		Metformin: Firm has submitted copy of commercial invoice dated 6-09-2017 specifying import of 1000Kg metformin hydrochloride. The invoice is attested by AD (I&E) DRAP Islamabad.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted documents for procurement of working and impurity standards.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate (No. ZJ20170047) issued by CFDA, valid till 02-07-2022.
		Metformin: Copy of GMP certificate (No. 19101625) issued by Food and Drugs Control Administration Gujrat state India, valid till 02-10-2021.
5.	Mechanism for Vendor pre-qualification	The firm has submitted copy of vendor evaluation and qualification form.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted certificate of analysis of API, working standard and impurity standard.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted copy of Commercial invoices/COAs of all the excipients used in the formulation of applied product
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in R&D department.
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development for applied product.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of three Batches
11.	Record of remaining quantities of stability batches.	Firm has submitted record of remaining quantities of the stability batches as: T#01: 166 tablets T#02: 166 tablets T#03: 166 tablets
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted method used for analysis of API along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e.	The firm has submitted Finished Product Testing method for the finished product

	chromatograms, lab reports, raw data sheets etc.)	
15.	Reports of stability studies of API from manufacturer.	The firm has submitted data sheets for real time and accelerated stability study data for both API as per the conditions of Zone IV-A.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has submitted the compatibility profile of all excipients used in their formulation through various literature sources including handbook of pharmaceutical excipients and FDA NDA product chemistry review.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers against reference product. The firm has calculated f2 values and their results are within acceptance criteria.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for the testing of their product.

Remarks of the evaluator:

- Firm's dissolution specification for dapagliflozin layer was NLT 85% in 30 and 45 minutes, the dissolution for the FDA approved reference product is performed at 30 minutes. The results of dissolution were above 85% at 30 minutes.

Shortcomings communicated	Response by the firm
Record of Comparative Dissolution Profile (CDP) needs to be submitted as per the checklist of 278th meeting of Registration Board.	The firm has submitted that following strengths of the same product have been already approved by Registration Board. • Dapaduo XR Tablet 5/500mg • Dapaduo XR Tablet 10/1000mg • Dapaduo XR Tablet 10/500mg The comparative dissolution profile (CDP) for the applied product i.e. Dapaduo XR Tablet 5/1000mg was not submitted with the exemption data due to unavailability of the Innovator product. The excipients of the lower strength and higher strength of Dapaduo product were same, however quantities of active were different. Therefore you are requested to kindly waive off CDP for Dapaduo XR Tablet 5/1000mg Tablet.

Decision: Registration Board decided to approve registration of Dapaduo XR Tablets 5/1000mg with Innovator's specifications by M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
3440.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Tenovir Tablet 25mg Each Film Coated Tablet Contains: Tenofovir Alfenamide as fumarate…25mg	Form 5D Dy No. 1152 09-01-2018 PKR 50,000/- 27-12-2017	Vemlidy Tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

STABILITY STUDY DATA			
Drug	Tenovir Tablet		
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt) Ltd E-127-129, North Western Industrial Zone, Bin Qasim, Karachi		
Manufacturer of API	Yichang Chang Jiang Pharmaceutical Co. Ltd., No. 38, Binjiang Road, Yidu County, Yichang City Hubei Province China.		
API Lot No.	20180812		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	11-2017	05-2018	05-2018
Date of Initiation	14-12-2017	16-08-2018	25-06-2018
No. of Batches	03		
Date of Submission	22269 (29-10-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API.	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HB20190516) issued by CFDA China. The certificate is valid till 04-07-2024.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 29-03-2017. Firm has submitted that due to small quantity of API, the firm has received the material through DHL. The firm has submitted DHL invoice.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 29-03-2017. Due to small quantity of API, the firm has received the material through DHL. The firm has submitted DHL invoice.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted that the API supplier has sent them reference standard along with the API through DHL courier.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HB20190516) issued by CFDA China. The certificate is valid till 04-07-2024.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor certification checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted certificate of analysis of tenofovir alafenamide fumarate.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-01: 680 Tablet TF-02: 710 Tablet TF-03: 710 Tablet
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copy of record of digital data logger for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e.	The firm has submitted copy of Finished Product Testing Procedure and specification.

	chromatograms, lab reports, raw data sheets etc.)	
15.	Reports of stability studies of API from manufacturer.	Firm has submitted stability study data of 3 batches of API
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution at 0.1 N HCl pH 1.2, 4.5 pH acetate buffer and 6.8pH phosphate buffer.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

<table>
<tr><th>Shortcomings communicated</th><th>Response by the firm</th></tr>
<tr><td>Justify the acceptance criteria of dissolution test i.e. NLT 75% in 30 minutes without defining the time and value of “Q” since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. The FDA guidance “Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances” specifies under the heading DISSOLUTION ACCEPTANCE CRITERIA that for immediate release solid oral drug products containing a high solubility drug substance, the dissolution criterion is Q=80% in 30 minutes. Furthermore, USFDA chemistry review for the innovator product “Vemlidy Tablet” specifies that the acceptance criteria for dissolution test is NLT (Q+5) in 15 minutes.</td><td>Our value of “Q” for dissolution testing of tenofovir tablet is 75%, we have used the dissolution specification i.e. NLT 75% (Q) in 30 minutes because the specifications of the innovator product was not available at FDA dissolution database. Later on as per the guidelines and decision of 293rd meeting of Registration Board we have revised our dissolution specifications to NLT 75%(Q) in 15 minutes. To comply with the decision of Registration Board, we have also performed dissolution testing of two batches i.e. TF-02 and TF-03 at 15 minutes time point and performed one month stability studies at both real time as well as accelerated conditions using the same revised specification. The results of 1 month stability study of both batches performed at 15 min time point is found within specifications. The firm has submitted results along with raw data sheets and other associated documents.
The results are as under:
<table>
<tr><th>Batch number</th><th>Initial</th><th>1st month (Accelerated)</th></tr>
<tr><td>TF-02</td><td>89.63</td><td>92.92</td></tr>
<tr><td>TF-03</td><td>94.83</td><td>96.96</td></tr>
</table>
<table>
<tr><th>Batch number</th><th>Initial</th><th>1st month (R.T)</th></tr>
<tr><td>TF-02</td><td>89.63</td><td>92</td></tr>
<tr><td>TF-03</td><td>94.83</td><td>92.82</td></tr>
</table></td></tr>
<tr><td>Specify the exact storage conditions at which the API was kept after import till the manufacturing of batches.</td><td>Firm has submitted that they have kept the API as per the storage conditions recommended by API supplier. The storage conditions were 2 – 8 °C.</td></tr>
</table>

Decision: Registration Board decided to approve registration of Tenovir Tablet 25mg with Innovator’s specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
3441.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Apixa 2.5mg Tablet Each Film Coated Tablet Contains: Apixaban…2.5mg	Form-5D Dy.No 25403 14-12-2017 Rs.50,000 07-12-2017	Eliquis Tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Apixa 2.5mg Tablet		
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt) Ltd E-127-129, North Western Industrial Zone, Bin Qasim, Karachi		
Manufacturer of API	Glenmark Life Sciences Limited. A-80, MIDC Kurkumbh District Pune-Zone 4, India.		
API Lot No.	801804675		
Description of Pack (Container closure system)	Alu-Pvc blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	TF-02	TF-03	TF-04
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	08-2018	08-2018	08-2018
Date of Initiation	24-09-2018	24-09-2018	24-09-2018
No. of Batches	03		
Date of Submission	26120 (05-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API.	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6086071) issued by Food and Drug Administration Mahrashtra State India. The certificate is valid till 28-01-2020. Firm has also submitted copy of certificate (# 68799/2018/11/23717). This certificate is valid till 24/05/2021
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

Documents confirming import of API etc.	Firm has submitted copy of attested commercial invoice dated 31-06-2018 specifying import of 10g Apixaban. Firm has also submitted copy of commercial invoice dated 28-06-2018 specifying import of another 10.5g. Firm has submitted that due to very small quantity of API we have imported this quantity through DHL.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

ADMINISTRATIVE PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of attested commercial invoice dated 31-06-2018 specifying import of 10g Apixaban. Firm has also submitted copy of commercial invoice dated 28-06-2018 specifying import of another 10.5g. Firm has submitted that due to very small quantity of API we have imported this quantity through DHL.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted that the API supplier has sent them reference standard along with the API through DHL courier. Firm has also submitted commercial invoice specifying reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6086071) issued by Food and Drug Administration Mahrashtra State India. The certificate is valid till 28-01-2020. Firm has also submitted copy of certificate (# 68799/2018/11/23717). This certificate is valid till 24/05/2021.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor certification checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted certificate of analysis of Apixaban.

7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
	PRODUCTION DATA	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-02: 164 Tablet TF-03: 164 Tablet TF-04: 164 Tablet
	QA / QC DATA	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copy of record of digital data logger for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted copy of Finished Product Testing Procedure and specification.
15.	Reports of stability studies of API from manufacturer.	Firm has submitted stability study data of 3 batches of API at accelerated (6 months) and long term conditions (48 months). The long term stability study data has been conducted as per zone IV-A conditions.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution at 0.1 N HCl pH 1.2, 4.5 pH acetate buffer, 6.8pH phosphate buffer.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcomings communicated	Response by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 75% (Q) in 45 minutes since USFDA chemistry review for the innovator product "Eliquis Tablet" specifies that the acceptance criteria for dissolution test is NLT (Q+5) in 30 minutes.	We have used the dissolution specifications i.e. NLT 75% (Q) in 45 minutes because the specifications of innovator product were not available at FDA dissolution database. Later on as per the guidelines and decision of 293rd meeting of Registration Board, we have revised out specifications of NLT 75% (Q) in 30 minutes as per the innovator product. Our product has also complied to the revised specifications as well.
Real time stability study data of 3 batches of API	Firm has submitted stability study data of 3

needs to be submitted as per the conditions of zone IV-A, since the submitted long term stability data is conducted at 25°C / 60% RH.	batches of API at accelerated (6 months) and long term conditions (48 months). The long term stability study data has been conducted as per zone IV-A conditions.

Decision: Registration Board decided to approve registration of Apixa 2.5mg Tablet with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
3442.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Apixa 5mg Tablet Each Film Coated Tablet Contains: Apixaban…5mg	Form-5 Dy.No 7576 21-02-2019 Rs.20,000 19-02-2019	Eliquis Tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Apixa 5mg Tablet		
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt) Ltd E-127-129, North Western Industrial Zone, Bin Qasim, Karachi		
Manufacturer of API	Glenmark Life Sciences Limited. A-80, MIDC Kurkumbh District Pune-Zone 4, India.		
API Lot No.	801804675		
Description of Pack (Container closure system)	Alu-Pvc blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	08-2018	08-2018	08-2018
Date of Initiation	24-09-2018	24-09-2018	24-09-2018
No. of Batches	03		
Date of Submission	26121 (05-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API.	Yes

Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.		Firm has submitted copy of GMP certificate (No. 6086071) issued by Food and Drug Administration Mahrashtra State India. The certificate is valid till 28-01-2020. Firm has also submitted copy of certificate (# 68799/2018/11/23717). This certificate is valid till 24/05/2021
Protocols followed for conduction of stability study and details of tests.		Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.		Yes
Documents confirming import of API etc.		Firm has submitted copy of attested commercial invoice dated 31-06-2018 specifying import of 10g Apixaban. Firm has also submitted copy of commercial invoice dated 28-06-2018 specifying import of another 10.5g. Firm has submitted that due to very small quantity of API we have imported this quantity through DHL.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.		Yes
Commitment to continue real time stability study till assigned shelf life of the product.		Yes
Commitment to follow Drug Specification Rules, 1978.		Yes
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:		
ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of attested commercial invoice dated 31-06-2018 specifying import of 10g Apixaban. Firm has also submitted copy of commercial invoice dated 28-06-2018 specifying import of another 10.5g. Firm has submitted that due to very small quantity of API we have imported this quantity through DHL.
3.	Documents for the procurement of reference	Firm has submitted that the API supplier has sent them

	standard and impurity standards.	reference standard along with the API through DHL courier. Firm has also submitted commercial invoice specifying reference standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6086071) issued by Food and Drug Administration Mahrashtra State India. The certificate is valid till 28-01-2020. Firm has also submitted copy of certificate (# 68799/2018/11/23717). This certificate is valid till 24/05/2021.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor certification checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted certificate of analysis of Apixaban.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-01: 184 Tablet TF-02: 184 Tablet TF-03: 164 Tablet
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copy of record of digital data logger for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted copy of Finished Product Testing Procedure and specification.
15.	Reports of stability studies of API from manufacturer.	Firm has submitted stability study data of 3 batches of API at accelerated (6 months) and long term conditions (48 months). The long term stability study data has been conducted as per zone IV-A conditions.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution at 0.1 N HCl pH 1.2, 4.5 pH acetate buffer, 6.8pH phosphate buffer.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcomings communicated	Response by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 75% (Q) in 45 minutes since USFDA chemistry review for the innovator product "Eliquis Tablet" specifies that the acceptance criteria for dissolution test is NLT (Q+5) in 30 minutes.	We have used the dissolution specifications i.e. NLT 75% (Q) in 45 minutes because the specifications of innovator product were not available at FDA dissolution database. Later on as per the guidelines and decision of 293rd meeting of Registration Board, we have revised out specifications of NLT 75% (Q) in 30 minutes as per the innovator product. Our product has also complied to the revised specifications as well.
Real time stability study data of 3 batches of API needs to be submitted as per the conditions of zone IV-A, since the submitted long term stability data is conducted at 25°C / 60% RH.	Firm has submitted stability study data of 3 batches of API at accelerated (6 months) and long term conditions (48 months). The long term stability study data has been conducted as per zone IV-A conditions.

Decision: Registration Board decided to approve registration of Apixa 5mg Tablet with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
3443.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Vortiox 10mg Tablet Each Film Coated Tablet Contains: Vortioxetine Hydrobromide Eq. to Vortioxetine…10mg	Form 5 Dy No. 21070 12-06-2018 PKR 20,000/- 08-06-2018	Trintellix Tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Vortiox 10mg Tablet		
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt) Ltd E-127-129, North Western Industrial Zone, Bin Qasim, Karachi		
Manufacturer of API	Lianyungang Jari Pharmaceutical Co Ltd. # 18, Zhenhua Road, Lianyungang, Jiangsu Province China.		
API Lot No.	20170117		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 Tablets	1000 Tablets	1000 Tablets

Manufacturing Date	04-2018	07-2018	07-2018
Date of Initiation	15-05-2018	20-08-2018	20-08-2018
No. of Batches	03		
Date of Submission	20566 (14-10-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API.	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. JS20191190) issued by CFDA China. The certificate is valid till 29-11-2024.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of Form 6 License to import drugs for clinical trial / examination / test or analysis dated 15-06-2017 specifying import of 150 gm Vortioxetine hydrobromide. Firm has submitted copy of commercial invoice signed by AD (I&E) specifying import of 150gm API.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

ADMINISTRATIVE PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 License to import drugs for clinical trial / examination / test or analysis dated 15-06-

		2017 specifying import of 150 gm Vortioxetine hydrobromide. Firm has submitted copy of commercial invoice signed by AD (I&E) specifying import of 150gm API.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted that the API supplier has sent them reference standard along with the API..
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. JS20191190) issued by CFDA China. The certificate is valid till 29-11-2024.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor certification checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted certificate of analysis of tenofovir alafenamide fumarate and vorking standard 100mg.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-01: 375 Tablet TF-02: 205 Tablet TF-03: 205 Tablet
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted copy of Finished Product Testing Procedure and specification.
15.	Reports of stability studies of API from manufacturer.	Firm has submitted stability study data of 3 batches of API at accelerated (6 months) and long term conditions (24 months). The long term stability study data has been conducted as per zone IV-A conditions.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution at 0.1 N HCl pH 1.2, 4.5 pH acetate buffer and 6.8pH phosphate buffer.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcomings communicated	Response by the firm
Specify the exact polymorphic form of API used in the manufacturing of stability batches	Our supplier has provided us with vortioxetine hydrobromide salt containing β polymorph. The same polymorph is also used by the innovator product.

Decision: Registration Board decided to approve registration of Vortiox 10mg Tablet with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Registration letter will be issued after comments of Legal affairs division, about patent issue of applied formulation.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
3444.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Vortiox 20mg Tablet Each Film Coated Tablet Contains: Vortioxetine Hydrobromide Eq. to Vortioxetine…20mg	Form 5 Dy No. 21069 12-06-2018 PKR 20,000/- 08-06-2018	Trintellix Tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Vortiox 20mg Tablet		
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt) Ltd E-127-129, North Western Industrial Zone, Bin Qasim, Karachi		
Manufacturer of API	Lianyungang Jari Pharmaceutical Co Ltd. # 18, Zhenhua Road, Lianyungang, Jiangsu Province China.		
API Lot No.	20170117		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1200 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	05-2018	07-2018	07-2018
Date of Initiation	06-06-2018	20-08-2018	20-08-2018
No. of Batches	03		
Date of Submission	20567 (14-10-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status

COA of API.	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. JS20191190) issued by CFDA China. The certificate is valid till 29-11-2024.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of Form 6 License to import drugs for clinical trial / examination / test or analysis dated 15-06-2017 specifying import of 150 gm Vortioxetine hydrobromide. Firm has submitted copy of commercial invoice signed by AD (I&E) specifying import of 150gm API.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

ADMINISTRATIVE PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 License to import drugs for clinical trial / examination / test or analysis dated 15-06-2017 specifying import of 150 gm Vortioxetine hydrobromide. Firm has submitted copy of commercial invoice signed by AD (I&E) specifying import of 150gm API.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted that the API supplier has sent them reference standard along with the API..
4.	Approval of API/ DML/GMP certificate of	Firm has submitted copy of GMP certificate (No.

	API manufacturer issued by regulatory authority of country of origin.	JS20191190) issued by CFDA China. The certificate is valid till 29-11-2024.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor certification checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted certificate of analysis of tenofovir alafenamide fumarate and vorking standard 100mg.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-01: 442 Tablet TF-02: 217 Tablet TF-03: 225 Tablet
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted copy of Finished Product Testing Procedure and specification.
15.	Reports of stability studies of API from manufacturer.	Firm has submitted stability study data of 3 batches of API at accelerated (6 months) and long term conditions (24 months). The long term stability study data has been conducted as per zone IV-A conditions.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution at 0.1 N HCl pH 1.2, 4.5 pH acetate buffer and 6.8pH phosphate buffer.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcomings communicated	Response by the firm
Specify the exact polymorphic form of API used in the manufacturing of stability batches	Our supplier has provided us with vortioxetine hydrobromide salt containing β polymorph. The same polymorph is also used by the innovator product.

Decision: Registration Board decided to approve registration of Vortiox 20mg Tablet with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin

Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Registration letter will be issued after comments of Legal affairs division, about patent issue of applied formulation.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
3445.	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Ticalor 60mg Tablet Each Film Coated Tablet Contains: Ticagrelor……60mg	Form-5D Dy.No.2627 21-06-2016 Fee. 50,000/-	Brilinta Tablets (**USFDA** Approved) GMP certificate issued on the basis of inspection conducted dated 08-11-2018.
3446.	M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore	Ticalor 90mg Tablet Each Film Coated Tablet Contains: Ticagrelor……90mg	Form 5 25-9-2014 Fee 20,000/- 25-9-2014	

STABILITY STUDY DATA

Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd. No. 2 Tonghai Si Road, Ynagkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong Jiangsu Province China.		
API Lot No.	RD-TG-201808021		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0, 3 6 (months)		
TICALOR 60MG TABLET			
Batch No.	RD-19030	RD-19031	RD-19032
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	28-03-2019	28-03-2019	28-03-2019
TICALOR 90MG TABLET			
Batch No.	RD-19039	RD-19040	RD-19041
Batch Size	2000 Tablets	2000 Tablets	2000 Tablets
Manufacturing Date	03-2019	03-2019	03-2019
Date of Initiation	28-03-2019	28-03-2019	28-03-2019
No. of Batches	03		
Date of submission	30389 (15-01-2020)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Yes

Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020. Firm has also submitted copy of inspection report letter issued by FDA on 05-08-2019 in which the facility of Nantong Chanyoo was considered to be in minimally acceptable state of compliance to GMP
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 02-10-2018 specifying import of 5Kg Ticagrelor. The invoice has been signed by AD DRAP Lahore.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA

ADMINISTRATIVE PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Daplozmet Tablet 5mg/1000mg and Daplozmet Tablet 5mg/850mg (Dapagliflozin propanediol monohydrate + metformin HCl) Tablets", which was presented in 288th meeting of Registration Board wherein the Board decided to approve registration of Daplozmet Tablet. Date of inspection: 1st January, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 02-10-2018 specifying import of 5Kg Ticagrelor. The invoice has been signed by AD DRAP Lahore.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted that the reference standard was received through DHL.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020. Firm has also submitted copy of inspection report letter issued by FDA on 05-08-2019 in which the facility of Nantong Chanyoo was considered to be in minimally acceptable state of compliance to GMP
5.	Mechanism for Vendor pre-qualification	Firm has submitted flow chart for vendor qualification mechanism.
6.	Certificate of analysis of the API, reference	Firm has submitted COA of API, and working standard.

	standards and impurity standards	
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted protocols / SOPSs for product development.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of each strength.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: **TICALOR 60MG TABLET** RD-19030: 8 Packs on real time stability RD-19031: 8 Packs on real time stability RD-19032: 8 Packs on real time stability **OCLAWIL TABLETS 10MG** RD-19039: 8 Packs on real time stability RD-19040: 8 Packs on real time stability RD-19041: 8 Packs on real time stability
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches of both API's. The stability study data till 1 year was provided.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted results of compatibility study report of ticagrelor API with all the excipients using binary mixtures and study of compatibility using HPLC analysis.
18.	Record of comparative dissolution data.	Firm has submitted CDP data of their 60mg strength with 90mg strength of innovator product
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Justify the dissolution specification NLT 80%(Q) after 45 minutes, since the USFDA chemistry review document of the innovator product specify	The dissolution acceptance criteria was not disclosed in NDA available on FDA website, therefore based on comparative dissolution prodile

dissolution testing at two time points i.e. NLT (Q) at 45 minutes and NLT (Q) at 60 minutes. USFDA guidelines "*Dissolution Testing of Immediate Release Solid Oral Dosage Forms*" recommends that for slowly dissolving or poorly water soluble drugs, a two-point dissolution specification, one at earlier time to include a dissolution range (a dissolution window) and the other at a later point (30, 45, or 60 minutes) to ensure 85% dissolution, is recommended to characterize the quality of the product. The innovator product has also used the same approach and selected two time points for dissolution, justify how your finished product specification without a test for measure of dissolution range at 45 minutes and at 60 minutes to ensure 85% drug release be considered similar to that of innovator product. If your product shows more than 85% release in 45 minutes, how can it be considered similar with innovator product in terms of drug release.	in proposed dissolution media the lower drug release 85% was achieved as single time point for dissolution with acceptance criteria of 80%(Q). This selection was based on ICH Q6A decision tree #7 according to which generally single point dissolution acceptance criteria with lower limit are acceptable. Please note that we have compared CDP profile of both innovator product and our product in proposed media and submitted the data. The results are comparable with f2>50. Based on this study we selected the lower time point 45 minutes for single time point testing. However to comply with instructions of DRAP we have revised our specifications and incorporated two time point testing at 45 min and 60 min as per the innovator product. We have tested the stability batches at additional 13 month time point at 45 and 60 min and the results fall in acceptance criteria.. The remaining time points of stability will also be performed as per revised specifications.
Specify the exact polymorphic form of ticagrelor used in the manufacturing of stability batches.	Polymorphic form used in the stability batches was Form-II.
Justify why comparative dissolution profile of 60mg strength is studied against the 90mg strength of innovator product.	As both 60 and 90mg formulations are proportionate therefore due to non-availability of 60mg strength in the market we have performed CDP of 60mg strength with 90mg of innovator product. Please note that both 60 and 90mg tablets have proportionate composition therefore their dissolution will have similar release rates. Based on this we have compared the dissolution profile of ticagrelor 60mg tablet with Brilinta 90mg Tablet in FDA suggested media as well as in proposed media.

Decision: Registration Board decided to approve registration of Ticalor 60mg Tablet and Ticalor 90mg Tablet with Innovator's specifications by M/s Highnoon Laboratories Limited 17.5 K. M. Multan Road, Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
3447.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Lurasid 40mg Tablet Each film coated tablet contains: Lurasidone HCl…40mg	Form 5 20-10-2017 PKR 20,000/- 04-10-2017	Latuda Tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Lurasid 40mg Tablet
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt) Ltd E-127-129, North Western Industrial Zone,

	Bin Qasim, Karachi		
Manufacturer of API	ZCL Chemicals Limited Plot no. 3102/B, G.I.D.C, Ankleshwar 393 002, Dist. Bharuch, Gujarat, India		
API Lot No.	SID3200216		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	TF-02	TF-03	TF-04
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	06-2018	07-2018	07-2018
Date of Initiation	13-07-2018	25-08-2018	25-08-2018
No. of Batches	03		
Date of Submission	26118 (05-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API.	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 1808977) issued by Food and Drug Administration Gujrat State India. The certificate is valid till 12-08-2021.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 18-12-2017 specifying import of Lurasidone HCl 350gm. The firm has submitted that due to small quantity of API our supplier has sent the API through DHL courier. Firm has submitted DHL invoice dated 18-12-2017.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

ADMINISTRATIVE PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th

	two years.	June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 18-12-2017 specifying import of Lurasidone HCl 350gm. The firm has submitted that due to small quantity of API our supplier has sent the API through DHL courier. Firm has submitted DHL invoice dated 18-12-2017.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted that they have received reference standard along with API from their supplier. Firm has submitted copy of DHL invoice.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 1808977) issued by Food and Drug Administration Gujrat State India. The certificate is valid till 12-08-2021.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor certification checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted certificate of analysis of Lurasidone HCl.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-02: 168 Tablet TF-03: 168 Tablet TF-04: 168 Tablet
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copy of record of data logger for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets	The firm has submitted copy of Finished Product Testing Procedure and specification.

	etc.)	
15.	Reports of stability studies of API from manufacturer.	Firm has submitted stability study data of 3 batches of API at accelerated (6 months) and long term conditions (36 months). The long term stability study data has been conducted as per zone IV-A conditions.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution at 0.1 N HCl pH 1.2, 4.5 pH acetate buffer, 6.8pH phosphate buffer and mcllvaine buffer.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcomings communicated	Response by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 75% (Q) in 30 minutes witsince USFDA chemistry review for the innovator product "Latuda Tablet" specifies that the acceptance criteria for dissolution test is NLT (Q+5) in 20 minutes.	We have used the dissolution specifications i.e. NLT 75% (Q) in 30 minutes because the specifications of innovator product were not available at FDA dissolution database. Later on as per the guidelines and decision of 293rd meeting of Registration Board, we have revised out specifications of NLT 75% (Q) in 20 minutes as per the innovator product. Our product has also complied to the revised specifications as well.
Real time stability study data of 3 batches of API needs to be submitted as per the conditions of zone IV-A, since the submitted long term stability data is conducted at 25°C / 60% RH.	Firm has submitted stability study data of 3 batches of API at accelerated (6 months) and long term conditions (36 months). The long term stability study data has been conducted as per zone IV-A conditions.

Decision: Registration Board decided to approve registration of Lurasid 40mg Tablet with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
3448.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Lurasid 80mg Tablet Each film coated tablet contains: Lurasidone HCl…80mg	Form 5 20-10-2017 PKR 20,000/- 04-10-2017	Latuda Tablets (**USFDA** Approved) 02-07-2019 Satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Lurasid 80mg Tablet
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt) Ltd E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
Manufacturer of API	ZCL Chemicals Limited Plot no. 3102/B, G.I.D.C, Ankleshwar 393 002, Dist.

	Bharuch, Gujarat, India		
API Lot No.	SID3200216		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time : 0, 3, 6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	07-2018	09-2018	09-2018
Date of Initiation	15-10-2018	15-10-2018	15-10-2018
No. of Batches	03		
Date of Submission	26119 (05-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API.	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 1808977) issued by Food and Drug Administration Gujrat State India. The certificate is valid till 12-08-2021.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 18-12-2017 specifying import of Lurasidone HCl 350gm. The firm has submitted that due to small quantity of API our supplier has sent the API through DHL courier. Firm has submitted DHL invoice dated 18-12-2017.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

ADMINISTRATIVE PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd – 4th July,

		2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 18-12-2017 specifying import of Lurasidone HCl 350gm. The firm has submitted that due to small quantity of API our supplier has sent the API through DHL courier. Firm has submitted DHL invoice dated 18-12-2017.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted that they have received reference standard along with API from their supplier. Firm has submitted copy of DHL invoice.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 1808977) issued by Food and Drug Administration Gujrat State India. The certificate is valid till 12-08-2021.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor certification checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted certificate of analysis of Lurasidone HCl.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches.
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: TF-01: 185 Tablet TF-02: 185 Tablet TF-03: 185 Tablet
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copy of record of data logger for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted copy of Finished Product Testing Procedure and specification.
15.	Reports of stability studies of API from	Firm has submitted stability study data of 3 batches of API

	manufacturer.	at accelerated (6 months) and long term conditions (36 months). The long term stability study data has been conducted as per zone IV-A conditions.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	Firm has submitted that they have used same excipients in their formulation as used by the innovator. Therefore drug-excipient compatibility studies are not required.
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution at 0.1 N HCl pH 1.2, 4.5 pH acetate buffer, 6.8pH phosphate buffer and mcllvaine buffer.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcomings communicated	Response by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 75% (Q) in 30 minutes witsince USFDA chemistry review for the innovator product "Latuda Tablet" specifies that the acceptance criteria for dissolution test is NLT (Q+5) in 20 minutes.	We have used the dissolution specifications i.e. NLT 75% (Q) in 30 minutes because the specifications of innovator product were not available at FDA dissolution database. Later on as per the guidelines and decision of 293rd meeting of Registration Board, we have revised out specifications of NLT 75% (Q) in 20 minutes as per the innovator product. Our product has also complied to the revised specifications as well.
Real time stability study data of 3 batches of API needs to be submitted as per the conditions of zone IV-A, since the submitted long term stability data is conducted at 25°C / 60% RH.	Firm has submitted stability study data of 3 batches of API at accelerated (6 months) and long term conditions (36 months). The long term stability study data has been conducted as per zone IV-A conditions.

Decision: Registration Board decided to approve registration of Lurasid 80mg Tablet with Innovator's specifications by M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
3449.	M/s Wilson's Pharmaceuticals, I-9, Industrial Area Islamabad.	Oclawil Tablets 5mg Each film coated tablet contains: Obeticholic acid …… 5 mg	Form 5-D Diary No. 16643 07-03-2019 PKR 50,000/- 07-03-2019	Ocaliva Tablets (**USFDA** Approved) GMP inspection Dated 24-01-2018 Concludes very good level of GMP compliance.
3450.	M/s Wilson's Pharmaceuticals, I-9, Industrial Area Islamabad.	Oclawil Tablets 10mg Each film coated tablet contains: Obeticholic acid …… 10 mg	Form 5-D Diary No. 16644 07-03-2019 PKR 50,000/- 07-03-2019	

STABILITY STUDY DATA			
Manufacturer of API	Virupaksha organics Ltd, Unit 1, Survey No. 10, Gaddapotharam village, Jinnaram Mandal, Medak District Telanagana India.		
API Lot No.	AOBTC0118001		
Description of Pack (Container closure system)	Film coated tablet blistered in Alu-Alu strip, packed in card box unit carton.		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0, 3 & 6 (months) Accelerated: 0,1, 2, 3, 4 & 6 (months)		
OCLAWIL TABLETS 5MG			
Batch No.	Trial # 02	Trial # 03	Trial # 04
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	11-2018	11-2018	11-2018
Date of Initiation	09-11-2018	09-11-2018	10-11-2018
OCLAWIL TABLETS 10MG			
Batch No.	Trial # 01	Trial # 02	Trial # 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	11-2018	11-2018	11-2018
Date of Initiation	11-11-2018	11-11-2018	11-11-2018
No. of Batches	03		
Date of submission	26449 (09-12-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 5884/E1/2018) of M/s Virupaksha organics Ltd, issued by Drugs Control Administration, Government of Telangana. The certificate is issued on 27-3-2019. The certificate is valid for a period of three years from the date of issue.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	Firm has submitted copy of commercial invoice dated 03-04-2018 specifying import of 120gm obeticholic acid. The invoice has been signed by AD DRAP Islamabad.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules,	Yes

1978.		
DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to their last inspection report for their product "saferon tablet " Registration Board in its 278th meeting decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Date of Inspection: 10-12-2015 , 19-04-2017 & 20-01-2018 • Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 03-04-2018 specifying import of 120gm obeticholic acid. The invoice has been signed by AD DRAP Islamabad.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice of purchase of working reference standard and impurity standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 5884/E1/2018) of M/s Virupaksha organics Ltd, issued by Drugs Control Administration, Government of Telangana. The certificate is issued on 27-3-2019. The certificate is valid for a period of three years from the date of issue.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API, working standard and impurity standards.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted protocols / SOPSs for the development of applied product.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: **OCLAWIL TABLETS 5MG** Trial # 02: 284 Tablets Trial # 03: 284 Tablets Trial # 04: 284 Tablets **OCLAWIL TABLETS 10MG** Trial # 01: 284 Tablets Trial # 02: 284 Tablets Trial # 03: 284 Tablets
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability

	(real time and accelerated)	chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches of both API's.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted that their formulation is as per reference product so they do not require drug excipient compatibility studies. Firm has also submitted references of each excipient for compatibility from handbook of pharmaceutical excipients.
18.	Record of comparative dissolution data.	Firm has submitted that reference product is not available in Pakistan therefore they have requested to exempt CDP.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Evaluation by PEC:

The dissolution acceptance criteria of the firm is NLT 80% (Q=75%) in 15 minutes, as per the innovator product.

Shortcomings communicated	Response by the firm
Specify the value of "Q" for dissolution test as per United States Pharmacopoeia (USP) General Chapter <711> Dissolution.	We specify the value of Q as 75% as per the USP monograph<1092>
Comparative dissolution profile (CDP) data with the innovator / reference product along with calculation of factor *f*2 needs to be submitted as per the FDA guidelines on three media including pH 1.2 hydrochloric acid, pH 4.5 acetate buffer and pH 6.8 phosphate buffer.	Firm has submitted that the reference product is not available in Pakistan therefore they have not conducted by comparative dissolution profile.

Decision: Registration Board decided to approve registration of Oclawil Tablets 5mg and Oclawil Tablets 10mg with Innovator's specifications by M/s Wilson's Pharmaceuticals, I-9, Industrial Area Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

ii. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
3451.	The Searle company Limited F-319 S.I.T.E Karachi.	Trelaglip 50mg Tablet Each film coated tablet contains: Trelagliptin (as succinate)….50mg Antidiabetic	Form 5D 01-02-2017 PKR 50,000/- (01-02-2017) **DUPLICATE**	Zafatek Tablets (**PMDA Japan** Approved) Last inspection report dated 30-01-2019 confirms that firm is operating at a Good level of GMP compliance.
3452.	The Searle company Limited F-319 S.I.T.E Karachi.	Trelaglip 100mg Tablet Each film coated tablet contains: Trelagliptin (as succinate)….100mg Antidiabetic	Form 5D 01-02-2017 PKR 50,000/- (01-02-2017) **DUPLICATE**	Zafatek Tablets (**PMDA Japan** Approved) Last inspection report dated 30-01-2019 confirms that firm is operating at a Good level of GMP compliance.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA			
Manufacturer of API	Ruyuan HEC Pharm Co. Ltd. Xiaba Development zone, Ruyuan County, Shaoguan city, Guandong province China.		
API Lot No.	TGLT-201712001		
Description of Pack (Container closure system)	Pale yellowish red color, oval shaped biconvex film coated tablets packed in Alu-Alu blister (2x10's) in a carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Trelaglip 50mg Tablet			
Batch No.	18PD-116	18PD-128	18PD-130
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	06-2018	03-12-2018	03-12-2018
Trelaglip 100mg Tablet			
Batch No.	18PD-174	18PD-180	18PD-181
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	08-2018	08-2018	08-2018
Date of Initiation	06-2018	03-12-2018	03-12-2018
No. of Batches	03		

Date of Submission	19-08-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate for M/s Ruyuan HEC Pharm Co., Ltd, China issued by Shaoguan Food and Drug Administration, China is submitted. It is valid till 18-12-2019.
3.	Protocols followed for conduction of stability study and details of tests.	No
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	No
5.	Documents confirming import of API etc.	Firm has submitted copy of Assistant Director (I & E) DRAP attested invoice confirming import of 1Kg trelagliptin succinate dated 30-01-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcoming	Response by the firm
GMP certificate of the API manufacturer issued by provincial or federal regulatory authority since the submitted GMP certificate is issued by Shaoguan Food and Drug Administration which is a district regulatory authority.	Copy of GMP Certificate for M/s Ruyuan HEC Pharm Co., Ltd, China issued by Shaoguan Food and Drug Administration, China is submitted. It is valid till 12-04-2021.
Scientific justification for selection of dissolution specifications i.e. type of apparatus, volume, speed (rpm), dissolution medium and dissolution time.	Due to un availability of monograph for trelagliptin and there is no reference for dissolution available at US FDA. We, selected the dissolution specification of Sitagliptin from FDA dissolution data base for trelagliptin because both molecules are of same therapeutic class having same BCS classification and have similar mechanism of action.
Justify the variation in dissolution results of individual tablets i.e. 90.11% to 116.71% at first time point for batch 18PD-116	We have checked dissolution results of the said batch and the average values are within specified limits.

DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA

Firm has submitted data for exemption from onsite investigation of submitted stability data as per the guidelines of 293rd meeting of Registration Board.

1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to last onsite inspection of their product Tapendol Tablets 50mg, 75mg and 100mg (Tapentadol) which was considered and approved by Registration Board in its 289th Meeting with following

		details: • Date of Inspection: 11-03-2019
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted CoA of API from API manufacturer. Firm has also submitted copy of CoA of the API generated by FPP manufacturer.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Firm has submitted method of analysis of API from both API manufacturer as well as FPP manufacturer.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of API as per the conditions of zone IV-A.
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate for M/s Ruyuan HEC Pharm Co., Ltd, China issued by Shaoguan Food and Drug Administration, China is submitted. It is valid till 12-04-2021.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Assistant Director (I & E) DRAP attested invoice confirming import of 1Kg trelagliptin succinate dated 30-01-2018.
7.	Protocols followed for conduction of stability study	Firm has submitted protocols for conduction of stability studies.
8.	Method used for analysis of FPP	Firm has submitted drug product testing method.
9.	Drug-excipients compatibility studies (where applicable)	Firm has submitted that their formulation is as per reference product so they do not require drug excipient compatibility studies.
10.	Complete batch manufacturing record of three stability batches.	Firm has submitted batch manufacturing record of three batches of both strengths.
11.	Record of comparative dissolution data (where applicable)	Firm has submitted results of CDP of both strengths with the innovator product. The results of CDP were within acceptable limits.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes submitted by the firm
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted record of HPLC including audit trail reports for testing on the applied product
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.

REMARKS OF EVALUATOR

Scientific justification for selection of dissolution specifications i.e. type of apparatus, volume, speed (rpm), dissolution medium and dissolution time was provided by the firm in which they have responded that "Due to un availability of monograph for trelagliptin and there is no reference for dissolution available at US FDA. We, selected the dissolution specification of Sitagliptin from FDA dissolution data base for trelagliptin because both molecules are of same therapeutic class having same BCS classification and have similar mechanism of action"

Decision of 294th meeting of Registration Board:

Deferred for scientific justification of using dissolution specifications of Sitagliptin tablets for performing dissolution test of trelagliptin tablets.

Evaluation by PEC:

Firm has submitted following justifications:

- There is no reference for dissolution parameters available in FDA or PMDA site or review documents.
- We have performed CDP of our product against the innovator and from the CDP data it is evident that the innovator product as well as our product show similar release in all the three mediums.
- Our dissolution parameters as well as specifications falls within the recommendations of USP general chapter 1092 having title "The dissolution procedure: Development and validation".

Based on the above stated justifications, firm has requested to consider their case keeping in view the USP

recommendations of general chapter.
Decision: Registration Board decided to approve registration of Trelaglip 50mg Tablet and Trelaglip 100mg Tablet with Innovator's specifications by M/s The Searle company Limited F-319 S.I.T.E Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. The Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.

Case no. 06 Miscellaneous Cases

3453. **Request of M/s Vision Pharmaceuticals (Pvt) Ltd. Islamabad to hold the evaluation of CTD dossier of Tramax 100mg/2ml Injection**

M/s Vision Pharmaceuticals (Pvt) Ltd. Islamabad has submitted the following applications on CTD format on 01-07-2019.

Sr. No	Applied product	Details of Fee & Date of submission in DRAP
1.	Tramax 100mg/2ml Injection	Form-5F Dy.No 10294 dated 01-07-2019 Rs.20,000/- Dated 01-07-2019

The firm has submitted stability study data of 3 batches which was performed by using API which was procured and imported by M/s Global Pharmaceuticals (Pvt) Ltd, Islamabad.

Now the firm vide its letter dated 22-01-2020, has requested to hold the evaluation of CTD dossier of the applied product. The firm has submitted that "Initially we got a loan of API of Tramadol HCl from M/s Global Pharmaceuticals (Pvt) Ltd and we have performed stability of three trial batches. But due to legal issues, we M/s Vision Pharmaceuticals (Pvt) Ltd. have decided to import API of tramadol HCl for our own trial purpose and stability studies. It will take almost seven months to perform trials and conclude stability data. That's why we are requesting you to kindly hold our dossier evaluation for the said product."

Decision: Registration Board acceded to the request of firm and directed to submit data of Tramax 100mg/2ml Injection as per the requirements of Form5F.

Registration board appreciated efforts of PEC team of PE&R Division for their extensive working during COVID-19 pandemic. Registration Board applauded several times during the meeting for PEC team for timely evaluation and presentation of COVID-19 applications in Registration Board received even during the meeting as well.

Case No.1: Request for Change in Registration Status of Product from M/s OBS Pakistan (Pvt.) Ltd, Karachi to M/s. Aspin Pharma, Karachi.

Registration Board, in its 287th meeting held on 3rd & 4th January, 2019, deferred the request of M/s. Aspin Pharma (Pvt.) Ltd; Plot No.10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 for change of registration status of following product from M/s. OBS Pakistan (Pvt.) Ltd; Karachi to their name "***till the case regarding correction in registration certificates (as mentioned alongside the case) is under process"***. Details are given as under:

S. No.	Reg. No.	Brand name and composition	Registration History	Remarks
I	II	III	IV	V
1.	085632	Ursodol 250mg/5ml Suspension Each 5ml contains: Ursodeoxycholic acid.....250mg (BP Specification)	Initial date of Reg. 13-12-2017	UK MHRA approved. M/s OBS has already applied for correction in registration letter (regarding Contract Manufacturing from AGP) of instant product that is under process.

Management of the firm has provided following documents:-

i. Original challan Fee of Rs. 20,000/- for each product.
ii. Copies of initial letters of registration and renewal status as stated in column IV above.
iii. Section approval of M/s Aspin verified from Licensing Division's letter for renewal of DML (dated 09th June, 2016) confirming following sections;
   - Tablet (General)
   - Capsule (General)
   - Liquid Syrup
   - Ointment/ Cream.
iv. Copy of last GMP inspection report of M/s Aspin, Karachi dated 08th August, 2018 indicating "Satisfactory" level.
v. NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 19th November, 2018.
vi. DML of M/s Aspin dated 31st May, 2015.
vii. Form 5 dated 04.12.2018

M/s OBS Pakistan, Karachi has now been issued corrigendum (vide letter No.F.3-10/2017 Reg-II (M-273) dated 06-02-2020) for correction in manufacturer of Ursodol Suspension 250mg/5ml (Reg.No.085632) which was inadvertently mentioned as M/s OBS Pakistan (Pvt) Ltd, C-14, S.I.T.E, Karachi instead of M/s. AGP Ltd, B-23 S.I.T.E, Karachi (i.e., Contract Manufacturer).

Decision: Registration Board decided as follows:

i. **Cancellation of registration of Ursodol Suspension 250mg/5ml (R#085632) from the name of M/s. OBS Pakistan (Pvt.) Ltd., C-14, S.I.T.E, Karachi.**
ii. **Approved registration of Ursodol Suspension 250mg/5ml in the name of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 for manufacturing at their facility.**
iii. **Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).**

Case No.2. Request of Martin Dow Limited, Karachi for Registration of Fexinol Capsule (Reg. No. 024311)

Registration Board in its various meetings considered the request of Martin Dow Limited, Karachi for change in registration status of Fexinol Capsule, Reg. No. 024311 (from M/s Martin Dow Pharmaceutical (Pakistan) Ltd., 45 K.M Multan Road, Lahore to their name) Brief of the case is as under:

i. Initially the product was registered in the name M/s Martin Dow Pharmaceutical (Pakistan) Ltd., 45 K.M Multan Road, Lahore on 20th March, 2002.

ii. In 246th meeting of Registration Board, request for change in registration status in the name of M/s Martin Dow Limited, Plot No. 37, Sector19, Korangi Industrial Area, Karachi (change of manufacturing site) was approved. However, "Fexofenadine…80 mg" was recorded instead of "Fexofenadine… 60 mg" in the minutes of 246th meeting of Registration Board i.e reproduced below:

Name of applicant(s)	Name of existing manufacturer	Date of application, Diary No. & Form	Registration No.	Name of product with composition
M/s Martin Dow Ltd, Karachi	M/s Martin Dow Pharmaceuticals (Pakistan)Ltd, 45-KM, Multan Road, Lahore	14-04-2014 Dy.No.342 Form-5 Rs.20000/-	024311	Fexinol capsule Each capsule contains:- Fexofenadine HCl…….80mg

iii. The firm later on requested for correction in the minutes of 246th meeting and issuance of Registration letter.

iv. Registration Board in its 277th meeting reconsidered the case & deferred for confirmation of RRA status of product in capsule dosage form. Accordingly, approval status of the product in TGA Australia was provided by the firm.

v. The case was again presented in 282nd meeting & deferred for confirmation of renewal status.

vi. The firm then submitted initial registration letter & renewal history of the product, details of which have been tabulated below. The firm further informed that they did not submit the renewal due in 2017 because they were waiting to conclude its transfer case in the name of M/s Martin Dow Limited, Plot No. 37, Sector19, Korangi Industrial Area, Karachi. As after transfer they could have the renewal validity for 5 years. But due to mistake in minutes of M-246 for mentioning the strength "80mg" instead of "60mg" they are unable to get its transfer till now.

Name of product with composition & Reg. No.	Initial Registration Letter	1st Renewal	2nd Renewal	Transfer of registration
Fexinol capsule Each capsule contains:- Fexofenadine HCl…..60mg Reg. No. 024311	20-03-2002	Letter for M/s Martin Dow Pharmaceuticals (Pakistan) Ltd, Lahore dated 14-04-2008. Valid from 20-03-2007 to 19-03-2012.	Renewal applied by M/s Martin Dow Pharmaceuticals (Pakistan) Ltd, Lahore acknowledged on 11-05-2010	Acknowledged on 14-04-2014

vii. Registration Board in its 290th meeting reconsidered the case and observed that M/s Martin Dow Limited, Karachi had applied for registration of above mentioned product before expiry of validity of registration, therefore, the concerned section shall process the case for change in registration status accordingly.

The case is now placed for final decision of the Board regarding change in registration status from M/s Martin Dow Pharmaceutical (Pakistan) Ltd., 45 K.M Multan Road, Lahore to M/s Martin Dow Limited, Plot No. 37, Sector19, Korangi Industrial Area, Karachi along-with correction in strength (mentioned in M-246) from "80mg" to "60mg".

Decision: Registration Board decided as follows:

i. **Cancellation of registration of Fexinol Capsule 60mg (R#024311) from the name of M/s Martin Dow Pharmaceutical (Pakistan) Ltd, 45-KM, Multan Road, Lahore (New Title: M/s Seatle (Pvt) Ltd).**
ii. **Approved registration of Fexinol Capsule 60mg in the name of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
iii. **Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).**

Case No.3. Request of M/s Getz Pharma (Private) Limited, Karachi for Issuance of Separate Brand Names for DPI Capsule and MDI Dosage Forms of Same Molecule/API.

Registration Board in its 290th meeting approved the following products of M/s Getz Pharma (Pvt.) Ltd., Karachi.

I	II	III
Sr. No.	**Brand name of drug with composition and demanded specifications**	**Decision of M-290**
1.	Saltra DPI Powder for Inhalation 50mcg+500mcg Each capsule contains: Salmeterol Xinafoate eq. to Salmeterol……..…50mcg Fluticasone Propionate……...500mcg USP	Registration Board decided to approve applied formulation for "Dry Powder Inhaler" section with innovator's specifications. The Board directed the firm to submit following before sale and marketing of the product: • Performance Data for the test of "Uniformity of Delivered Dose" and "Aerodynamic particle size distribution". • Label claim for "Target Delivery Dose" based upon the studies with the intended delivery system under defined test conditions (i.e., flow rate, duration). • Description of Drug delivery device.
2.	Saltra DPI Powder for Inhalation 50mcg+250mcg Each capsule contains: Salmeterol Xinafoate eq. to Salmeterol……50mcg Fluticasone Propionate……..250mcg USP	

Applied brand name "**Saltra**" is already registered in the name of M/s Getz for same molecule in Inhaler (MDI) Dosage form (R# 081557). However the firm has requested for grant of brand name "**Salmiget**" stating that M/s Highnoon Laboratories, Lahore has been granted two different brand names for their registered DPI (i.e., Combivair Rotacaps R# 054316) & MDI (i.e., Foracort HFA Inhaler R# 072586) having same APIs/molecule.

Accordingly, the case has been placed for guidance in the light of decision taken by the Registration Board vide its 248th meeting which states that:

> *"One brand name will be assigned for one molecule / API in all dosage forms for a manufacturer / importer. Moreover, it will be the responsibility of manufacturer / importer to declare that he has no other brand name for same molecule / API."*

Decision: Registration Board was apprised that that presently same brand names are issued to a manufacturer/importer having same formulations. Now various applications have been received for issuance of same brand name under different scenario as follows:

a) Issuance of same brand names to same formulations of different manufacturer/importer.
b) Issuance of diffeeferent brand names for different dosage forms of same formulation
c) Issuance of same brand names for different similar formulation
d) Issuance of different brand names for different dosage form/ strength and indications
e) Issuance of same brand name to same/similar formulation of product registered as drug and enlisted as HOTC product.

Registration Board decided to seek guidance from DRAP Authority on above points.

Case No.4. Request of M/s Martin Dow Marker Limited, Quetta for Issuance of Same Brand Names for Products Having Different Molecule/ Composition.

Registration Board in its 288th meeting approved the following products M/s Martin Dow Marker Limited. 7, Jail Road, Quetta:

I	II	III
Sr. No.	**Brand name of drug with composition and demanded specifications**	**Decision of M-288**
1.	Cosome Fort 200/30 mg Tablets each film coated tablet contains: Ibuprofen……..…200mg Pseudoephedrine HCL……30mg USP	**Approved with change of brand name.**
2.	Cosome 400/60 mg Forte Tablets each film coated tablet contains: Ibuprofen…….400mg Pseudoephedrine HCL……60mg USP	

The firm has requested for grant of registration with brand name "**Cosome Plus**" stating that "**Cosome**" is their registered brand name for "**Cosome Cough Syrup**" containing Dextromethorphan + Pseudoephedrine + Chlorpheniramine & "**Cosome-E Cough Syrup**" containing Ammonium Chloride + Diphenhydramine + Aminophylline.

The firm has further informed that both registered products/ cough syrups have different APIs but brand name "**Cosome**" is awarded as both drugs are "**Anti Histamine**" and form one family. In Cosome Tablet & Cosome syrup, "**Pseudoephedrine**" is common active ingredient and "**Ibuprofen"** is additional active ingredient in Cosome Tablets & therefore the firm wants to form family with brand name of "**Cosome**"

Accordingly, the case has been placed for guidance in the light of decision taken by the Registration Board vide its 248th meeting which states that:

> *"One brand name will be assigned for one molecule / API in all dosage forms for a manufacturer / importer. Moreover, it will be the responsibility of manufacturer / importer to declare that he has no other brand name for same molecule / API."*

Decision: Registration Board was apprised that that presently same brand names are issued to a manufacturer/importer having same formulations. Now various applications have been received for issuance of same brand name under different scenario as follows:

a) **Issuance of same brand names to same formulations of different manufacturer/importer.**
b) **Issuance of diffeeferent brand names for different dosage forms of same formulation**
c) **Issuance of same brand names for different similar formulation**
d) **Issuance of different brand names for different dosage form/ strength and indications**
e) **Issuance of same brand name to same/similar formulation of product registered as drug and enlisted as HOTC product.**

Registration Board decided to seek guidance from DRAP Authority on above points.

Case No.5. Request of M/s Amarant Pharmaceuticals, Karachi for correction in pack size/ volume of Amta-Rose Injection.

Registration Board in its 290th meeting approved the following product M/s Amarant Pharmaceutical (Pvt) Ltd., 158-D Tore, Gadap Road, Super Highway Karachi with contract manufacturing from M/s Caraway Pharmaceutical, Islamabad:

Contract Giver / Applicant	Contract Acceptor / Manufacturer
M/s Amarant Pharmaceuticals (Pvt.) Ltd. 158, D. Tore, Gadap Road, Super Highway, Karachi.	M/s Caraway Pharmaceuticals Plot No. 12, street # N-3, National Industrial Zone, Rawat, Islamabad.

Amta-Rose Injection

1. Name of drug(s)
Amta-Rose Injection (Iron Sucrose)

2. Composition
Each ampoule (1ml) contains: Iron Sucrose Complex eq. to Elemental Iron…100mg

3. Dosage Form
Injection

4. Form, Fee, DY Date
Form 5
1024 dated 02-05-2013
Rs 150,000/-

5. Decision of Registration Board in 246th meeting
Deferred for rectification of following observation in the dossier:

i. Reference will be sent to B & A Division for verification of challan.
ii. Confirmation of installation and operational qualifications for TOC analyzer and liquid particle counter by the area FID.
iii. Initially on Form 5, firm mentioned quantity of active as 420 mg/ ampoule, in reply firm mentioned it as 1873 mg/ ampoule. Clarification is required. No clarification is provided in second reply.
iv. Letter of approval of injection section is required. Not provided in second reply. Inspection report dated 24-09-12 mentions Ampoule and Vial sections.

Submission by the Firm:

1. The original dossier of the firm has been traced with original fee deposit slip.
ii. Evidence of Approval status in Reference regulatory authorities
iii. Firm has submitted Approval of Liquid Ampoule (Injectable) manufacturing facility from Licensing Division
iv. Correct labelling information for treatment of Vit-D3 deficiency.

The original dossier has been traced out with original fee challans. Moreover, the firm has submitted following documents in support:

1. Justification of point raised in point No. 5
2. Undertaking of installation of TOC and liquid practical counter.
3. Section approval dated 15.04.2015.

Decision 271st Meeting of Registration Board:

Registration Board deferred the request of M/s Amarant Pharmaceuticals Karachi for submission of latest GMP report of M/s Amarant Pharmaceuticals, Karachi (contract giver / applicant) and M/s Caraway Pharmaceuticals, Rawat, Islamabad (contract acceptor / manufacturer).

Later on, the firm submitted the inspection reports in favor of M/s Amarant Pharmaceuticals, Karachi conducted on 26-February-2019 and M/s Caraway Pharmaceuticals, Rawat, Islamabad conducted on 24-July-2018, respectively.

Decision of M-290:

Registration Board approved registration of above mentioned products of M/s Amarant Pharmaceuticals, Karachi on contract manufacturing basis by M/s Caraway Pharmaceuticals, Rawat, Islamabad.

Registration Letter could not be issued as demanded pack size was not mentioned in minutes of 290th meeting. Furthermore, as per minutes the firm has applied: **"Each ampoule (1ml) contains: Iron Sucrose Complex eq. to Elemental Iron…100mg"**

However, the standard formulation approved by reference regulatory authority states:

"**Each 5ml ampoule contains: Iron (III) Hydroxide Sucrose Complex Eq. to Elemental Iron 100mg"**

Original Dossier/ Form-5 could not be retrieved. However, the firm has now submitted revised label claim along-with fee of **Rs.5000/-** (DS#1908821 dated 27-12-2019) as per following details:

"Each 5ml ampoule contains:
Iron (III) Hydroxide Sucrose Complex Eq. to Elemental Iron 100mg"

The firm has also informed that their demanded pack size and MRP is **"As Per SRO"**

Decision: Registration Board deferred for submission of remaining fee Rs.15000/-

Case No.6. Correction in composition of Mirofer Injection of M/s Epharm Laboratories, Karachi.

Registration Board in its 278th meeting approved the following product of Epharm Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North , Karachi as per below mentioned details:

Name and address of manufacturer / Applicant	M/s. Epharm Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North , Karachi
Brand Name +Dosage Form + Strength	Mirofer Injection
Composition	Each 5ml contains: Iron-III Hydroxide **Polymaltose** Complex eq. to elemental Iron…100mg
Diary No. Date of R& I & fee	Dy. No. 289, 25-08-2015 , Rs. 20,000/- (24-08-2015)
Pharmacological Group	Haematinic
Type of Form	Form 5
Finished product Specifications	USP
Pack size & Demanded Price	5mlx5, Ampoule As per SRO
Approval status of product in Reference Regulatory Authorities	USFDA approved
Me-too status	**Venofer by Gastro care**
GMP status	Last inspection conducted on 15-09-2016, "Good".
Remarks of the Evaluator	• Method of sterilization of product is filtration rather than terminal sterilization. Firm has not justified on the basis of scientific data. • Pharmacotherapeutic group: Anti-anaemic preparation, iron, parenteral preparation.(MHRA)
Previous Decision	Deferred in 274th meeting for the submission of GMP inspection report within the period of last one year.
Evaluation by PEC	The firm has submitted copy of panel inspection on 27-4-2017 recommending grant of GMP certificate to the site.
Decision: Approved	

M/s Epharm, Karachi has submitted clarification regarding their applied product i.e., Iron (III) Hydroxide Sucrose Complex eq. to Elemental Iron" instead of "Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron" (mentioned in minutes of 278th meeting). Original dossier couldn't be retrieved, however, the firm has submitted DRAP's endorsed receipt (25-08-2015) & copy of form-5 stating **"Iron Sucrose Eq. to Iron 100mg/5ml Injection"**.

Accordingly, the case regarding correction in composition along-with standardization of label claim is submitted for consideration of Registration Board.

Decision: Registration Board deferred the case for verification of applied composition from original dossier submitted submitted by the firm at the time of initial application.

Case No.7. Request of M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan for correction in Packaging Material/ Container Closure System of Atracurium Besylate Injections

Registration Board in its 290th meeting approved the following products of M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan as per below mentioned details:

Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan Contract Manufactured By: M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore
Brand Name +Dosage Form + Strength	Atracurium Besylate 25mg/2.5ml Injection
Composition	Each 2.5ml vial contains: Atracurium Besylate…….25mg
Diary No. Date of R& I & fee	Dy. No 17946 Dated 15-05-2018, Rs. 50,000/- 15-05-2018
Pharmacological Group	muscle relaxant
Type of Form	Form 5
Finished product Specifications	USP Specification
Pack size & Demanded Price	5'sx2.5ml
Approval status of product in Reference Regulatory Authorities	Atracurium 10mg/ml Solution for Injection or Infusion (UK)
Me-too status	Efacurim 25mg /2.5ml I.V Injection of M/s Pharmedic
GMP status	Last GMP inspection dated 5th & 27th December conclusion by Panel "The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection"
Remarks of the Evaluator	
Decision: Approved	
Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals Pvt. Ltd. H.I.T.E. Baluchistan Contract Manufactured By: M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore
Brand Name +Dosage Form + Strength	Atracurium Besylate 50mg/5ml Injection
Composition	Each 5ml vial contains: Atracurium Besylate…….50mg
Diary No. Date of R& I & fee	Dy. No 17947 Dated 15-05-2018, Rs. 50,000/- 15-05-2018
Pharmacological Group	muscle relaxant
Type of Form	Form 5
Finished product Specifications	USP Specification
Pack size & Demanded Price	5'sx5ml
Approval status of product in Reference Regulatory Authorities	Atracurium 10mg/ml Solution for Injection or Infusion (UK)
Me-too status	Arium Injection 50Mg of M/s Cirin
GMP status	Last GMP inspection dated 5th & 27th December conclusion by Panel "The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection"
Remarks of the Evaluator	
Decision: Approved	

Registration letter has been issued. However, the firm has now informed that their applied packaging material was "**Ampoule**" instead of "**Vial**". Original Dossier/ Form-5 couldn't be retrieved, however, the firm has submitted copy of form-5 wherein "Ampoule" is mentioned on 1st page and against S.No. 4 (strength of active ingredient per unit). Furthermore, the firm has also submitted a copy of approval for addition section issued to M/s NovaMed Pharmaceuticals (Pvt.) Ltd., Lahore (Contract Manufacturer) vide letter No.F.6-1/2013-Lic (M-232) dated 29-08-2013 stating following sections:

1. General Liquid Injection (Ampoule)
2. General Liquid Injection Vial (SVP)

Decision: Registration Board deferred the case for verification of applied packaging material/container closure system from original dossier submitted by the firm at the time of initial application.

Case No.8. Request of M/s Barret Hodgson, Karachi for correction in Demanded MRP of Opsilk Lubricant Eye Drops

Registration Board in its 275th meeting approved Opsilk Lubricant Eye Drops of M/s Barrett Hodgson Pakistan, F/423, S.I.T.E, Karachi as per below mentioned details:

Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan, F/423, S.I.T.E, Karachi.
Brand Name +Dosage Form + Strength	Opsilk Lubricant eye drops
Composition	Each ml contains: Polyethylene Glycol 400 …… 4 mg Propylene Glycol …….. 3 mg
Diary No. Date of R& I & fee	Dy. No.46; 06-07-2015; Rs.20,000/- (06-07-2015)
Pharmacological Group	Ocular lubricant
Type of Form	Form-5
Finished product Specification	Manufacturer specifications
Pack size & Demanded Price	**10ml; Rs.33.35/- 15ml; Rs.19.55/- 30 ml; Rs. 575/-**
Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
Me-too status	Systane Lubricant Eye Drops M/s Ali Gohar & Company (Pvt) Ltd., Karachi (Reg.# 044834)
GMP status	Last inspection report dated 8-8-2017 confirms satisfactory compliance to GMP
Remarks of the Evaluator.	
Decision: Approved with innovator's specification.	

Price has not been fixed for demanded pack sizes. Furthermore, MRP demanded for 10ml pack appears to be less than that approved for 5ml pack vide 12th DPC. Accordingly, as per practice in vogue, the case was referred to C&P Division for Price confirmation/fixation.

However, the firm has informed that there are discrepancies in demanded prices mentioned in M-275 (held on 25th - 27th Oct, 2019) and their applied demanded prices as per following details. Furthermore, the firm has also stated that they intimated timely via letter dated 2-04-2018. In this regard, the firm has also submitted copy of form-5 along-with undertaking because the original dossier couldn't be retrieved.

S/N	Pack Size	Actual Demanded Price On Form-5 at the Time of Registration Application	Demanded Price Erroneously Mentioned in Minutes of 275th Meeting
1.	10ml	Rs.210/-	Rs.33.35/-
2.	15 ml	Rs.300/-	Rs.19.55/-
3.	30ml	Rs.575/-	Rs.575/-

Decision: Registration Board deferred the case for verification of demanded MRP from original dossier submitted by the firm at the time of initial application.

Case No.9. Issuance of duplicate registration letter of "Paingay Ointment" (Reg. No. 012777) of M/s Marvi Pharmaceuticals, Karachi

M/s Marvi Pharmaceuticals, Karachi has requested for issuance of duplicate registration letter of their product "Pain Gay Ointment" containing Methyl Salicylate 150mg + Menthol 100mg (Methyl Salicylate 15% + Menthol 10%), Registration number 012777.

The case regarding renewal has been discussed in various meetings of Registration Board & in last meeting i.e., 292nd it was decided that ***the firm will be asked to apply for issuance of duplicate registration letter for further grant of renewal.***

Detail of the complete case is as under:

i. M/s Marvi Pharmaceuticals, Karachi applied for regularization of renewal of registration of following product of year 2015 vide SRO 1005(I)/2017 05th October, 2017 along with 3 times applicable fee i.e. Rs.30,000. The firm was advised to submit the evidence of initial registration letter and post registration variation (if any) for further preceding the case. In reply, the firm submitted only the evidence of renewal of year 2010. However, the firm was again requested for

submission of initial registration letter. In response, they stated that due to ill health followed by demise of one of their directors, several documents were stolen or misplaced/ lost including registration letters issued by Ministry of Health. Due to the reason they fail to apply renewal within due time. The firm has also submitted the copy of daily dairy record of concerned Police Station regarding the report of stolen/ misplaced/ lost registration letter. In this regard the case has been placed in various Registration Board meetings with the detail of evidence of registration in the name of M/s Marvi i.e as under :

ii. The product "Pain-Gay Ointment", Registration # 012777 was registered in the name of M/s Marvi, Karachi with reference to record available in the form of National Formulary, RDI database and provisional list of registered medicines available on official website of DRAP.

iii. Furthermore, registration letter number along-with date of registration and the then MRP/pack sizes of the product have been mentioned in register containing old record of registered products (Column III & IV of below table). Detail of product is as under:

Reg. No.	Brand Name & Composition (As per National Formulary)	Reg. Letter No. & Date of registration (As per Register)	MRP/ Pack size (As per Register)
I	**II**	**III**	**IV**
012777	Pain Gay Ointment Methyl Salicylate….....15gm Menthol……...10gm	F.3-6/91-Reg-II (M-94) dated 18-07-1991	Rs.4.50/30gm Rs.7.25/45gm

iv. Further to inform that the same brand name i.e., Pain-Gay Cream (R# 060314) has also been registered in the name of M/s Friends Pharma (Pvt) Ltd., Lahore, having same composition as that of Pain-Gay Ointment.

In the light of above submission the case has been placed before the Registration Board for issuance of **duplicate** registration letter as well as regularization of onward renewal of registration.

Decision: **Registration Board decided to refer the case to Legal Affairs Division, DRAP along-with complete details regarding available facts and seek guidance regarding contents of duplicate registration letter especially with reference to mentioning of MRP.**

Case No.10. Court Case Filed by M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd. Karachi versus FOP & others in Sindh High Court, Karachi

Registration Board in its various meeting considered the case regarding *"Risks and Cncerns associated with mislabeled Dydrogesterone"* and referred the case to the Appellate Board with the request to review the decision taken vide its 134th meeting, held on 17-06-2008 with respect to appeal filed by M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd. Karachi.

The case was considered by the Appellate Board in its 152nd meeting held on 24th and 25th April, 2019 and order dated 26.04.2019 was passed, whereby the Appellate Board directed the pharmaceutical Evaluation and Registration Division to ensure that all registered formulation/products and evaluation of Dydrogesterone products must comply with the official pharmacopeial monograph i.e USP. The board further directed the division of QA&LT to allow the import of API for registered products of Dydrogesterone as per official monograph only and to issue a circular for information of all concerned.

Accordingly, Registration Board (in its 289th meeting) advised to comply directions / decision of Appellate Board.

Later on, M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd. Karachi filed suit No. 840/2019 versus FOP & others in Sindh High Court, wherein the the decision of Appellate Board was challenged and stay has been granted to M/s Zafa vide court order dated 10-05-2019. Accordingly, all registration holders of dydrogesterone containing products (including fixed dose combinations) were issued letters regarding "Conformance to USP Specifications" except M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd. Karachi.

Recently, a copy of order dated 13.03.2020 passed by the Hon'ble High Court of Sindh, Karachi in CMA No. 7247/2019 in Suit No. 840/2019 filed by M/s. Zafa Pharmaceutical Labs (Pvt) Ltd Vs. Federation of Pakistan and Others has been received from Deputy Director (Legal Affairs). It has been informed that *the Hon'ble Court has allowed the aforesaid CMA and suspended the impugned order*

dated 26.04.2019 passed by the Drug Appellate Board to the extent of the Plaintiff till final decision in the Suit. However, it is clarified by the court that suspending the impugned order dated 26.04.2019 does not , in any manner, overrides or can be considered as an impediment for the Registration Board to act in accordance with Section 7(11) of the Drugs Act, 1976, and so also Rule 27 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Section 7(11) reflects that if the Registration Board, on the basis of information received or any inquiry conducted by it, is of the opinion that the registration of a drug was procured by fraud or misrepresentation; or the circumstances in which a drug was registered no longer exist; or there has been a violation of the conditions subject to which a drug was registered; or it is necessary in the public interest so to do; the Registration Board may, after affording opportunity of showing cause to the person on whose application the drug was registered for the action proposed to be taken including its cancellation, suspension or specifying any further conditions, to which the said registration shall be subject to.

Furthermore, in pursuance to aforementioned order, a complaint has been received from M/s Abbott Laboratories Pakistan Ltd. requesting to consider it as a fresh complaint in respect of the mislabeled product i.e. Dirogest, which is claimed to contain the 'Cis-Isomer of Dydrogesterone' or '6-Dehydroprogesterone'. The firm has requested the Registration Board to issue notice to both Zafa and Abbott for a hearing in respect of the cancellation/suspension of the registration of Dirogest and if their complaint is found to be correct, then the Registration Board may be pleased to either suspend the registration of Dirogest till Zafa is able to provide internationally recognized clinical data and scientific evidence supporting the safety, efficacy and quality of Dirogest or cancel the registration.

Decision: **Registration Board deliberated and decided the case as under:**

Member from Law and Justice reviewed the court order dated 13.03.2020 and apprised that the Board can proceed in accordance with Section 7(11) of the Drugs Act, 1976 in all other cases except "Dirogest Tablet (R#024214)" of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd., Karachi for which the Hon'ble Court has allowed the CMA No. 7247/2019 and suspended the impugned order dated 26.04.2019 passed by the Drug Appellate Board till final decision in the Suit No. 840/2019.

Accordingly Registration board decided/advised to prepare a fresh reference for the Hon'ble Sindh Court including complete details of the case on which the Drug Appellate Board passed order dated 26.04.2019 along-with proceedings of current meeting and request for urgent hearing in the case.

Case No.11. Request of M/s Abbott, Karachi for Registered Products Containing Dydrogesterone

Registration Board in its 289th meeting, held on 14th-15th May, 2019 considered the case regarding ***"Risks and Concerns associated with Dydrogesterone"*** and advised to comply directions /decision of Appellate Board i.e., as under:

> ***"The Appellate Board directed the pharmaceutical Evaluation and Registration Division to ensure that all registered formulation/ products and evaluation of Dydrogesterone products must comply with the official pharmacopeial monograph i.e USP."***

Accordingly, all registration holders of dydrogesterone containing products (including fixed dose combinations) were issued letter regarding "Conformance to USP Specifications".

Later on, M/s Abbott responded w.r.t to their following registered products stating that Abbott's Dydrogesterone (API) and Duphaston (Finished Product) is a research-based API and the Finished Product respectively. Hence being the Innovator, Abbott follows the in-house Manufacturers Specifications for the release of API and the Finished Product. In addition, the Appellate Boards in its own proceeding has accepted Abbott's Dydrogesterone as original molecule. Moreover, Abbott is also inventor of European Pharmacopoeia monograph for this molecule and internal specification/methods are fully aligned with European Pharmacopoeia. As product is not marketed in US for commercial reason, USP monograph will be withdrawn accordingly to USP committee notification to Abbott.

Furthermore, w.r.t products at Sr.No.02-04 (below table), the firm also informed that the products are imported as Finished Products and currently none of the combination listed above are part of USP. Abbott being the innovator for these products, the internal specification/methods are fully aligned with European Pharmacopoeia. Hence, considering above facts and information, the firm requested to be exempted from conformance to USP Specifications for above listed products.

Sr.No	Reg. No.	Brand Name of Drug(s) with Composition
1.	006654	Duphaston 10mg Tablet Each tablet contains: Dydrogesterone…….10mg
2.	027349	Femoston 1/10 Tablets Each tablet of one strip (14 Tabs.) contains: Estradiol…….……..1mg Each tablet of 2nd strip (14 Tabs.) contains: Estradiol…….……..1mg Dydrogesterone……...…….10mg
3.	019420	Femoston (R) 2/10 Tablets Each tablet contains: Estradiol Miconized……..2mg Dydrogesterone Miconized …….10mg
4.	027354	Femoston Conti Tablets Each film coated tablet contains: Estradiol……1mg Dydrogesterone…….5mg

- Dydrogesterone is a research molecule of Abbott Laboratories.
- Dydrogesterone is manufactured using a unique technology in which normal steroid structure of Proketal is converted into retrosteroid i.e Retroketal under the influence of UV light. This Retroketal is then converted into Dydrogesterone. No chemical alternative exists to achieve the same conversion from steroid to retrosteroid ring system.
- Nowhere in the world, Dydrogesterone is manufactured as a generic whether be stringent regulatory authority or any other country. This is evident by extract from Martindale 39th edition. Despite mentioned in USP.
- All claimed data available by research companies of more than 649 published articles is conducted on Abbott's Dydrogesterone which established clinical safety/efficacy of the API.
- The registered specifications of Dydrogesterone is manufacturer's (Originator) Specs hence there is no change in specifications of Dydrogesterone for already approved registered specifications by the Registration Board.

M/s Abbott has also submitted statement from Abbott Healthcare B.V. The Netherlands regarding comparison of Abbott in-house Specifications vs USP Specifications stating that ***"specifications of Abbott (who is the innovator of the product) are more stringent than the USP Specifications. The method use by Abbott and the method described in the USP are equivalent. It is claimed that Abbotts Specification is superior to the specification as given in the USP monograph for Dydrogesterone."***

Table 1. Abbott in-house specification versus USP specification

Test	In-house Acceptance Criteria	USP Acceptance Criteria
Appearance	A Round, biconvex, scored white film-coated tablet, one side with inscription '155' on either side of the score.	-
Identification		
Infrared Spectroscopy	-	Corresponds to reference
Retention time (HPLC)	Positive	-
UV spectrum	Positive	-
Colour additive Titanium dioxide	Positive	-
Purity (HPLC)		-
Unspecified , each	≤0.2%	-
Sum of degradation products (HPLC)	≤1.0%	-
Content		
Dydrogesterone (HPLC,mg/tablet)	9.5-10.5	90-110% of label claim
Uniformity of dosage units	Complies with EP 2.9.40	Meet the requirement <905>
Average tablet weight (mg)	136.8-151.2	-
Dissolution	Q= 75% after 45 min	Q= 75% at 60 min

Microbiological quality TAMC(Total aerobic microbial count) TYMC(Total aerobic yeasts/moulds count) Escherichia coli	Complies with Ph.Eur. 5.1.4 (non-aqueous preparations for oral use) $<10^3$ CFU/g $<10^2$ CFU/g absent /g	-

Table 2. Abbott in-house specification versus USP specification

Test	Abbot in-house methods (=Innovator FPT method)	USP methods
Appearance	Visual	-
Identification		
Infared	IR	IR
Retention time (HPLC)	HPLC (same method as used for determination of the content)	-
UV spectrum	HPLC Diode array (same method as used for determination of the content)	-
Colour additive titanium dioxide	Color reaction	-
Purity (HPLC)	Same method as used for determination of the content	-
Unspecified , each		-
Sum of degradation products (HPLC)		-
Content Dydrogesterone (HPLC)	310nm C18 column 4.6mmx15cm; 3µm particles Column temperature 40°C Flow:1ml/min Water/acetonitrile (600:425) Injection of 20ul of 0.1mg/ml solution	280nm C18 column 4.6mmx15cm; 3µm particles Column temperature 40°C Flow:1ml/min Water/ethanol/acetonitrile (530:260:210) Injection of 20ul of 0.1mg/ml solution
Uniformity of dosage units[1)]	Complies with EP 2.9.40	Meet the requirement <905>
Average tablet weight (mg)	Weighing	-
Dissolution	0.3% SLS, 500ml 100rpm NLT 75% (=Q) dissolved in 45 min	0.3% SLS, 500ml 100rpm NLT 75% (=Q) dissolved in 60 min
Microbiological quality	Ph.Eur 2.6.12 Ph.Eur 2.6.13	-
TAMC(Total aerobic microbial count)		
TYMC(Total aerobic yeasts/moulds count)		
Escherichia coli		

1) EP 2.9.40 and USP <905> method for uniformity of dosage units are harmonized.

Decision of M-293:

Registration Board advised the firm to submit numeric ranges of analytical results instead of mentioning statements such as "meet the requirements" or "complies" for all pharmacopeial parameters to establish that their limits are more stringent to pharmacopeial limits.

The firm has now submitted following documents:

i. EP monograph (EP 2.9.40)
ii. EP monograph (EP 2.6.12)
iii. EP monograph (EP 2.6.13)
iv. USP monograph <905>
v. In-house testing methods with ranges and test records

vi. Certificate of Analysis of Dupahston 10mg Tablet
vii. Letter from Abbott Healthcare Products B.V. The Netherlands, for numeric values and pharmacopoeial references.

Table- 3

Test	In-house Acceptance Criteria Highnoon	Acceptance Criteria USP
Appearance	A Round, biconvex, scored white film coated tablet, one side inscribed with '155' and break mark.	-
Identification		
Retention time (HPLC)	Corresponds to reference	-
Infrared Spectroscopy	-	Corresponds to reference
Average tablet weight (mg)	144mg (139.7-148.3mg)	-
Weight Variation	18/20± 7.5% (133-155mg) 2/20± 15% (122-166mg)	-
Disintegration	Not more than 30minutes	-
Dissolution	Q= 75% after 45 min	Q= 75% after 60 min
Content Uniformity	85.00-115.00%	Meet the requirement <905>
Purity		
Sum of degradation products (HPLC)	Not more than 1.0%	-
Assay	95.00-105.00%	90-110%

- Both the in-house specification and the USP specification include a test on identification using a reference standard, applying HPLC or infrared spectroscopy, respectively.
- The in-house specifications has additional test parameters included:
  Appearance, average weight, weight variation, disintegration, purity.
- The acceptance criteria for dissolution and assay are more stringent for the in-house specification compared to the USP specification.

In support of their request the firm has further stated:

1. The Appellate Board passed the Order dated: 26-04-2019 whereby, it directed the Pharmaceutical Evaluation and Registration Division to ensure that all registered formulations of Dydrogesterone products must comply with the official pharmocopeial monograph i.e. USP. It is essential to understand the reason why the said Order was passed and on what basis it was passed. Firstly, the Order dated: 26-04-2019 was passed on the specific complaint filed by Abbott in respect of mislabeled and misbranded products claiming to contain Dydrogesterone. Secondly, the Order dated: 26-04-2019 was passed making our product, Duphaston, and the molecule Dydrogesterone, the criterion for safety and efficacy to judge other products. Thirdly, the evidence provided by Abbott was considered as the basis for safety and efficacy of all registered manufacturers of products containing, or claiming to contain, Dydrogesterone. Therefore, it follows from the above that the aforementioned Order dated: 26-04-2019 was passed on our Complaint, on the basis of our product and molecule as a benchmark for judging other products and in view of the evidence submitted by Abbott in relation thereto. Hence, the safety and efficacy of Abbott's product, Duphaston and its molecule, Dydrogesterone was impliedly upheld by the Appellate Board vide the Order dated: 26-04-2019.
2. It is obvious from the aforementioned that the purpose and spirit of the Order dated: 26-04-2019 is to ensure the safety and efficacy of all registered formulations of products containing, or claiming to contain, Dydrogesterone, which is why the Appellate Board has directed that the USP specifications be complied with. However, as explained to you in our previous correspondence, the in-house specification used by M/s Highnoon Laboratories Limited, who manufactures Duphaston for Abbott under a Contract Manufacturing Agreement, is more stringent than the USP specification and the methods used by Highnoon are equivalent to those described in the USP. It is submitted that the in-house specification is superior to the specification as given in the USP monograph. Therefore, as no question has been raised on

the safety and efficacy of Duphaston and the in-house specification used for its manufacture are more stringent, it is obvious and apparent that Abbott is in compliance with the spirit and purpose of the Appellate Board Order dated: 26-04-2019, which is to ensure the safety and efficacy of all registered products containing, or claiming to contain, Dydrogesterone.

3. In view of the foregoing, it is requested that the in-house stringent specifications and methods used by Abbott may be considered and approved as they are in compliance with the spirit and purpose of the Appellate Board Order dated: 26.04.2019.

Decision: **Registration Board acceded to the request of M/s Abbott Laboratories (Pakistan) Ltd., Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi to continue with "Manufacturer's Specifications" of Duphaston Tablet 10mg (R#006654) for being more stringent than "USP Specifications". The Board also advised to mention complete specifications (as mentioned in Table-3 above) on approval letter.**

Case No.12. **Request of M/s Pfizer Pakistan Limited, Karachi for issuance of Innovator's specifications for Zoloft Tablet (Reg. No.)**

Registration Board in its 278th meeting approved Zoloft Tablet of M/s Pfizer Pakistan, Limited, B-2 SITE Karachi as per below mentioned details:

Name and address of manufacturer / Applicant	M/s Pfizer Pakistan Limited, Head Office: 12, Dockyard Road, West Wharf, Karachi. Plant site:B-2 SITE, Karachi
Brand Name +Dosage Form + Strength	ZOLOFT Tablets 100mg
Composition	Each film coated tablet contains: Sertraline as HCl…… 100mg
Diary No. Date of R& I & fee	Dy. No. 944, Dated 16/11/2015, Rs 20,000/= Dated 16/11/2015,
Pharmacological Group	Anti-Depressant (SSRI Inhibitor)
Type of Form	Form – 5
Finished product Specifications	USP
Pack size & Demanded Price	Pack Size: 3×30's/ Price: As per S.R.O
Approval status of product in Reference Regulatory Authorities	Lustral film coated tablets 100mg by M/s Pfizer, MHRA Approved.
Me-too status	Ertalin 100mg tablet by M/s Genome Pharmaceuticals (Reg # 076845)
GMP status	Last inspection report Dated 16/05/2016 confirms the maintenance of GMP in warehouse, manufacturing and packaging areas.
Remarks of the Evaluator	• The firm has claimed In House manufacturing specifications while the product is present in USP/BP. • Registration letter for the same product was issued to the firm on 27th December, 1997 for the same product. The firm has stated that the product could not be renewed in time and the registration became invalid. The firm has submitted the application for re-registration of the product.
Previous Decision	Deferred in 274th meeting for the submission of last inspection report conducted within the last one year.
Evaluation by PEC	• Panel inspection conducted on 30-10-2017 found an optimal level of compliance and unanimously recommended the renewal of DML. • However, it was advised that the firm must have separate facility for manufacturing of their only registered corticosteroid products.
Decision: Approved as per Innovator's specifications.	

In the light of decision taken by the Central Licensing & Registration Board in its 197th meeting held on 3rd - 4th May, 2006 (reproduced below) and subsequently decision taken by the Registration Board in its 267th meeting, Registration letter of "Zoloft Tablet" was issued with "**USP Specification**" as USP monograph is available for "**Sertraline Hydrochloride Tablet**".

Decision of M-197

"All the firms shall adopt the specifications mentioned in the official pharmacopeias for all the formulations except those drugs not included in the official pharmacopeias. For these drugs manufacturer may adopt their own specifications till the inclusion of that formulation in the official pharmacopeias. After this decision firms will not be allowed to adopt their own specifications for the drugs which are included in any of the official pharmacopeias, listed in the section 3 of Drugs Act, 1976"

M/s Pfizer Pakistan has now requested for issuance of corrigendum regarding finished product specifications stating that the product was approved in M-278 with "As per innovator's Specifications", however, the approval letter bears "USP Specifications". In this regard, the firm has also informed that all the parameters of shelf life and release specifications are same as USP Specification except one Pfizer release parameter i.e., **Assay** which is more stringent than USP. Following specifications comparison of Sertraline Hydrochloride Tablet has also been submitted by the firm:

Sr.No.	Test	USP Specification	Pfizer Specification (Shelf Life)	Pfizer Specification (Release)
1.	Identification	By HPLC	BY HPLC	BY HPLC
2.	Weight Variation	± 7.5% of its average weight	N/A	± 7.5% of its average weight
3.	Assay	**90.0%-110.0%**	**90.0%-110.0%**	**95.0%-105.0%**
4.	Dissolution Test	NLT 85%	NLT 85%	NLT 85%
5.	Content Uniformity	L1 NMT 15.0	N/A	L1 NMT 15.0

Decision: Registration Board deferred the case and advised the firm to submit complete comparison including all testing parameters mentioned in updated edition of USP.

Case No.12. Request of M/s GSK Pakistan Limited, Karachi for Regularization of Manufacturing Site Address.

M/s GSK Pakistan Limited, Karachi has applied for regularization of manufacturing sites of their already registered locally manufactured products stating that:

- The site address mentioned on initial registration certificate of the product was not specific to actual manufacturing site.
- Historically, the practice of mentioning specific manufacturing site address was not regular which time and again resulted in queries.
- The product practically cannot be manufactured at any other GSK site except West Wharf site since our manufacturing sites have specific sections for dosage forms.

In this regard, the firm has submitted the following information/ documents:

i. Fee of Rs.5000/- per product.
ii. Evidence confirming approval of relevant manufacturing facility/section (i.e., copy of section approval issued by Licensing Division/ Panel Inspection Report for renewal of DML)
iii. Copies of initial registration letters/certificates along-with post registration approvals (where available) confirming current manufacturing sites.
iv. Previous and current in-use cartons.
v. Copies of Form-5B submitted for renewal.

Detail of Approved Sections		
GSK Pakistan Ltd., 35-Dockyard Road West Wharf, Karachi (DML 000017)		
S.No.	**Name of Section**	**Reference**
1.	Ointment (General)	No.F.2-2/2000-Lic (Vol-II) dated 04-10-2019
2.	Ear Drops	-do-
3.	Oral Powder ENO Section	-do-
4.	Non Pariel Seeds (NPS)- (In house only)	-do-
5.	Capsules/ Spansules (General)	-do-
6.	Eye Ointment	-do-
GSK Pakistan Ltd., F-268, S.I.T.E, Karachi (DML 000233)		
1.	Tablet (New)	No.F.2-11/97-Lic (M-156) dated 19-12-2000
2.	Tablet (Penicillin)	No.F.2-18/2000-Lic (M-211) dated 27-12-

		2007
3.	Capsule (Penicillin)	-do-
4.	Dry Powder Suspension (Penicillin)	-do-
5.	Dry Powder Drops (Penicillin)	-do-
6.	Liquid (General) Section	Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019

TABLE-I

West Wharf Site Product List

S/N	Reg.No	Brand Name & Composition	Initial Date of Registration & Address mentioned on Initial Registration Letter	Transfer from M/s GSK Wellcome to M/s GSK Pakistan Ltd. & Address mentioned on Registration Transfer Letter	Section Approval / Last Inspection Reports	Supporting Documents/ Evidence Confirming Manufacturing Site Address
Cases with Evidence (DRA Approvals) Confirming Manufacturing Site						
1	010399	Bactroban Ointment Contains: Mupirocin 2% w/w	19-02-1990 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ointment (General) Section Approval dated 04-10-2019	Renewal of registration issued vide letter No. F.3-10/2019-RRR (M-288) dated 27-06-2019 Validity: 30-08-2018 to 29-08-2023
2	000249	Betnesol eye ointment Betamethasone sodium phosphate 0.1% w/w	20-04-1976 Glaxo Laboratories (Pakistan) Limited, West Wharf, Karachi	-do-	Eye Ointment Section Approval dated 04-10-2019	-do-
3	000251	Betnesol N eye ointment Betamethasone sodium phosphate 0.1% w/w, Neomycin Sulphate 0.5% w/w	20-04-1976 Glaxo Laboratories (Pakistan) Limited, West Wharf, Karachi	-do-	Eye Ointment Section Approval dated 04-10-2019	-do-
4	000256	Betnovate cream Betamethasone as Betamethasone Valerate 0.1% w/w	20-04-1976 Glaxo Laboratories (Pakistan) Limited, West Wharf, Karachi	-do-	Ointment (General) Section Approval dated 04-10-2019	-do-
5	000253	Betnovate lotion Betamethasone as Betamethasone Valerate 0.1% w/v	20-04-1976 Glaxo Laboratories (Pakistan) Limited, West Wharf, Karachi	-do-	Ointment (General) Section Approval dated 04-10-2019	-do-
6	000254	Betnovate N cream Betamethasone as Betamethasone Valerate 0.1% w/w, Neomycin Sulphate 0.5% w/w	20-04-1976 Glaxo Laboratories (Pakistan) Limited, West Wharf, Karachi	-do-	Ointment (General) Section Approval dated 04-10-2019	-do-

7	000252	Betnovate N lotion Betamethasone as Betamethasone Valerate 0.1% w/v, Neomycin Sulphate 0.5% w/v	20-04-1976 Glaxo Laboratories (Pakistan) Limited, West Wharf, Karachi	-do-	Ointment (General) Section Approval dated 04-10-2019	-do-
8	000255	Betnovate N ointment Betamethasone as Betamethasone Valerare 0.1% w/w, Neomycin Sulphate 0.5% w/w	20-04-1976 Glaxo Laboratories (Pakistan) Limited, West Wharf, Karachi	-do-	Ointment (General) Section Approval dated 04-10-2019	-do-
9	000257	Betnovate ointment Betamethasone as Betamethasone Valerate 0.1% w/w	20-04-1976 Glaxo Laboratories (Pakistan) Limited, West Wharf, Karachi	-do-	Ointment (General) Section Approval dated 04-10-2019	-do-
10	028094	Bactroban Cream Mupirocin Calcium (Micronized) (as Mupirocin free acid) 2% w/w	12-07-2002 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi Toll manufactured by M/s S.K & F, Karachi	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-4/2008-Reg-II(s) dated 17-07-2008 for approval of packing material along-with copy of Form-5B and unit cartons. Last renewal applied on 03-09-2018
11	027811	Cutivate cream Contains: Fluticasone Propionate 0.05%w/w	04-05-2002 GlaxoWelcome Pakistan Ltd., Karachi	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-4/2008-Reg-II(s) dated 17-07-2008 for approval of packing material along-with copy of Form-5B and unit cartons. Last renewal applied on 03-09-2018
12	045446	Cutivate Ointment 0.005% Each gram contains: Fluticasone Propionate (micronized) HSE….50 microgram	28-06-2007 Glaxo Smith Kline B-63, Estate Avenue, S.I.T.E., Karachi	Transfer Not Applicable However, the firm has submitted copy of GMP inspection report (30-05-2019) of GSK Pakistan Ltd., 35-DockYard Road, West Wharf, Karachi stating sampling of Cutivate Ointment (B.No. ICVAM) for test and analysis	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-1/2014-DDC(P) dated 06-05-2016 for approval of additional pack along-with copy of Form-5B and unit cartons. Last renewal applied on 30-05-2017
13	003100	Dermovate cream Clobetasone Propionate0.05% w/w	10-12-1977 Glaxo Laboratories (pak) Ltd., Press Trust House, I.I.Chundrigarh Road,	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE,	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-1/2014-DDC(P) dated 10-08-2016 for approval of additional pack

			Karachi	Karachi.		along-with copy of Form-5B and unit cartons. Last renewal applied on 20-07-2018
14	006230	Dermovate NN ointment Contains: Clobetasole Propionate 0.05% w/w, Neomycin Sulphate 0.5% w/w Nystatin 100,000 units per gram	16-03-1982 Glaxo Laboratories (Pakistan)Limited, P.O.Box No. 4674, Karachi	-do-	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-1/2014-DDC(P) dated 10-08-2016 for approval of additional pack along-with copy of Form-5B and unit cartons. Last renewal applied on 20-07-2018
15	003139	Dermovate ointment Clobetasole Propionate 0.05% w/w	10-12-1977 Glaxo Laboratories (pak) Ltd., Press Trust House, I.I.Chundrigarh Road, Karachi	-do-	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-1/2014-DDC(P) dated 10-08-2016 for approval of additional pack along-with copy of Form-5B and unit cartons. Last renewal applied on 20-07-2018
16	000401	Fefol Spansule Each spansule capsule contains: Exsiccated Ferrous Sulphate 150mg + Folic acid 0.5mg	24-03-1976 Smith Kline and French of Pakistan Ltd., Karachi	-do-	Capsule/ Spansules (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-1/2010-DDC(P)-Vol-1 dated 25-01-2011 for approval of additional pack along-with copy of Form-5B and unit cartons. Last renewal applied on 28-07-2018
17	004129	Fefol-Vit Spansule Each spansule capsule contains: Exsiccated Ferrous Sulphate 150mg, Folic Acid 0.5mg, Vitamin B1 2mg, Vitamin B2 2mg, Vitamin B 6 1mg, Nicotinamide 10mg, Vitamin C 50mg	30-05-1978 Spencer and Co. (Pak) Ltd. Spencer's Building, I.I.Chundrigar Road, Karachi Manufacturer: S.K & F	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule/ Spansules (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-1/2010-DDC(P)- dated 20-02-2010 for approval of additional pack along-with copy of Form-5B and unit cartons. Last renewal applied on 04-09-2018
18	000365	Lidosporin ear drops Polymyxin B Sulphate 10,000 Units, Lignocaine HCl 50mg, Propylene Glycol 0.92ml	17-04-1976 Welcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ear Drops Section Approval dated 04-10-2019	Copy of Letter No. F.1-29/2004-Reg-II(s)(Pt-II)- dated 05-06-2007 for shifting of printing material from manual packing to automatic cartooning machines along-with copy of Form-5B and unit

						cartons. Last renewal applied on 20-07-2018
19	010516	Lotrix cream Permethrine(5% w/w)	13-03-1990 Wellcome Pakistan Ltd. P.O. Box 3696,D/43, Taxtile Avenue, S.I.T.E., Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-4/2008-Reg-II(s) dated 17-07-2008 for approval of packing material along-with copy of Form-5B and unit cartons. Last renewal applied on 04-09-2018
20	000370	Otosporin ear drops Polymyxin B sulphate 10,000 units, Hydrocortisone Acetate 10mg, Neomycin 3400 units	17-04-1976 Welcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ear Drops Section Approval dated 04-10-2019	Copy of Letter No. F.1-29/2004-Reg-II(s)(Pt-II)- dated 05-06-2007 for shifting of printing material from manual packing to automatic cartooning machines along-with copy of Form-5B and unit cartons. Last renewal applied on 20-07-2018
21	000372	Polyfax eye ointment Polymyxin B sulphate 10,000 units, Bacitracin zinc 500units, Petroleum Base 1gm	17-04-1976 Welcome Pakistan Ltd., Karachi	-do-	Eye Ointment Section Approval dated 04-10-2019	Copy of Letter No. F.3-8/2003-Price dated 16-06-2003 for approval of additional pack along-with copy of Form-5B and unit cartons. Last renewal applied on 02-08-2018
22	023511	Polyfax plus skin ointment Each gram contains: Polymyxin B sulphate 10,000 units Bacitracin zinc 500units Lignocaine 40mg	16-04-1999 Glaxo Wellcome Pakistan Ltd., F/268, S.I.T.E., Karachi-75700	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-1/2010-DDC(P)-Vol-II dated 11-12-2012 for approval of additional pack along-with copy of Form-5B and unit cartons. Last renewal applied on 04-09-2018
23	013350	Ventolin respirator solution Salbutamol as Salbutamol Sulphate 0.5% w/v	25-05-1992 GlaxoLaboratories (Pakistan) Ltd., Dockyard Road, West Wharf, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Aerosol (General) Section HFA "**Not Recommended**" in panel inspection report for renewal of DML (dated 05-09-2019) **as per**	Copy of Letter No. F.1-54/2005-Reg-II(s) dated 23-08-2008 for approval of change of container and reduction in shelf life along-with copy of Form-5B and unit cartons.

					submission of the firm (stating constraints of economical and human resources)	Last renewal applied on 02-08-2018
24	017270	Pilzcin cream Each gm contains: Croconazole hydrochloride 10mg	27-04-1995 Welcome Pakistan Ltd., D/43, & F-268, S.I.T.E., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-4/2008-Reg-II(s) dated 27-07-2008 for approval of packing materials along-with copy of Form-5B and unit cartons. Last renewal applied on 20-07-2018
25	022433	Silvate cream Contains: Silver Sulphadiazine USP 1%w/w	26-11-1998 Glaxo Wellcome Pakistan Ltd., F/268, S.I.T.E., Karachi-75700	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ointment (General) Section Approval dated 04-10-2019	Copy of Letter No. F.3-17/97-Price dated 15-02-2000 for approval of additional pack along-with copy of Form-5B and unit cartons. Last renewal applied on 04-09-2018
26	004130	Fesovit - Z Spansule Capsule Each spansule capsule contains: Ferrous sulphate 150mg, Zinc Sulphate Monohydrate 6.18mg, vitamin C 50mg, Vitamin B1 2mg, Vitamin B2 2mg, Vitamin B6 1mg, Nicotinamide 10mg	30-05-1978 Spencer and Co. (Pak) Ltd. Spencer's Building, I.I.Chundrigar Road, Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Capsule/ Spansules (General) Section Approval dated 04-10-2019	Copy of Letter No. F.9-1/2010-DDC (P)-Vol-1dated 25-01-2011 for approval of additional pack along-with copy of Form-5B. Last renewal applied on 04-09-2018
Cases with Supporting Documents Stating Manufacturing Site						
27	000357	Cortisporin eye ointment Each gram contains: Polymyxin B Sulphate 5000 units, Neomycin Sulphate 3400 units, Bacitracin Zinc 400 units, Hydrocortisone 10mg, Petroleum Base 1gm	17-04-1976 Welcome Pakistan Ltd., Karachi	30-Aug-2003 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Eye Ointment Section Approval dated 04-10-2019	Copy of Form-5B and unit cartons Last renewal applied on 20-07-2018
28	000371	Polyfax skin ointment Contains:Polymyxin B sulphate 10,000 units, Bacitracin zinc 500units, Petroleum Base 1gm	17-04-1976 Welcome Pakistan Ltd., Karachi	30-08-2003 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Ointment (General) Section Approval dated 04-10-2019	Copy of Form-5B and unit cartons. Last renewal applied on 02-08-2018

29	020543	Fefol Z Spansule Each capsule contains: Dried Ferrous Sulphate 150mg, Zinc Sulphate Mono hydrate (Eq. to 22.5mg elemental zinc) 61.8mg,Folic Acid 0.5mg	12-11-1997 Smith Kline and French of Pakistan Ltd., Karachi B-63, Estate Avenue, S.I.T.E., Karachi	30-08-2003 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule/ Spansules (General) Section Approval dated 04-10-2019	Copy of Form-5B. Last renewal applied on 28-07-2018
30	000402	Feospan Z Spansule Capsule Exsiccated Ferrous Sulphate 150mg ,Zinc Sulphate monohydrate 61.8 mg	22-03-1976 Smith Kline and French of Pakistan Ltd., Karachi	30-08-2003 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule/ Spansules (General) Section Approval dated 04-10-2019	Copy of Form-5B. Last renewal applied on 28-07-2018
31	010890	Z-Spansule Capsule Each capsule contains: Zinc Sulphate Monohydrate 61.8mg B/N "Z-Span Spansule Capsule mentioned on Registration Letter	05-04-1990 Smith Kline and French of Pakistan Ltd., Karachi B-63, Estate Avenue, S.I.T.E., Karachi	30-08-2003 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule/ Spansules (General) Section Approval dated 04-10-2019	Copy of Form-5B. Last renewal applied on 02-08-2018

TABLE-II

F-268 Site Product List

S/ N	Reg.No	Brand Name & Composition	Initial Date of Registration & Address mentioned on Initial Registration Letter	Transfer from M/s GSK Wellcome to M/s GSK Pakistan Ltd. & Address mentioned on Registration Transfer Letter	Section Approval / Last Inspection Reports	Supporting Documents/ Evidence Confirming Manufacturing Site Address
Cases with Evidence (DRA Approvals) Confirming Manufacturing Site						
1	006669	Amoxil Capsule 500mg Each capsule contains: Amoxycillin Trihydrate eq. to Amoxycillin Base 500mg	20-07-1999 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-10/2019-RRR (M-288) dated 26-06-2019 Validity: 30-08-2018 to 29-08-2023
2	000509	Amoxil Drops 125mg Each 1.25ml contains: Amoxycillin as Amoxicillin Trihydrate 125mg	16-04-1976 Beecham Pakistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Drops (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-10/2019-RRR (M-288) dated 26-06-2019 Validity: 30-08-2018 to

						29-08-2023
3	000508	Amoxil Syrup 125mg Each 5ml contains: Amoxycillin as Amoxicillin Trihydrate 125mg	16-04-1976 Beecham Pkistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Suspension (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-10/2019-RRR (M-288) dated 26-06-2019 Validity: 30-08-2018 to 29-08-2023
4	006814	Amoxil Forte Syrup 250mg Each 5ml contains: Amoxycillin as Amoxicillin Trihydrate 250mg	07-03-1986 Beecham Pkistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Suspension (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-10/2019-RRR (M-288) dated 26-06-2019 Validity: 30-08-2018 to 29-08-2023
5	000182	Ampiclox Capsule 500mg Each capsule contains:Ampicillin Trihydrate eq. to Ampicillin Base 250mg, Cloxacillin Sodium eq. to Cloxacillin Base 250mg	20-07-1999 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-10/2019-RRR (M-288) dated 26-06-2019 Validity: 30-08-2018 to 29-08-2023
6	000183	Ampiclox drops 90mg Each 0.6ml contains: Ampicillin as Ampicillin Trihydrate 60mg, Cloxacillin as Cloxacillin Sodium 30mg	16-04-1976 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Drops (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-10/2019-RRR (M-288) dated 26-06-2019 Validity: 30-08-2018 to 29-08-2023
7	000194	Ampiclox syrup 250mg Each 5ml contains:Ampicillin Trihydrate eq. to Ampicillin Base 125mg, Cloxacillin Sodium eq. to Cloxacillin Base 125mg	16-04-1976 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Suspension (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-10/2019-RRR (M-288) dated 26-06-2019 Validity: 30-08-2018 to 29-08-2023

8	009264	Augmentin syrup Each 5ml contains: Amoxicillin trihydrate eq. to Amoxycillin 125mg Potassium Clavulanate eq. to Clavulanic Acid 31.25mg	16-03-1988 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Suspension (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-8/2018-RRR (M-286) dated 18-01-2019 Validity: 30-08-2018 to 29-08-2023
9	018360	Augmentin DS syrup Each 5ml contains: Amoxicillin trihydrate eq. to Amoxycillin 250mg Potassium Clavulanate eq. to Clavulanic Acid 62.50mg	18-10-1995 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Suspension (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-8/2018-RRR (M-286) dated 18-01-2019 Validity: 30-08-2018 to 29-08-2023
10	022244	Augmentin BD Tablet Each tablet contains: Amoxicillin trihydrate eq. to Amoxycillin 875mg Potassium Clavulanate eq. to Clavulanic Acid 125mg	29-08-1998 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-8/2018-RRR (M-286) dated 18-01-2019 Validity: 15-09-2018 to 14-09-2023
11	006747	Augmentin Tablets 375mg Each tablet contains: Amoxicillin trihydrate eq. to Amoxycillin 250mg Potassium Clavulanate eq. to Clavulanic Acid 125mg	01-04-1985 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-8/2018-RRR (M-286) dated 18-01-2019 Validity: 30-08-2018 to 29-08-2023
12	017297	Augmentin Tablets 625mg Each tablet contains: Amoxicillin trihydrate eq. to Amoxycillin 500mg Potassium Clavulanate eq. to Clavulanic Acid 125mg	11-06-1995 Beecham Pakistan (Pvt.) Ltd., 94 Deh Landhi, Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Renewal of registration issued vide letter No. F.3-8/2018-RRR (M-286) dated 18-01-2019 Validity: 30-08-2018 to 29-08-2023

13	048644	Actilix- CTZ Tablets Each tablet contains: Cetrizine Dihydrochloride ..10mg	21-06-2008 GlaxoSmithKline Pakistan Limited Ltd., 94 Deh Landhi, Karachi.	Transfer Not Applicable	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Last Renewal application of year 2018 approved by the RB Validity: 21-06-2018 to 20-06-2023
14	000213	Amoxil Capsule 250 mg Each capsule contains: Amoxycillin as Amoxycillin Trihydrate B.P 250mg	16-04-1976 Beecham Pakistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Copy of Letter No. F.9-24/2017-DD (P)-Vol-1dated 18-01-2019 for approval of additional pack along-with copy of Form-5B. Last renewal applied on 14-05-2018
15	000181	Ampiclox Capsule 250mg Each capsule contains: Ampicillin 125mg, Cloxacillin 125mg	16-04-1976 Beecham Pakistan Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Copy of Letter No. F.9-24/2017-DD (P)-Vol-1dated 18-01-2019 for approval of additional pack along-with copy of Form-5B. Last renewal applied on 14-05-2018
16	000260	Betnelan Tablets Betamethasone 0.5mg	15-08-1976 Glaxo Laboratories Ltd., West Wharf, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000 **Tablet (steroid) section is required for this product**	Copy of Letter No. F.9-24/2017-DD (P)-Vol-1dated 21-12-2018 for approval of additional pack along-with copy of Form-5B. Last renewal applied on 14-05-2018
17	000262	Betnesol Tablets Betamethasone sodium phosphate 0.5mg	15-08-1976 Glaxo Laboratories Ltd., West Wharf, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000 **Tablet (steroid) section is required for this product**	Copy of Letter No. F.9-24/2017-DD (P)-Vol-1dated 21-12-2018 for approval of additional pack along-with copy of Form-5B. Last renewal applied on 14-05-2018

18	012427	Calpol 6 plus suspension 250mg Each 5ml contains: Paracetamol 250mg	14-03-1991 Wellcome Pakistan Ltd., D/43, Textile Avenue, S.I.T.E., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Letter No. F.3-2/2018-Reg-II (M-279) (Misc)dated 06-06-2018 for approval of change in primary packaging material along-with copy of Form-5B. Last renewal applied on 20-07-2018
19	000354	Calpol paed. Suspension Each 5ml contains:Paracetamol 120mg	17-04-1976 Wellcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Letter No. F.3-2/2018-Reg-II (M-279) (Misc)dated 06-06-2018 for approval of change in primary packaging material along-with copy of Form-5B. Last renewal applied on 20-07-2018
20	000179	Maxolon Syrup Each 5ml contains: Metoclopramide hydrochloride 5mg	16-04-1976 Beecham Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Letter No. F.3-2/2018-Reg-II (M-279) (Misc)dated 06-06-2018 for approval of change in primary packaging material along-with copy of Form-5B. Last renewal applied on 20-07-2018
21	000299	Piriton Expectorant Linctus <u>Composition mentioned on PRV Approval:</u> Each 5ml contains: Ammonium Chloride 100mg, Chlorpheniramine Maleate 2 mg,	20-04-1976 Glaxo Laboratories (Pakistan) Ltd., West Wharf, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Letter No. F.3-2/2018-Reg-II (M-279) (Misc)dated 06-06-2018 for approval of change in primary packaging material along-with copy of Form-5B. Last renewal

		Sodium Citrate 60mg, Ephedrine HCl 2mg Menthol 1mg. <u>Composition as per Form 5B and Unit Carton:</u> Each 5ml contains: Ammonium Chloride 125mg, Chlorpheniramine Maleate 2.5mg, Sodium Citrate 55mg, Glycerine 150mg The firm has informed that controlled substance '**Ephedrine'** is not used in composition of this product. Furthermore, Evidence of in-use composition is verifiable with renewal form 5B and existing packaging material of the product				applied on 03-08-2018
22	000384	Septran suspension Each 5ml contains: Trimethoprim 40mg, Sulfamethoxazole 200mg	17-04-1976 Wellcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Letter No. F.3-2/2018-Reg-II (M-279) (Misc)dated 06-06-2018 for approval of change in primary packaging material along-with copy of Form-5B. Last renewal applied on 03-08-2018
23	000287	Ventolin Syrup Each 5ml contains: Salbutamol as Sulphate 2mg	20-04-1976 Glaxo Laboratories (Pakistan) Ltd., West Wharf, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Liquid (General) Section Panel Inspection Report for Renewal of DML dated	Copy of Letter No. F.3-2/2018-Reg-II (M-279) (Misc)dated 06-06-2018 for approval of change in

					26,27-03- & 01-04-2019	primary packaging material along-with copy of Form-5B. Last renewal applied on 03-08-2018
24	001628	Ventolin Tab 4mg Each tablet contains: Salbutamol 4mg	15-08-1976 Glaxo Laboratories Ltd., West Wharf, Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Letter No. F.9-24/2017-DD (P)-Vol-1 dated 21-12-2018 for approval of additional pack along-with copy of Form-5B. Last renewal applied on 14-05-2018
25	000381	Zyloric 100mg Tablets Each tablet contains: Allopurinol 100mg	17-04-1976 Wellcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Letter No. F.9-24/2017-DD (P)-Vol-1 dated 21-12-2018 for approval of additional pack along-with copy of Form-5B. Last renewal applied on 14-05-2018
Cases with Supporting Documents Stating Manufacturing Site						
26	000348	Actidil Elixir Each 5ml contains: Triprolidine HCl 1.25mg	17-04-1976 Wellcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 28-06-2018
27	000352	Angised Tablets Each tablet contains: Glyceryl Trinitrate 0.5mg	17-04-1976 Wellcome Pakistan Ltd., Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited,D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
28	021770	Calpol plus Tablets Each tablet contains: Paracetamol 500mg Caffeine 65mg	20-05-1998 Glaxo Wellcome Pakistan Ltd., F-268, S.I.T.E., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 20-07-2018

29	001612	Calpol Tablets Each tablet contains: Paracetamol 500mg	15-08-1976 Wellcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 20-07-2018
30	000355	Cicatrin Powder Neomycin 3300 units per gram, Bacitracin Zinc 250 units per gram	17-04-1976 Wellcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	The firm has informed that the details/ evidence of manufacturing section would be provided later. You may please defer this product at present	Copy of Form-5B. Last renewal applied on 20-07-2018
31	050687	CipVal 250mg Tablets Each tablet contains: Ciprofloxacin as Hydrochloride 250mg	23-09-2008 GlaxoSmithKline Pakistan Limited 35-DockYard Road, West Wharf, Karachi.	Transfer Not Applicable	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
32	050688	CipVal 500mg Tablets Each tablet contains: Ciprofloxacin as Hydrochloride 500mg	23-09-2008 GlaxoSmithKline Pakistan Limited 35-DockYard Road, West Wharf, Karachi.	Transfer Not Applicable	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
33	000363	Kemadrin Tablets Each tablet contains: Procyclidine Hydrochloride 5mg	17-04-1976 Wellcome Pakistan Ltd., Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
34	000364	Lanoxin Tablets Each tablet contains: Digoxin 0.25mg	17-04-1976 Wellcome Pakistan Ltd., Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
35	008382	Marzine Syrup Each 5ml contains: Cyclizine Hydrochloride 12.5mg	18-06-1985 Wellcome Pakistan Ltd., D/43, Taxtile Avenue, S.I.T.E., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 20-07-2018

36	000177	Maxolon 10mg Tablets Each tablet contains: Metoclopramide Hydrochloride 10mg	16-04-1976 Beecham Pkistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited,D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 14-05-2018
37	000383	Migril Tablets Each tablet contains: Caffeine hydrate 100mg, Cyclizine hydrochloride 50mg, Ergotamine tartrate 2mg.	17-04-1976 Wellcome Pakistan Ltd., Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
38	000188	Penbritin 250mg Capsules Each capsule contains: Ampicillin as Trihydrate 250mg	16-04-1976 Beecham Pakistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Capsule (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Copy of Form-5B. Last renewal applied on 03-08-2018
39	000189	Penbritin 500mg Capsules Each capsule contains: Ampicillin as Trihydrate 500mg	16-04-1976 Beecham Pkistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Capsule (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Copy of Form-5B. Last renewal applied on 03-08-2018
40	000217	Penbritin Drops Each 1.25ml contains: Ampicillin as Trihydrate 125mg	16-04-1976 Beecham Pkistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Drops (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Copy of Form-5B. Last renewal applied on 03-08-2018
41	000216	Penbritin Syrup 125mg Each 5ml contains: Ampicillin as Trihydrate 125mg	16-04-1976 Beecham Pkistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Dry Powder Suspension (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Copy of Form-5B. Last renewal applied on 03-08-2018
42	000293	Piriton Tablets Each tablet contains: Chlorpheniramine Maleate 4mg	20-04-1976 Glaxo Laboratories (Pakistan) Ltd., West Wharf, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018

43	008752	Septran DS suspension Each 5ml contains: Trimethoprim 80mg, SulfamethOxazole 400mg	24-02-1986 Wellcome Pakistan Ltd., D/43, Taxtile Avenue, S.I.T.E., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 03-08-2018
44	004926	Septran DS tablets Each tablet contains: Trimethoprim 160mg, Sulfamethoxazole 800mg	22-08-1979 Wellcome Pakistan Ltd., D/43, Taxtile Avenue, S.I.T.E., Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
45	000388	Septran Tablets Each tablet contains: Trimethoprim 80mg, Sulfamethoxazole 400mg	17-04-1976 Wellcome Pakistan Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited,D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018
46	000374	Thyroxine Tablets Each tablets contains: Thyroxine Sodium 50mcg	17-04-1976 Wellcome Pakistan Ltd., Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Approval of Hormone Tablet Section is required. However, the firm has submitted GMP inspection report of F268 site , conductedon 07-01-2014, 21-01-2014 & 19-02-2014, which contains brief of previous inspection (14-11-2012), stating "Thyroxine production is being carried out to maintain sustain market supply."	Copy of Form-5B. Last renewal applied on 04-09-2018
47	006226	Ventolin expectorant Each 5ml contains: Salbutamol as Sulphate 1mg, Guaiphenesin 50mg	03-02-1982 Glaxo Laboratories (Pakistan) Ltd., Off. Press Trust House, I.I.Chundrigar Road, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- &	Copy of Form-5B. Last renewal applied on 03-08-2018

					01-04-2019	
48	017692	Ventolin SR. tab. 4mg Each SR Tablet contains: Salbutamol as Sulphate 4mg	17-10-1995 Glaxo Laboratories (Pakistan) Ltd., West Wharf, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018
49	010807	Ventolin SR. tab. 8mg Each SR Tablet contains: Salbutamol as Sulphate 8mg	24-03-1990 Glaxo Laboratories (Pakistan) Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018
50	000286	Ventolin tab 2mg Each Tablet contains: Salbutamol as Sulphate 2mg	20-04-1976 Glaxo Laboratories (Pakistan) Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018
51	006520	Zantac tablets 150mg Each tablet contains: Ranitidine as Hydrochloride 150mg	16-09-1982 Glaxo Laboratories (Pakistan) Ltd., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 14-05-2018
52	022034	Zantac tablets 300mg Each tablet contains: Ranitidine as Hydrochloride 300mg	29-07-1998 Glaxo Wellcome Pakistan Ltd., F-268, S.I.T.E., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018
53	006730	Zentel Suspension Each 5ml contains: Albendazole 100mg	20-06-1985 Smith Kline & French of (Pak) Ltd.,B-63, Estate Avenue, S.I.T.E., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 03-08-2018
54	006729	Zentel Tablet 200mg Each tablet contains: Albendazole 200mg	20-06-1985 Smith Kline & French of (Pak) Ltd.,B-63, Estate Avenue, S.I.T.E., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited,D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018

55	004509	Zyloric 300mg tablets Each tablet contains: Allopurinol 300mg	20-11-1978 Wellcome Pakistan Ltd., D/43, Taxtile Avenue, S.I.T.E., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018
56	000068	Furadantin Tablet Each tablet contains: Nitrofurantoin 100mg	22-03-1976 Smith Kline & French of (Pak) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 20-07-2018
57	000301	Cytacon liquid Each 5ml contains: Cyanocobalamin 35mcg	20-04-1976 Glaxo Laboratories (Pakistan) Ltd., West Wharf, Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 20-07-2018
58	000400	Dependal - M Tab Each tablet contains: Furazolidone 100mg, Metronidazole 300mg	22-11-1984 Smith Kline & French of Pakistan Ltd., Karachi.	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
59	003709	Dependal - M Susp Each 5ml contains: Furazolidone 25mg, Metronidazole 75mg, Pectin 50mg, Kaolin 1gm	22-11-1984 Smith Kline & French of Pakistan Ltd., Karachi.	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 04-09-2018
60	000219	Orbenin Syrup 125mg Each 5ml contains: Cloxacillin as Cloxacillin Sodium 125mg	16-04-1976 Beecham Pkistan (Pvt.) Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Dry Powder Suspension (Penicillin) Section Approval dated No.F.2-18/2000-Lic (M-211) dated 27-12-2007	Copy of Form-5B. Last renewal applied on 20-07-2018
61	000813	Philip Milk of Magnesia Contains: Magnesium Hydroxide 7.9% w/w	15-08-1976 Beecham Pakistan (Pvt) Ltd., B-63, Estate Avenue, S.I.T.E., Karachi	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 04-09-2018

62	013321	Nemazole suspension Each 5ml contains: Mebendazole 100mg	25-05-1992 Wellcome Pakistan Ltd., D/43, Taxtile Avenue, S.I.T.E., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 20-07-2018
63	017306	Nemazole-500 ChewableTablets Each tablet contains: Mebendazole 500mg	21-06-1995 Wellcome Pakistan Ltd., D/43, Taxtile Avenue, S.I.T.E., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited,D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 20-07-2018
64	013320	Nemazole tablets Each tablet contains: Mebendazole 100mg	25-05-1992 Wellcome Pakistan Ltd., D/43, Taxtile Avenue, S.I.T.E., Karachi	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 20-07-2018
65	000395	Stelabid tablets Each tablet contains: Isopropamide as Iodide 5mg, Trifluoperazine as HCl 1mg	22-03-1976 Smith Kline & French of Pakistan Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018
66	000063	Stelazine Tablet 1mg Each tablet contains: Trifluoperazine as HCl 1mg	22-03-1976 Smith Kline & French of Pakistan Ltd., Karachi.	30-Aug-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 03-08-2018
67	006662	Wellcosine syrup Each 5ml contains: Thiamine HCl 5mg, Riboflavin 1.66mg, Pyridoxine HCl 1mg, Nicotinamide 20mg, d-panthenol 2.5mg, Cyanocobalamin 10mcg, Inositol 5mg, Vitamin C 75mg, L-Lysine Mono HCl 35mg	17-01-1985 Wellcome Pakistan Ltd., D/43, Taxtile Avenue, S.I.T.E., Karachi	10-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 04-09-2018

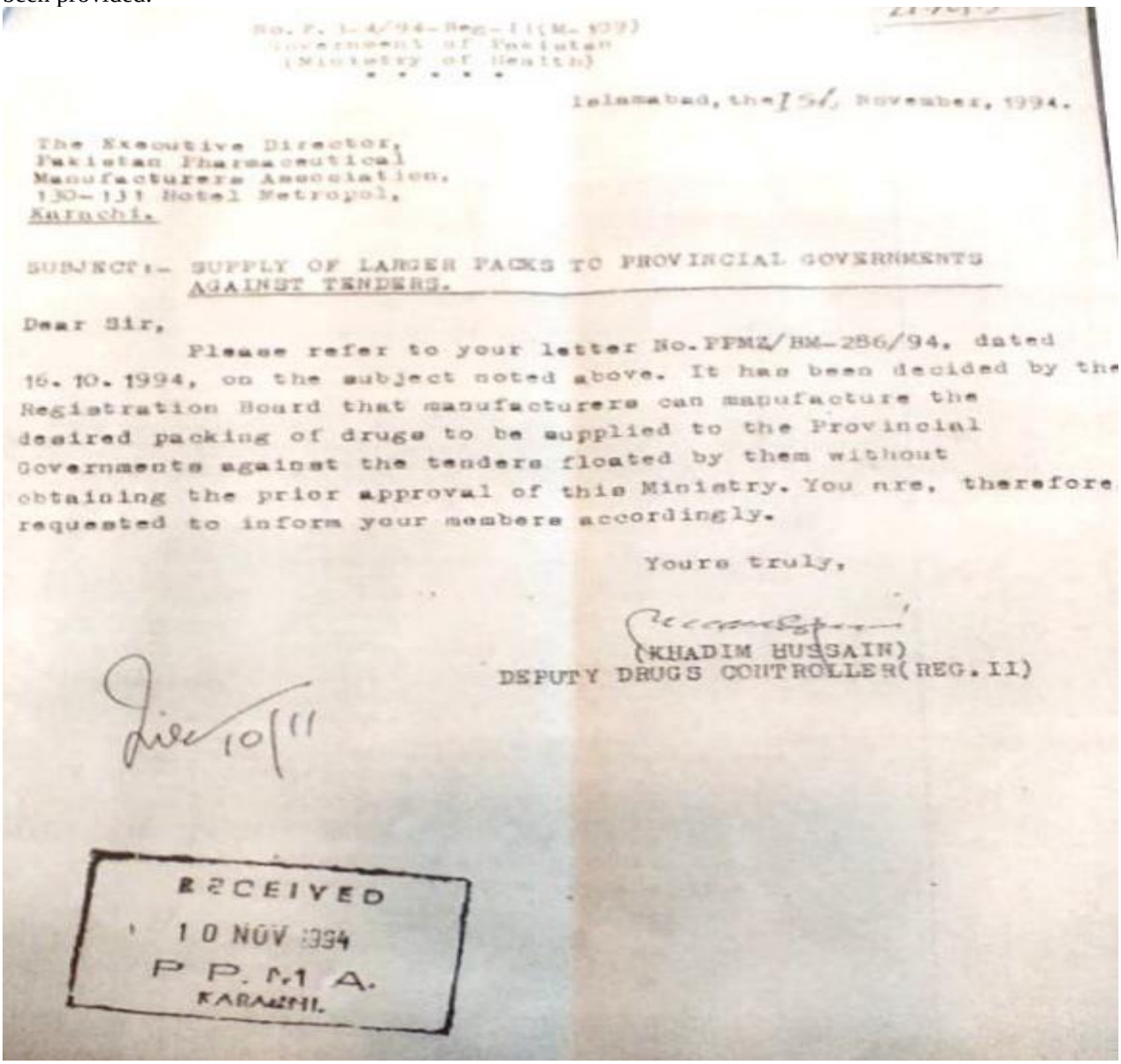
68	027803	Actifen Suspension Each 5ml contains: Ibuprofen 100mg	05-09-2002 GlaxoWellcome Pakistan Ltd. F-268 S.I.T.E & West Wharf, Karachi	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Liquid (General) Section Panel Inspection Report for Renewal of DML dated 26,27-03- & 01-04-2019	Copy of Form-5B. Last renewal applied on 04-09-2018
69	027800	Actifen Tablet 200mg Each tablet contains: lbuprofen 200mg	05-09-2002 GlaxoWellcome Pakistan Ltd. F-268 S.I.T.E & West Wharf, Karachi.	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
70	027801	Actifen Tablet 400mg Each tablet contains: Ibuprofen 400mg	05-09-2002 GlaxoWellcome Pakistan Ltd. F-268 S.I.T.E & West Wharf, Karachi.	15-Sep-03 GlaxoSmithKline Pakistan Limited, D/43, Textile Avenue, SITE, Karachi.	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018
71	027802	Actifen Tablet 600mg Each tablet contains: Ibuprofen 600mg	05-09-2002 GlaxoWellcome Pakistan Ltd.F-268 S.I.T.E & West Wharf, Karachi.	15-Sep-03 GlaxoSmithKline Pakistan Limited,D/43, Textile Avenue, SITE, Karachi	Tablet (New) Section Approval dated No.F.2-11/97-Lic (M-156) dated 19-12-2000	Copy of Form-5B. Last renewal applied on 04-09-2018

Decision: Registration Board decided as under:

i. **Regularized M/s GSK Pakistan Ltd., 35-Dockyard Road West Wharf, Karachi (DML 000017) as manufacturing site address for products at S.No.1-22 & 24-31 of TABLE-I.**
ii. **Regularized M/s GSK Pakistan Ltd., F-268, S.I.T.E, Karachi (DML 000233) as manufacturing site address for products at S.No.1-15, 18-20, 22-29 & 31-71 of TABLE-II.**
iii. **Deferred the products at S.No. 23 of TABLE-I and S.No.16,17 & 30 of TABLE-II for confirmation of requisite manufacturing facility from Licensing Division, DRAP.**
iv. **Deferred the product at S.No. 21 of TABLE-II and advised the firm to submit evidence for approval of composition mentioned on unit carton.**

Case No.13. Clarification Regarding Former Approval/Permission Letters Issued by the then Ministry of Health

Director General Health Services, Punjab has requested to clarify whether a firm/ manufacturer can quote the product in larger packs to Provincial Governments against tenders. In this regard, a copy of following letter No. F.3-4/94-Reg-II (M-109) dated 01-11-1994 issued by the then Ministry of Health stating "Supply of Larger Packs to Provincial Governments against Tenders" has also been provided:



No. F. 3-4/94-Reg-II(M-109)
Government of Pakistan
(Ministry of Health)

Islamabad, the 1st November, 1994.

The Executive Director,
Pakistan Pharmaceutical
Manufacturers Association,
130-131 Hotel Metropol,
Karachi.

SUBJECT:- SUPPLY OF LARGER PACKS TO PROVINCIAL GOVERNMENTS AGAINST TENDERS.

Dear Sir,

Please refer to your letter No.PPMA/BM-286/94, dated 16.10.1994, on the subject noted above. It has been decided by the Registration Board that manufacturers can mapufacture the desired packing of drugs to be supplied to the Provincial Governments against the tenders floated by them without obtaining the prior approval of this Ministry. You are, therefore requested to inform your members accordingly.

Yours truly,

(KHADIM HUSSAIN)
DEPUTY DRUGS CONTROLLER(REG.II)

10/11

RECEIVED
10 NOV 1994
P.P.M.A.
KARACHI.

As the above referred letter dates back to almost 25 years. However, the case has been placed before the Board for deliberation regarding rationality/requirement of such permission in current situation. Furthermore, guidance is also requested regarding authenticity of all such former approvals/permissions which require confirmation from old record.

Decision of M-294:

Registration Board deferred the case for further deliberation.

Decision: **Registration Board deliberated the case keeping in view the existing practice regarding grant of additional pack size for which formal approval from Costing & Pricing Division is required and accordingly referred the case to DRAP's Authority with request to withdraw the above mentioned approval issued vide letter No. F.3-4/94-Reg-II (M-109) dated 01-11-1994. The Board further recommended to DRAP's Authority that provincial governments may be advised to confirm status of similar type of other letters issued by former Drugs Control Administration, Ministry of Health before their implementation to avoid any later confusion.**

Case No.14. Request of M/s Sayyed Pharmaceutical Industries (Pvt) Ltd, Hattar for Import of Controlled Drug Substances for Trial/Development and Stability Purposes.

M/s Sayyed Pharmaceutical Industries (Pvt) Ltd.,67/2, Phase 3, Industrial Estate, Hattar has requested for permission to import controlled drug substances for trial/development and stability Purposes as required in Form-5F. Details are given below:

1. Alprazolam

S.No.	Product Name	Quantity Required	Source
1	Alprazolam tablet 0.25mg	18.25gm	**Centaur Pharmaceuticals Pvt.Ltd. API Division Plot Nos.75,76 & 76/1,Chikhloli MIDC Ambernath (West) District:Thane-421501 Maharashtra (India)**
2	Alprazolam tablet 0.50mg	16.50gm	
3	Alprazolam tablet 1.00mg	33.00gm	
	Total	**67.75gm**	
4	Alprazolam working standard	600mg	
5	Alprazolam related compound A	30mg	
6	2-Amino-5-chlorobenzophenone	30mg	
7	Chlordiazepoxide related compound A	30mg	

The breakup of quantities for three strengths are as follows.

i. Alprazolam 0.25mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Alprazolam 0.25mg Tablet**	Alprazolam	**0.25**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	8.25	For chemical testing:5.0 Retention sample:5.0 Total:10.0	18.25

ii. Alprazolam 0.5mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Alprazolam 0.5mg Tablet**	Alprazolam	**0.5**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	16.50	--	16.50

iii. Alprazolam 1.0mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Alprazolam 1.0mg Tablet**	Alprazolam	**1.0**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch**	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g

				(10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial batches (3) Stability batches (3)	33.00	--	33.00

2. <u>Bromazepam</u>

S.No	Product Name	Quantity Required	Source
1	Bromazepam tablet 1.5 mg	59.5gm	**Centaur Pharmaceuticals Pvt.Ltd. API Division Plot Nos.75,76 & 76/1,Chikhloli MIDC Ambernath (West) District:Thane-421501 Maharashtra (India)**
2	Bromazepam tablet 3.0 mg	99.00gm	
3	Bromazepam tablet 6.0 mg	198.00gm	
	Total	**356.5gm**	
4	Bromazepam working standard	1000mg	
5	Bromazepam Impurity A	40mg	
6	Bromazepam Impurity B	40mg	
7	Bromazepam Impurity C	40mg	
8	Bromazepam Impurity D	40mg	
9	Bromazepam Impurity E	40mg	

The breakup of quantities for three strengths are as follows.

i. Bromazepam 1.5mg

S #	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Bromazepam 1.5mg Tablet**	Bromazepam	**1.5**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						<u>g</u>	<u>g</u>	<u>g</u>
					Trial batches (3) Stability batches (3)	49.50	For chemical testing:5.0 Retention sample:5.0 0 Total:10.0	59.50

ii. Bromazepam 3mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Bromazepam3mg Tablet**	Bromazepam	**3.00**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						<u>g</u>	<u>g</u>	<u>g</u>
					Trial batches (3) Stability batches	99.00	--	99.00

				Batch size for Pilot batch 2 (10,000 tablets)	(3)			

iii. Bromazepam 6mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Bromazepam6mg Tablet**	Bromazepam	**6.0**	**Batch size for trial batch** (1,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
				Batch size of Lab batch (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial batches (3) Stability batches (3)	198.00	--	198.00

3. Methylphenidate HCl

S.No	Product Name	Quantity Required	Source
1	Methylphenidate Hcl tablet 10 mg	340.00g	**Centaur Pharmaceuticals Pvt.Ltd. API Division Plot Nos.75,76 & 76/1,Chikhloli MIDC Ambernath (West) District:Thane-421501 Maharashtra (India)**
	Total	**340.00g**	
2	Methylphenidate Hcl working standard	600mg	
3	Methylphenidate Hcl Related compound A	30mg	
4	Phenyl acetic acid	30mg	
5	Erythro Isomer	20mg (10ml)	
6	Methyl Phenidate	30mg	
7	Ethyl Phenidate	30mg	
8	Bis Methyl Phenidate	30mg	

The breakup of quantities is as follows.

i. Methylphenidate HCl tablet 10mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Methylphenidate Hcl tablet 10 mg**	**Methylphenidate Hcl**	**10.0**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch**	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
					Trial batches (3)	330.00	For chemical testing:5.0 Retention	340.00

				(10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Stability batches (3)		sample:5.00 Total:10.0	

4. Clonazepam

S.No	Product Name	Quantity Required	Source
1	Clonazepam tablet 0.5 mg	26.5gm	**Centaur Pharmaceuticals Pvt.Ltd. API Division Plot Nos.75,76 & 76/1,Chikhloli MIDC Ambernath (West) District:Thane-421501 Maharashtra (India)**
2	Clonazepam tablet 2.0 mg	66.00gm	
	Total	**92.5gm**	
3	Clonazepam working standard	400mg	
4	Clonazepam Related compound A	20mg	
5	Clonazepam Related compound B	20mg	
6	Clonazepam Related compound C	20mg	

The breakup of quantities for two strengths are as follows.

i. Clonazepam 0.5mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Clonazepam 0.5mg Tablet**	Clonazepam	**0.5**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	16.50	For chemical testing:5.0 Retention sample:5.00 Total:10.0	26.50

ii. Clonazepam 2mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	**Clonazepam 2mg Tablet**	Clonazepam	**2.00**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	66.00	--	66.00

5. Zolpidem Tartrate

S.No	Product Name	Quantity Required	Source
1	Zolpidem tartrate tablet 10 mg	340.00gm	**AARTI DRUGS LIMITED E-22,MIDC,TARAPUR,TAL-PALGHAR,DIST-THANE 401506 MAHARASHTRA STATE,INDIA.**
	Total	**340.00gm**	
2	Zolpidem tartrate working standard	200mg	
3	Zolpidem Related compound A	15mg	

The breakup of quantities is as follows.

i. Zolpidem 10mg

S#	Product	API	Mg/Tab	No of Tab/batch	No of batches	Quantity of API Required		
1.	Zolpidem tartrate tablet 10 mg	Zolpidem tartrate	**10.0**	**Batch size for trial batch** (1,000 tablets) **Batch size of Lab batch** (10,000 tablets) **Batch size for Pilot batch 1** (10,000 tablets) **Batch size for Pilot batch 2** (10,000 tablets)	Trial + Stability	For formulation development	For QC testing and retention	Total
						g	g	g
					Trial batches (3) Stability batches (3)	330.00	For chemical testing:5.0 Retention sample:5.00 Total:10.0	340.00

Decision: **Registration Board decided to recommend allocation of controlled drug substances i.e., i) Alprazolam ii) Bromazepam iii) Methylphenidate iv) Clonazepam v) Zolpidem Tartarate along-with above mentioned Reference Standards for trial/stability batches of above mentioned products.**
The Board further advised the firm to maintain records of used substances and waste materials having above APIs and shall be destroyed after approval of Controlled Drug Division, DRAP.

Case No.15. Deferred Products of M/s Hicon Pharmacuticals, Peshawar

Registration Board in its 238th meeting deferred the following products of M/s Hicon, Pehsawar as per details given below (Column I-VI);

S. No.	Brand Name / Label Claim	Demanded Pack Size	Demanded Price	Date of Submission	Recommendations of Me-Too Committee	Remarks
I	**II**	**III**	**IV**	**V**	**VI**	**VII**
1.	Supricon 500 mg Tablets Each tablet contains:- Mycophenolate mofetil…500 mg (Immunosuppressive agent)	5x10's	As Per SRO	11-5-10	Deferred for P.S.I by Director DTL, Peshawar FID, Peshawar.	The firm has now submitted revised formulation i.e **"Film coated tablet"** in line with that approved by RRAs (MHRA/USFDA) along with fee of Rs.5000/-
2.	B-Con-12 Syrup Each 5 ml contains:- Cyanocobalamine…….35 µg (Vitamin)	120 ml	As Per SRO	11-5-10	Deferred for product specic inspection by Director DTL Peshawar and FID.	RRA status: MHRA Me-Too Status: Nytacon Liquid of M/s Neomedix , Rawat (Reg # 033698)

3.	Hitaline Syrup Each 5 ml contains:- Terbutaline sulphate…….0.3 mg (Beta-2 adrenergic agonist)	60 ml	As Per SRO	11-5-10	Deferred for submission of correct method of manufacturing and product specification.	RRA status: MHRA (Bricanyl 0.3mg/ml syrup) Me-Too Status: Britanyl 0.3mg/ml Syrup M/s Barret Hodgson, Karachi (R # 044255) The firm has submitted fee of Rs.5000/- along with Method of Manufacturing, revised Formulation & Master Formula stating that there is a typographical mistake i.e ***"Each 5ml contains: Terbutaline Sulphate 0.3mg"*** instead of ***"Each ml contains: Terbutaline Sulphate 0.3mg".***

The firm has also submitted following documents:

1. Last Inspection Report for renewal of DML dated 26-07-2018, wherein the panel has recommended renewal of DML by way of formulation for following sections:
   - Tablet section (General)
   - Tablet Section (General) Antibiotics
   - Liquid Syrup Section (General)
2. The firm has submitted panel inspection report conducted on 30-12-2013, wherein the panel (comprising of Dr. M Khalid, Director DTL Peshawar and Rehmatullah Baig Alvi, Area FID) has recommended the grant of approval of registration for
   - Cyanocobalamine Syrup 35 µg/5ml
   - Mycophenolate Mofetil Tablets 500mg.

Decision: **Registration Board decided as under:**

i. **Approved the products at S.No.1and 2 of above table. Fee shall be verified as per procedure adopted by the Board in its 285th meeting.**
ii. **Deferred the product at S.No.3 of above table for submission of complete fee along-with requisite information/documents.**

Case No.16. Approved Products of M/s Usawa Pharmacuticals, Risalpur.

Registration Board in its 227th meeting approved the following products of M/s Usawa Pharmaceuticals, Rislapur as per details given below (Column I-VI):

S. No	Brand Name / Label Claim	Demanded Pack Size	Demanded Price	Date of Submission	Recommenda-tions of Me-Too Committee	Remarks
I	II	III	IV	V	VI	VII
1.	Sulpade-Levo 25mg Tablets Each film coated tablet contains:- Levosulpiride….25mg (Antidepressant)(Usawa Sapec)	2x10's	Rs.9.55 per tablet	9-10-2009	Approved subject to panel GMP inspection	Standard formulation approved by RRAs is not "film coated"
2.	Sulpade-Levo 50mg Tablets Each film coated tablet contains:-	2x10's	Rs.19.10 per tablet		-do-	Standard formulation approved by RRAs is not

	Levosulpiride….50mg (Antidepressant) (Usawa Sapec)					"film coated"
3.	Sulpade-Levo 100mg Tablets Each film coated tablet contains:- Levosulpiride..100mg (Antidepressant) (Usawa Sapec)	2x10's	Rs.38.15 per tablet	-do-	-do-	Standard formulation approved by RRAs is not "film coated"
4.	Beta-Simroxy Tablets Each tablet contains:- Piroxicam B-cyclodextrin equivalent to Piroxicam….20mg (Antirheumatic)	20's	Rs.8.03 per tablet	-do-	-do-	ANSM, France Approved
5.	Awa-Bone 0.5mcg Tablets Each tablet contains:- Alfacalcidol....0.5mcg (Vitamin D analogue)	20's	Rs.13.20 per tablet	-do-	-do-	PMDA, Japan Approved
6.	U-Sapip Tablets 10mg Each film coated tablet contains:- Aripiprazole….10mg (Dopamin partial agonist)	30's	Rs.10.00 per tablet	-do-	-do-	Standard formulation approved by RRAs is not "film coated"
7.	U-Sapip Tablets 15mg Each film coated tablet contains:- Aripiprazole…..15mg (Dopamin partial agonist)	30's	Rs.7.5 per tablet	-do-	-do-	Standard formulation approved by RRAs is not "film coated"
8.	U-Mefant DS Tablets Each tablet contains:- Artimether……40mg Lumefantrine..240mg (Sunthetic Antimalarail)	8's	Rs.33.00 per tablet	-do-	-do-	WHO approved
9.	Awa-Xam Capsules Each capsule contains:- Tranexamic Acid……250mg (Haemostatic)	2x10's	Rs.6.5 per capsule	-do-	-do-	AIFA, Italy Approved
10.	U-Prolac Tablets Each tablet contains:- Bromocriptine…2.5mg (Dopamin agonist)	30's	Rs.13.54 per tablet	18-11-2009	Approved subject to panel GMP inspection	Standard formulation approved by RRAs contains: "Bromocriptine as Mesylate…2.5mg"
11.	Awa-Xam Capsules Each capsule contains:- Tranexamic Acid…….500mg (Haemostatic)	20's	As Per SRO	-do-	-do-	AIFA, Italy Approved

The firm has now submitted following documents:

1. Panel Inspection report Renewal of DML dated 22-03-2017 stating following sections:
    i. Tablet General/Antibiotic
    ii. Capsule General
    iii. Capsule Cephalosporin
    iv. Dry Suspension Cephalosporin
2. Last GMP Inspection report dated 08-01-2019 (Satisfactory Level of GMP).
3. Photocopies of differential fee challans (Rs.12000/- each) verified by the concerned bank and photocopies of fee challan of Rs.8000/-each.

Decision: **Registration Board decided as under:**

i. Approved the products at S.No.4,5,8,9and 11 of above table. Fee shall be verified as per procedure adopted by the Board in its 285th meeting.

ii. Deferred the products at S.No.1-3,6,7 and 10 of above table for evidence of approval of applied formulations in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.

Case No.17. Deferred Products of M/s Nabiqasim Industries Pvt. Limited, Karachi

Registration Board in its 265th meeting deferred the following products of M/s Nabiqasim Industries Pvt. Limited, Karachi as per details given below (Column I-VI):

S. No.	Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification	Type of Form Initial date, diary Fee including differential fee Demanded Price / Pack size	Remarks on the formulation (if any) including International status in stringent drug regulatory agencies / authorities Me-too status GMP status as depicted in latest inspection report (with date) by the Evaluator	Remarks by Evaluator	Decision
I	II	III	IV	V	VI
1.	Bacip Dry Suspension Each 5ml (after reconstitution) contains: Ciprofloxacin as HCl…….250mg Quinolones, Anti-Infectives	Form5 31-12-2013 Dy.No.2086 Rs.20,000/- 31-12-2013 30ml,60ml As per PRC	MHRA UK Ciproxin – Byer Health Care Amity – Scotmann Last inspection report 11-4-2016 GMP status as acceptable	The firm has claimed Manufacturer Specifications. The product cannot be confirmed in available pharmacopoeia(US P39, BP2013)	Deferred for revision of formulation as per decision of 250th DRB meeting

The firm has now submitted following documents:

1- Copy of application for below mentioned revised formulation along-with photocopy of fee challan of Rs.5000/-

"Each 5ml (after reconstitution) contains:
Ciprofloxacin …….250mg"
Diluent: As per Innovator's

2- Source of Ciprofloxacin Granules: Surge Laboratories Private Limited, 10th Kilometer Faisalabad Road, Bikhi, District, Sheikhupura.

3- Copy of approval for "Dry Powder (general/ Antibiotic)" section of M/s Nabiqasim issued by Licensing Division dated 27-04-2020.

Decision: **Registration Board approved the grant of registration for "Bacip Dry Suspension 250mg/5ml" of M/s Nabiqasim Industries Pvt. Limited, Karachi with following details:**

Each 5ml (after reconstitution) contains:
Ciprofloxacin …….250mg
(USP Specifications)
Diluent: As per Innovator's
Source of Ciprofloxacin Granules:
M/s Surge Laboratories Private Limited, 10th Kilometer Faisalabad Road, Bikhi, District, Sheikhupura.

Furthermore, fee shall be verified as per procedure adopted by the Board in its 285th meeting.

Case No.18. Change in Registration Status of Etipro 20mg Capsules From M/s The Searle Company, Limited, Karachi to M/s ICI Pakistan Limited (Formerly Cirin Pharmaceuticals (Pvt.) Ltd.), Hattar.

M/s ICI Pakistan Limited (Formerly Cirin Pharmaceuticals (Pvt.) Ltd.), 32/2A Phase 3, Industria Estate, Hattar (DML # 000363) has applied for change in registration status of "**Etipro 20mg (Omeprazole) Capsules**" from M/s The Searle Company Limited, Karachi to their name as per following details:

I	II	III	IV	V
Reg. No.	**Brand name & Composition as per Initial Registration Letter**	**Brand Name & Revised Composition applied by M/s ICI**	**Remarks of RRR section Regarding Renewal Status**	**Dy. No. & Date of Submission**
019147	**Etipro SR 20mg Capsule** Each capsule contains:- Omeprazole ……..20mg as SR Microgranules **(Toll manufacture for ICI Pak Limited, Karachi)** **Source of Pellets:** M/s Precise Chemipharm a Pvt Ltd, India.	**Etipro 20mg Capsule** Each capsule contains:- Omeprazole Enteric Coated Pellets eq. to Omeprazole……..20mg (USP Specifications) **Source of Pellets:** M/s Precise Chemipharm a Pvt Ltd, Gut No. 215/1 & 215/2, Khatwad Phata, At Psot Talegaon, Taluka Dindori, Nashik 422202 Maharashtra State, India **India.**	As per computer record of RRR section, renewal application is received on 06-04-2016 and initial date of registration is 10-04-1996. Firm has submitted additional fee in case of imported pellets on 27-02-2018. Case has to be placed before the Reg. Board for regularization and final status will be communicated afterwards	Initial application submitted by M/s Cirin Pharmaceuticals, Hattar; Dy. No.113; 26-01-2018 **with Fee of** Rs. 100000/- (Challan No. 0713297). After change in title, fresh application has been received from M/s ICI Pakistan Limited; Dy. No.606; 03-06-2020 **with Fee of** Rs. 100000/- (Challan No. 1959577).

The firm has now submitted following documents:

i. Capsule (General) Section approval of M/s Cirin, Hattar verified from Licensing Division's letter for renewal of DML (dated 02nd March, 2016).
ii. Copy of last GMP inspection report of M/s Cirin Pharmaceuticals (Pvt.) Ltd.), 32/2A Phase 3, Industria Estate, Hattar dated 07th May, 2018 indicating "Good" level.
iii. NOC from M/s The Searle Company Limited, Karachi dated 01-06-2020.
iv. DML of M/s Cirin, Hattar dated 18-09-2015.
v. Copy of approval for change in title and management of M/s Cirin, Hattar issued by Licensing Division dated 18-02-2020.
vi. Copy of GMP certificate of M/s Chemipharma, India valid upto 27-02-2022. However, the firm had previously submitted legalized GMP Certificate valid upto 22-01-2019 along-with Accelerated & Real Time statbility studies.

Decision: **Registration Board deliberated the case in correlation with succeeding Case No.19 and directed the firm to submit clarification/justification for their instant request as they already hold registration of same molecule in same dosage form & strength i.e., Acizol (Omeprazole) Caps 20mg (Reg. No. 017715).**

Case No.19. Request for Withdrawal of Registration of Acizol (Omeprazole) Caps 20mg (Reg. No. 017715)

M/s ICI Pakistan Limited. 32/2 A, Industrial Estate Hattar (Formerly known as Cirin Pharmaceuticals (Pvt.) Limited - DML No. 000363) has requested to withdraw an existing registration of Acizol 20mg (registered in the name of M/s Cirin, Hattar) to expedite their application for change in registration status of Etipro Caps 20mg (R# 019147) from M/s the Searle Company Limited, Karachi to M/s ICI Pakistan Limited, Hattar.

S/N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	017715	Acizol Capsule 20mg Each Capsule contains: Omeprazole…..20mg	To expedite their application for change in registration status of Etipro Caps 20mg (R# 019147) from M/s the Searle Company Limited, Karachi to M/s ICI Pakistan Limited, Hattar.	1. Alpazol of M/s Medicaids Pakistan (Pvt) Ltd. 2. Amazole of M/s Medera Pharmaceuticals (Pvt). 3. Anmol of M/s Roryan Pharmaceutical Industries.	Reg. Letter date: 18-07-1995 Last Renewal date: 10-07-2015

The firm has now submitted following documents:

- Copy of registration letters and Last renewal.
- List of alternatives brands available in Pakistan
- An Undertaking that:
    i. No case is pending at any forum/ court of law regarding above mentioned products.
    ii. Provided information/ documents are true/ correct.

Decision: **Registration Board deferred the case to be considered after submission of clarification/ justification in preceeding Case No.18.**

Case No.20. Request of M/s Pfizer Pakistan Limited, Karachi for De-Registration of Ponston Suspension (Mefenamic Acid) 60ml (Reg. No. 005539)

M/s Pfizer Pakistan Limited, Karchi has applied for de-registration of Ponston Suspension (Mefenamic Acid) 60ml (Reg. No. 005539) stating that the product manufactured by Pfizer in Karachi, Pakistan is in accordance with approved product specifications, arisk assessment was performed by Pfizer in the light of the updated International Council for Harmonization (ICH) Q3 guidelines. Based on Risk Assessment, Pfizer has consucted a global recall of Ponstan Suspension due to risk of exceeding ICH Q3D Permitted Daily Exposure levels for the elemental impurities lead and lithium caused by Aluminum Magnesium Silicate used in the formulation. This recall is only specific to Ponstan Suspension 500mg/5ml, and has no impact on other formulations of Ponstan. Subsequently, Pfizer has decided to withdraw license of Ponstan Suspension Worldwide.

S/N	Reg.No.	Brand name and composition	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	005539	Ponstan Suspension Each 5ml contains: Mefenamio Acid B.P…….50mg	1- Acimef of M/s Trigon 2- Gardan of M/s Sanofi 3- Dologin of M/s Opal 4- Delmic of M/s Delta 5- Hefmic of M/s Heal.	**Reg. Date** 15-04-1981 (M/s Parke-Davis & Company, Karachi) **Last Renewal date:** 27-05-2016 (Submitted by Pfizer

				Pakistan Ltd, Karachi)

The firm has submitted following documents:

a. Fee of Rs.5000/-
b. Copy of Registration Letter & Last Renewal Status.
c. List of alternate brands available in the country.
d. Justification.
e. An Undertaking that:

i. No case is pending at any forum/ court of law regarding above mentioned product.

Decision: **Registration Board deliberated that Mefenamic Acid Suspension 500mg/5ml (M/s Chjemidex Pharma, UK) is still approved in MHRA and available in market as well. The Board, therefore, advised M/s M/s Pfizer Pakistan to clarify that whether problem is with their formulation or otherwise.**

Case No.21. De-Registration of Locally Manufactured Products of M/s Nawan Laboratories (Pvt) Ltd, Karachi.

M/s Nawan Laboratories (Pvt) Ltd, 136,Sector 15 Korangi Industrial Area Karachi (DML # 000442) has applied for de-registration of their following registered products.

S/N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	082230	Cipra 200mg/100ml Injection Each 100ml contains:- Ciprofloxacin as Lactate…….200mg (USP Specification)	The firm has informed that the Licensing Board in its 271st Meeting decide to cancel their Liquid Injectable Section (General) under section 41 of the Drugs Act 1976 read with under Rule 12 of Drugs (LRA) Rules, 1976	1. Cipesta IV Infusion 200mg/100ml of M/s Getz Pharma, Karachi 2. Novidat Injection 200mg/100ml of M/s Sami, Karachi. 3. Gen-Cipro Infusion 200mg/100ml of M/s Brookes Pharmaceuticals, Karachi.	**26-09-2017 Renewal not Due**
2.	086600	Halet 500mg/100ml Injection Each 100ml contains:- Levofloxacin (as hemihydrates)..500 mg (As per *Innovator's Specification)		1. Levocil IV Infusion 500mg/100ml of M/s CCL Pharmaceuticals, Karachi 2. Qumic IV Infusion 500mg/100ml of M/s Bosch Pharmaceuticals, Karachi. 3. Leflox IV Infusion 500mg/100ml of M/s Getz Pharma, Karachi	**15-01-2018 Renewal not Due**
2.	089173	Maroxi Infusion 400mg/250ml Each vial contains: Moxifloxacin HCl eq to Moxifloxacin…..400mg (As per *Innovator's Specifications)		1. Moxiget Infusion 400mg/250ml of M/s Getz Pharma, Karachi 2. Molox IV Infusion 400mg/250ml of M/s CCL Pharmaceuticals, Karachi 3. Mob Infusion 400mg/250ml of M/s IndusPharma, Karachi	**25-06-2018 Renewal not Due**

In the light of SOP approved vide 283rd meeting, the firm has submitted following documents:

a. Copy of Registration Letter.
b. List of alternate brands available in the country.

c. Justification.
d. An Undertaking that:
i. No case is pending at any forum/ court of law regarding above mentioned products.
ii. Provided information/ documents are true/ correct.

Decision: Registration Board acceded to the request of M/s Nawan Laboratories (Pvt) Ltd, Karachi for de-registration of their above mentioned products.

Case No.22. Request of M/s Abbott Laboratories (Pvt) Ltd, Karachi for Cancellation of Registration.

M/s Abbott Laboratories (Pvt) Ltd, Opp. Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi has applied for cancellation of registration of their following products.

S/N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	016869	Nicor Liquid. Each 10ml contains: Paracetamol Powder……..200mg Pseudoephedrine HCl……13.33mg Pholcodine…..…..3.33mg Diphenhydramine HCl……...3.33mg	With introduction of new formulations in the market, usage and patronage of Daycor syrup and Nicor Syrup by Physician has declined remarkably. This decline in medical needs has resulted in very low volume of production and sale, which eventually have made both Daycor Syrup and Nicor Syrup commercially non-viable, to continue market these products.	1. Actified DM of m/s GSK Pakistan 2. Adicos M of M/s Zafa Pharmaceuticals, Karachi 3. Combinol Junior & Combinol D of M/s Atco, Karachi. 4. Sancos & Triaminic cough & Triaminic Flu, cough, fever & Triaminic DM of M/s Novartis Pharma (Pak) Ltd. 5. Tricof & Tricof-SF M/s Wilson Pharmaceuticals.	Reg. Date 18-04-1995 Last Renewal Date: 13-01-2015
2.	016870	Daycor Liquid. Each 10ml contains: Paracetamol Powder……..200mg Pseudoephedrine HCl……13.33mg Pholcodine…..…..3.33mg			Reg. Date 18-04-1995 Last Renewal Date: 13-01-2015

In the light of SOP approved vide 283rd meeting, the firm has submitted following documents:

a. Copy of Registration Letter & Last Renewal Status.
b. List of alternate brands available in the country.
c. Justification.
d. An Undertaking that:
i. No case is pending at any forum/ court of law regarding above mentioned products.
ii. Provided information/ documents are true/ correct.

Decision: Registration Board referred the case to DRAP's committee for availability of drugs for its opinion.

Case No.23. De-Registration of Furacin Cream of M/s GlaxoSmithKline Pakistan Limited, Karachi.

M/s GlaxoSmithKline Pakistan Limited , 35- Dockyard road, West Wharf, Karachi has applied for de-registration of their following registered product.

S/N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	000060	Furacin Cream Contains: Nitrofurazone	1. Suitable therapeutic alternatives and advance therapies are available in the market. 2. Better/New Molecules to cater the same portfolio are also available in the market. 3. Virtually there is no demand of this product in local market.	1. Furatop of M/s Zafa, Karachi. 2. Furacillin of M/s Lisko, Karachi. 3. Neufrazone of M/s Nutro Pharma.	Reg. Letter date: 22-03-1976 Last Renewal date: 20-07-2018 Transfer Of Reg date: 30-08-2003

In the light of SOP approved vide 283rd meeting, the firm has submitted following documents:

a. Copy of Registration Letter & Last Renewal Status.
b. List of alternate brands available in the country.
c. Justification.
d. An Undertaking that:
    i. No case is pending at any forum/ court of law regarding above mentioned products.
    ii. Provided information/ documents are true/ correct.

Decision: Registration Board referred the case to DRAP's committee for availability of drugs for its opinion.

Case No.24. Withdrawal of Registration Application of "Fermax-Plus Injection (Ferric Carboxymaltose 50mg) of M/s Cirin Pharmaceuticals (Pvt) Ltd, Hattar.

M/s Cirin Pharmaceuticals (Pvt) Limited, 32/2A Phase III Industrial Estate Hattar, was granted approval for registration of "Fermax Plus Injection" in 269th meeting of Registration Board but approval letter couldn't be issued due to patent issue.

In terms of settlement/joint application filed and order dated 19-11-2019 (mentioned below) passed by the Intellectual Property Tribunal in Civil Suit 12/2018 Vifor (International) AG vs M/s Cirin Pharmaceuticals (Pvt) Limited, the firm has requested to withdraw their application for registration of Fermax Plus.

"After filing of the suit the defendant put up his appearance in the court and the case was fixed for inter see settlement between the parties. Today a joint application has been filed by the plaintiff and defendant, and as per application under order 23 rule 3 CPC in terms of the agreement settled between the parties, the suit in hand is partially decreed that the defendant will not infringe the registered patent No. 138733 of the plaintiff in any manner, while to the extent of damages the suit of the plaintiff is dismissed as not been pressed. The application filed by the parties will become the part of the decree sheet."

Decision: Registration Board acceded to the request of M/s Cirin Pharmaceuticals (Pvt) Ltd, (New Tiltle: ICI Pakistan Limited) 32/2A Phase III Industrial Estate Hattar, Haripur for withdrawal of registration application of "Fermax-Plus Injection (Ferric Carboxymaltose 50mg)" approved in 269th meeting of Registration Board.

Case No.01 Approval status of Diclofenac Potassium 75mg & 100mg in Reference Regulatory Authorities

The Registration Board in its 254th meeting deferred the following product of M/s Vision Pharmaceuticals, Islamabad for verification of their registration status in the reference agencies while considering the request of firm for change of registration of these products from their previous site Plot No.224, Street No.1, I-10/3, Islamabad to new site Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad:

S. No	Reg. No	Product Name
1	037574	Diclovis -K 75mg Tablets Each tablet contains:- Diclofenac potassium….75mg

The firm requested to re-considered these products for change of registration of these products from their previous site Plot No.224, Street No.1, I-10/3, Islamabad to new site Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad. They have ensured that "At time when show cause notices are issued to all other companies, same could be issued to us as well and we will accept this whole heartedly".

Registration Board in 258th meeting considered the request of M/s. Vision Pharma, Islamabad and decided as Diclofenac Potassium is not registered in any reference country in dose more than 50mg, thus Registration Board decided to issue show cause notices to manufacturers of Diclofenac Potassium (75 and 100mg) for de-registration of these products. Accordingly, show case notices were served to the firms having registration of Diclofenac Potassium (75mg & 100mg) Tablet. In response M/s. Quper Pharma, Sargodha, submitted petition No. 1695 of 2017 in the Islamabad High Court, Islamabad, against the decision of the Registration Board. The Islamabad High Court, Islamabad dismissed the application of M/s. Quper Pharma, Sargodha vide its orders dated 29-01-2020 being without merit.

Decision: Registration Board deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to all the firms who have registration of Diclofenac Potassium 75mg & 100mg in forthcoming meeting of Registration Board.

Case No.02: Allocation of Quota for Control Substances Ephedrine HCl for the year 2017 to M/s. Sharex Laboratories, Sadiqabad.

The case of M/s. Sharex Laboratories, Sadiqabad was considered in 275th and 286th meeting of Registration Board as per detailed below:-

Proceedings of 275th of Registration Board:

The instant case was presented based on the letter received from Assistant Director (CD) (Dated 21st Sep, 2017) wherein it has been stated that M/s Sharex Laboratories, sadiqabad applied for quota allocation of product ―Tracodil syrup (Reg. 003158). The case was presented before 43rd meeting of committee on allocation of controlled drug held on 26th July, 2017, the comittee deferred the case for issuance of show cause by DRAP for manufacturing of Tracodil syrup (Reg. 003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of Tracodil syrup (Reg. 003158) 400ml pack size.

The approved pack sizes of product ―Tracodil Syrup‖ (Reg no. 003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October 1988).

Decision of 275th meeting of Registration Board:-

Registration decided to call M/s Sharex Laboratories, Sadiqabad for personal hearing and for deliberating above mentioned matter before the Registration Board.

Proceedings of 286th meeting of Registration Board:-

Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm for applying quota of 400ml pack size of product ―Tracodil syrup (Reg.003158) without approval.

Decision of 286th meeting of Registration Board:-

Registration Board in its 286th meeting decided to refer the case to Legal Affair division for legal opinion.

Accordingly, the case was refer to Legal Affairs, Division and in response, Legal Affairs, Division has provided following opinion:-

i. That M/s. Sharex Laboratory applied for the quota allocation of product ―Tracodil Syrup‖ (Reg.No.003158).

ii. That the Committee on Allocation of Controlled Drugs held on 26.07.2017 deferred the case for issuance of show cause by DRAP for manufacturing of ―Tracodil Syrup‖ (Reg.No.003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of ―Tracodil Syrup‖ (Reg.No.003158) and 60ml (dated 27th October, 1988).

iii. That the approved pack size of the product ―Tracodil Syrup‖ (Reg.No.003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October, 1988).

iv. That Mr. Muhammad Ishfaq production pharmacist, appeared in 286th meeting before Board and apologized on behalf of the firm for applying quota of 400ml pack size of product ―Tracodil Syrup‖ (Reg.No.003158) without approval.

v. That the Registration Board in 286th meeting referred the case to Legal Affairs, Division for legal opinion.

vi. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(a)(f) prohibit to supply an incorrect, imcomplete or misleading information when required to furnish any information under this Act or the rules.

vii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

Decision of 289th meeting of Registration Board: -

In light of the opinion of Legal Affair's Division on the matter, Registration Board deliberated the case and decided to issue show cause notice to M/s Sharex Laboratories, Sadiqabad for violation of condition of drug registration, as follows:

- Cancellation of registration.
- Suspension of registration.
- Prosecution in Drug Court

Accordingly show cause notice has been served to M/s. Sharex Laboratories, Sadiqabad.

Decision: Registration Board deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to M/s. Sharex Laboratories, Sadiqabad in forthcoming meeting of Registration Board.

Case No.03 Registration of Drug(s) of M/s. Jawa Pharmaceuticals (Pvt.) Ltd; Lahore.

Registration Board in its 214th and 228th meeting had approved the following products of M/s. Jawa Pharmaceuticals, Lahore and the firm has requested that they have not yet received the registrations of these product. They have requested to issue the registration of below mentioned products. Case was presented in 293rd meeting of Registration Board and Board decided below as mentioned against each in column V.

S. No.	Name of Drug(s)	Demanded Pack size	Demanded MRP	Decision of Registration Board	Remarks
I	II	III	IV	V	VI
1.	Fertovit Capsule Each capsule contains:- Ferrous Sulphate…..150mg Ascorbic Acid……50mg Riboflavine……2mg Pyridoxine HCl……..1mg Nicotinamide……10mg	3x10's	Rs.81.04	Deferred for evidence of approval status in RRA M-293	International availability not confirmed. Fee of Rs.12000/- submitted.

	Folic Acid…….0.5mg (BP Specification)				
2.	J-Vit Syrup Each 5ml contains:- Vitamin B1……10mg Vitamin B2…….10mg Vitamin B6…….10mg Vitamin B12……5mcg Calcium Pantothenate….3mg Vitamin C……150mg Niacinamide……50mg Lysine monohydrate……20mg (BP Specification)	120ml	Rs.93.72	Deferred for evidence of approval status in RRA M-293	International availability not confirmed. Fee of Rs.12000/- submitted.
3.	Frutogen Syrup Each 5ml contains:- Vitamin A……..5000Units Vitamin D..……..500 Units Vitamin B1…….3mg Vitamin B2……..……2mg Vitamin B6…….0.2mg Vitamin C……50mg Niacinamide……20mg Vitamin B12……5mcg Pantothenic Acid……1mg (BP Specification)	120ml	Rs.39.29	Deferred for evidence of approval status in RRA M-293	International availability not confirmed. Fee of Rs.12000/- submitted.
4.	Carti-Cure Tablets Each tablet contains:- Glucosamine Sulphate ……750mg Chondroitin Sulfate …… 600mg (USP Specification)	1x10's	Rs.200.00	Deferred for evidence of approval status in RRA M-293	International availability not confirmed. Fee of Rs.12000/- submitted.
5.	Paracedine Tablet Each tablet contains:- Paracetamol…..500mg Codeine phosphate…..15mg	10's	-do-	Deferred for submission of differential fee M-293	Available in MHRA. Fee of Rs.12000/- submitted.
6.	T-Dol 50mg Capsules Each capsule contains:- Tramadol…..50mg (non-narcotic analgesics)	10's 30's	-do-	Deferred for submission of differential fee M-293	Available in MHRA. Fee of Rs.12000/- submitted.
7.	Zonox 10mg Tablets Each tablet contains:- Zolpidem tartrate…..10mg	10's 20's	-do-	Deferred for submission of differential fee M-293	Available in MHRA. Fee of Rs.12000/- submitted.
8.	Calamol Tablets Each tablet contains:- Paracetamol…….500mg Caffeine……....65mg	100's 10's	-do-	Deferred for submission of differential fee M-293	Available in MHRA. Fee of Rs.12000/- submitted.

9.	Paracedine –C Tablet Each tablet contains:- Paracetamol…….500mg Codeine Phosphate ……15mg Caffiene Anhydrous……..30mg	10's 30's 100's	-do-	Deferred for evidence of approval status in RRA M-293	International availability not confirmed. Differential fee also required
10.	Cetam-D Tablets Each tablet contains:- Paracetamol…..325mg Dextropropoxyphene…30mg	20's 100's	-do-	Deferred for evidence of approval status in RRA M-293	International availability not confirmed. Differential fee also required

Decision: Registration Board decided as under;

i. **Approved the registration of products at Sr. No. 5-6. Fee shall be verified as per procedure adopted by the Board in its 285th meeting.**

ii. **Deferred the products at Sr. No. 1-4, 9 &10 for evidence of approval status of formulation in the reference regulatory authorities.**

Case No.04 Registration of Drug(s) of M/s. Pharma Lord, Layyah.

Registration Board in its 237th meetings approved the following product of M/s. Pharma Lord, layyah, Lahore as per below mentioned details. In minutes of 237th meeting of Registration Board, there was typographic error where Ciprofloxacin 250mg Dry Powder Suspension was mentioned instead of Ciprofloxacin 125mg Dry Powder Suspension however Ciprofloxacin 250mg Dry Powder Suspension is already registered (076845) in the name of Pharma Lord.

Name of product.	Proposed correction	Demanded MRP/ Pack size	Date of Submission
Cpro 250mg Dry Powder Suspension Each 5ml contains:- Ciprofloxacin……250mg (anti-infectives, quinolones)	Cpro 125mg Dry Powder Suspension Each 5ml contains:- Ciprofloxacin……125mg (anti-infectives, quinolones)	60ml Rs.220.00	22.01.2013

Case was presented before Registration Board in 275th meeting and Registration Board deferred for further deliberation.

Supportive documents (copy of fee challan and receiving of application in R&I section etc) have been verified. Firm requested for granting registration of their applied product i.e. Cpro 125mg Dry Powder Suspension

Registration Board in its 277th noted the correction in minutes i.e. Cpro (ciprofloxacin) 125mg Dry Powder Suspension instead of Cpro (ciprofloxacin) 250mg Dry Powder Suspension. However, product deferred for deliberation in light of decision taken in 269th Registration Board meeting regarding manufacturing facility of diluent for reconstitution of ciprofloxacin suspension.

Now the firm has submitted fee of Rs.5000/- for correction of formulation in light of decision of Registration Board in its 290th meeting. The source of granules is M/s. Vision Pharmaceuticals, Islamabad.

Decision: Registration Board deferred the case for confirmation of applied strength from registration dossier.

Case No.05 M/s Ambrosia Pharmaceuticals, Islamabad.

M/s Ambrosia Pharmaceuticals, Islamabad have requested for correction in brand name, pack and MRP of their registered product with following details.

S. No.	Reg. No.	Existing Name of drug(s) with formulation	Demanded Corrections	Existing Pack & MRP	Demand pack & MRP	Decision of 9th PRVC
I	II	III	IV	V	VI	VII
1.	040815	Amrotose comples syrup Each 5ml contains: Iron (III) Hydroxide Polymaltose complex …..…50mg	Amrotose **Complex** Syrup Each 5ml contains: Iron (III) Hydroxide Polymaltose complex ……50mg	Rs.70/120ml	Rs.133/120ml	The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to defer the request of M/s Ambrosia Pharmaceuticals, Islamabad for submission of copy of form-5 for verification of brand name and decided to advise the firm to apply in C & P Division for additional pack of 120ml.

Now the firm has submitted copy of Form-5 which shows that firm has applied with the brand name of **Polytose complex syrup**.

Remarks of the section:

The approved price for Iron (III) Hydroxide Polymaltose complex 50mg/5ml syrup is Rs.70/60ml. The demanded price i.e. Rs.133/120ml is not available in pricing minutes.

The firm has submitted following documents:

i. Copy of registration letter dated 13-07-2005
ii. Last Renewal applied: 10-07-2015
iii. NOC of CRF clearance valid till 31-12-2018

Decision of Chairman RB taken in 11th meeting of PRVC:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to approve the request of M/s Ambrosia Pharmaceuticals, Islamabad for issuance of corrigendum in brand name of above product while for correction of pack and MRP, the case is referred to Registration Board.

Decision of RB taken in its 284th meeting: Registration Board deferred the request of the firm for confirmation of demanded MRP and pack size from record.

Now the record has been checked and found that firm has demanded Rs.98.80 for 60ml pack.

Registration Board in its 286th meeting decided to refer the case to C & P Division.

Latterly it was discussed that firm's demanded MRP/Pack size is Rs.98.80/60ml as mentioned in 286th meeting. Firm has also submitted an undertaking regarding demanded MRP/Pack size. Accordingly, case is re-submitted for consideration of Registration Board.

Decision: Registration Board deferred the case for confirmation of demanded MRP and pack size from registration dossier.

Case No.06 Deferred product of M/s Nimrall Pharmceuticals, Rawat, Islamabad

Registration Board in its 234th meeting approved following product of M/s Nimrall Pharmceuticals, Rawat, Islamabad.

S.No.	Name and Composition of Product	Pack size	Demanded Price	Decision (M-234)
1.	Xinia Plus Injection Each ml contains:- Diclofenac Sodium……..25mg Lidocaine Hydrochloride…....20mg	3mlx5's Amps	As Per SRO	Approved

The firm later on pointed out that the above formulation was actually applied for **75mg of Diclofenac Sodium** with 20mg Lidocaine hydrochloride instead of above mentioned formulation wherein **Diclofenac Sodium is 25mg** with 20mg Lidocaine hydrochloride. The stance of firm has been found valid from the original file and the same formulation is registered in the name of M/s Bosch, (Aram), Global, (Articure) & English Pharma (D-Pain).

The firm has requested for grant of registration of above product.

Registration Board in its 254th meeting deferred the case for issuance of registration letter till confirmation of formulation status in the reference drug regulatory authorities.

The firm has informed that the product is available in Switzerland which is verified from following link.

https://www.swissmedicinfo.ch/

Decision: Registration Board deferred the case for confirmation of applied strength from registration dossier.

Case No.07 Deferred product of M/s. Shrooq Pharmaceuticals (Pvt.) Ltd, Lahore

Registration Board in its various meetings decided the following products of M/s. Shrooq Pharmaceuticals (Pvt.) Ltd; 21-Km, Feruz Pur Road, Lahore. Details are given as under:-

S.No	Brand Name/Label claim	Demanded Pack size	Demanded Price	Decision of RB	Remarks
1.	Zamid Tablet Each tablet contains:- Zonisamide….25mg	10's	As Per SRO	Deferred for expert opinion M-228	Available in FDA
2.	Zamid Tablet Each tablet contains:- Zonisamide….50mg	10's	As Per SRO	Deferred for expert opinion M-228	Available in FDA
3.	Virocil Cream Each gram contains:- Acyclovir……. 5.00% (Anti-viral)	05g 10g	As per SRO	Deferred for confirmation of formulation, submission of duplicate file and completion of registration dossier. M-235	Available in FDA. Firm has submitted duplicate dossier.
4.	Valrox Syrup Each 5ml contains:- Divalproex Sodium…….500mg (Anti-epileptics)	60ml	As per SRO	Approved. The Board advised to submit finished product specifications. M-238	Firm has now requested to change strength of formulation as **Each 5ml contains:-** **Divalproex Sodium…..250mg**
5.	Cegrel-Ap Tablet Each tablet contains:- Clopidogrel (Bisulphate)…75mg Aspirin……...150mg	10's	As Per SRO	Deferred for latest GMP report M-263	Firm has now requested to change strength of formulation as **Each tablet contains:-** **Clopidogrel (Bisulphate)… 75mg** **Aspirin…… 75mg**

6.	Airvent Tablet 8mg Each tablet contains Montelukast Sodium……. 8mg Leukotriene receptor antagonist	7's	Rs.155	Deferred for confirmation of the applied formulation in references regulatory authorities M-265	Firm has now requested to change strength of formulation as **Each chewable tablet contains** **Montelukast Sodium……. 4mg**

Firm has submitted following documents;

i. Form 5.
ii. Evidence of fee of Rs.8000/- (Photocopy) along with fresh submission of Rs.12000/- for each product.
iii. cGMP certificate based upon evaluation conducted on 29-01-2019.

Decision: Registration Board decided as under;

i. Approved the registration of products at Sr. No. 1-3. Fee shall be verified as per procedure adopted by the Board in its 285th meetingth meeting

ii. Deferred the products at Sr. No. 4-6 for submission of fee.

Case No.08 Registration of Drug(s), M/s. Sapeint Pharma, Lahore.

Registration Board in its 236th meeting approved the following products of M/s. Sapient Pharma 123/S Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore subject to the submission of complete pharmaceutical specifications and recommendations of the committee comprising of Prof. Rafi-Uz-Zaman, member Registration Board, Secretary Registration Board, DDG (Reg) and concerned DDC. The firm has requested to grant them registration of below mentioned products:-

S. No.	Name of Drug(s)	Demanded pack size	Demanded MRP	Decision of Registration Board.	Remarks
1.	Oscaar Tablets Each tablet contains:- Losartan Potassium……50mg (Anti-hypertensive)	2x10's	As per SRO	Approved subject to the submission of complete pharmaceutical specifications and recommendations of the committee comprising of Prof. Rafi-Uz-Zaman, member Registration Board, Secretary Registration Board, DDG (Reg) and concerned DDC.	Film coated tablet is approved in MHRA
2.	Atorvastat Tablet Each tablet contains:- Atorvastatin……10mg (Anti-Atheromas)	1x10's	As per SRO	-do-	Film coated tablet is approved in MHRA
3.	Atorvastat -20 Each tablet contains:- Atorvastatin……20mg (Lipid-Regulating Drugs)	1x10's	As per SRO	-do-	Film coated tablet is approved in MHRA
4.	Cofclear-DM Syrup Each 5ml contains:- Diphenhydramine HCl……5mg Dextromethorphan HBr……..6.25mg (Anti-histamines)	120ml	As per SRO	-do-	International availability not confirmed
5.	Sapidol Tablets 5mcg Each tablet contains:- Alfacalcidol…0.5mcg	10 Tablets	Rs.170.00	Approved subject to the submission of complete pharmaceutical	PMDA approved.

	(Vitamin A, D Combination)			specifications and recommendations of the committee comprising of Prof. Rafi-Uz-Zaman, member Registration Board, Secretary Registration Board, DDG (Reg) and concerned DDC. Five products per section will be granted on the priority list of the firm.	
6.	Atlopin Tablets Each tablet contains:- Atorvastatin Calcium…….10mg Amlodipine besylate……..5mg (Calcium Antagonists)	10 Tablets	Rs.200.00	Approved subject to the satisfactory last GMP Inspection report.	Film coated tablet is approved in USFDA
7.	Sapmin Tablets 500mcg Chewable Each tablet contains:- Mecobalamin…500mcg (Co-enzyme Type vitamin B12)	20 Tablets	Rs140.00	Approved subject to the satisfactory last GMP Inspection report.	Sugar coated tablet is approved in PMDA

Firm has submitted following documents:-

i. Duplicate registration application (Form-5)
ii. Evidence of fee of Rs.8000/- each (Photocopy) with fresh submission of Rs.12000/- each.
iii. DML renewal Inspection report conducted on 19-09-2019 & 18-11-2019.
iv. cGMP certificate based upon evaluation conducted on 18-11-2019.

Decision: Registration Board decided as under;

i. Approved the registration of products at Sr. No. 5. Fee shall be verified as per procedure adopted by the Board in its 285th meeting th meeting

ii. Deferred the products at Sr. No. 4 for evidence of approval status of formulation in the reference regulatory authorities.

iii. **Deferred the products at Sr. No. 1-3, 6 & 7 for submission of fee.**

Case No.09 Registration of Drugs M/s Sapient Pharma, Lahore.

Registration Board in its 238th meeting deferred the following products of M/s Sapient Pharma, Lahore as follows:-

S. No.	Name of Drug(s)	Demanded Pack size	Demanded MRP	Decision of Board	Remarks
1.	Gavison Suspension Each 5 ml contains:- Aluminum Hydroxide……... 215mg Magnesium hydroxide……... 80mg Simethicone…… 25mg (Antacids, Antiflatulent)	120ml	As per SRO	Deferred till removal of shortcomings of oral liquid section mentioned in the last inspection report dated 19-04-13.	i. In DML renewal inspection report, conducted on 19-09-2019 & 18-11-2019, panel recommended renewal of DML by way of formulation. ii. cGMP certificate iii. International Availability not confirmed
2.	Entrodyl Suspension Each 5 ml contains:- Metronidazole……..100mg Diloxanide……125mg	60ml	As per SRO	Deferred till removal of shortcomings of oral liquid	i. In DML renewal inspection report, conducted on 19-09-2019 & 18-11-2019, panel

	(Amoebicides)			section mentioned in the last inspection report dated 19-04-13.	recommended renewal of DML by way of formulation. ii. cGMP certificate International Availability not confirmed

The firm has provided copies of Form-5 and copies of challans of Rs. 8000/- & Rs.12,000/- for each product.

Decision: Registration Board deferred above products for evidence of approval status of formulation in the reference regulatory authorities.

Case No.10 Correction of formulation of M/s. CCL Pharmaceuticals, Lahore.

Registration Board in its 288th meeting approved following products of M/s. CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid e Azam Industrial Estate,Kot, Lakhpat, Lahore. Detail is as under;

Sr. No.	Name of Drug(s)	Decision of Registration Board	Remarks
1.	Colitis ER Tablet 400mg Each enteric coated Tablet contains: Mesalamine…400mg USP	Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board	Product is available in MHRA as **Modified release tablet**.
2.	Colitis ER Tablet 800mg Each enteric coated Tablet contains: Mesalamine…800mg USP	Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board	Product is available in MHRA as **Modified release tablet.**

Correction in minutes is required from **enteric coated** to **extended release tablet** as firm has applied for Extended release tablet which is confirmed from original dossier. The original fee challans also been traced from record.

Decision: - Registration Board approved the correction in minutes with following details and decided to process the case as per decision of 288th meeting.

i. Colitis ER Tablet 400mg
Each extended release tablet contains:
Mesalamine…400mg

ii. Colitis ER Tablet 800mg
Each extended release tablet contains:
Mesalamine…800mg

Case No.11 Registration of Drug of M/s. CCL Pharmaceuticals (Pvt.) Ltd; Lahore.

The Registration Board in its 227th meeting approved the following products of M/s. CCL Pharmaceuticals (Pvt.) Ltd; Lahore and registration letter was not issue due to Court case regarding patent rights by M/s. Amson Phamra, Islamabad:-

S. No.	Name of Drug(s)	Demanded Pack size	Demanded MRP	Decision of Board	Remarks
1.	Pulmonol D Syrup Each 5ml contains:- Dimemorfan phosphate ph.ext…12.5mg (Non-narcotic Antitussive)	60ml	As per SRO	Deferred for confirmation of International Availability	Approved in PMDA

The firm has stated the Additional District Judge, Islamabad and Islamabad High Court, Islamabad had dismissed the suit of the plaintiff firm i.e. M/s. Amson Vaccine & Pharma, Islamabad and requested to issue the registration letter. The firm has also submitted copy of judgement of Additional

District Judge, dated 15-05-2013 and copy of cause list of Islamabad High, Court dated 24-10-2013 regarding the dismissal of the case.

Firm has also submitted differential fee of Rs.12000/-.

Registration Board deferred the case in 293rd meeting due to confirmation of International availability.

Product is approved in PMDA and verified from following link.
http://www.pmda.go.jp/PmdaSearch/iyakuDetail/GeneralList/2229001

Decision: - Registration Board approved registration of above product in the name of M/s. CCL Pharmaceuticals, Lahore with change in brand name due to different formulations.

Case No.12 M/s. Vision Pharmaceuticals Islamabad.

M/s Vision Pharma Islamabad had been granted three additional sections, enlisted below, in its 247th CLB meeting:

i. Liquid Ampoule (General)
ii. Liquid vial (General)
iii. Dry Powder Injection (Steroids)

The firm had submitted various applications against above cited sections. Registration Board in its 260th meeting had considered 10 molecules Liquid Ampoule (General) section.

In 264th DRB meeting the firm submitted to surrender three products due to marketing reasons, which were approved in 260th registration board meeting but the registration letter is awaited, and requested to consider three products tabulated hereafter.

Sr.#	Products considered in 260th RB meeting	Alternate products requested by Firm for replacement
1	Tramax 50 mg injection Each ampoule (1ml) contains : Tramadol Hydrochloride ……. 50 mg	Tramax 100 mg injection Each 2ml ampoule contain: Tramadol Hydrochloride…100 mg Opioid analgesics Manufacturer's Specifications
2	Zytec 25 mg Injection Each ampoule (1 ml) contains: Ranitidine Hydrochloride equivalent to Ranitidine……25 mg (USP Specifications)	Zytec 50 mg Injection Each 2ml ampoule contains: Ranitidine hydrochloride eq. to Ranitidine….. 50mg Histamine H2 Receptor Antagonist (U.S.P. Specifications)
3	Pyritec 150mg Injection Each ampoule (1 ml) contains: Paracetamol USP …. 150 mg (Manufacturere's Specifications)	Pyritec 300 mg Injection Each 2ml ampoule contain: Paracetamol USP…. 300 mg Analgesic & Antipyretic (Manufacturer's Specifications)

Registration Board did not accede to firm's request for replacement of already approved products with other applications. Now the firm has submitted that we do not intend to seek approval of any new molecule rather we have requested for additional strengths of our already approved molecules as enlisted below:

I. Tramax 50 mg injection
Each ampoule (1 ml) contains:
Tramadol Hydrochloride ……. 50 mg

II. Zytec 25 mg Injection
Each ampoule (1 ml) contains:
Ranitidine Hydrochloride equivalent to Ranitidine……25 mg
(USP Specifications)

Details of additional strengths of above formulations, requested by firm are as follows:

Sr.#	Name and address of manufacturer / Applicant	Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification	Type of Form Initial date, diary Fee including differential fee Demanded Price / Pack size	Remarks on the formulation (if any) including International status in stringent drug regulatory agencies / authorities Me-too status GMP status as depicted in latest inspection report (with date) by the Evaluator
1.	M/s Vision Pharma Plot 22-23 Industrial triangle, Kahuta road, Islamabad	Tramax 100 mg injection Each 2ml ampoule contain: Tramadol Hydrochloride … 100 mg Opioid analgesics	Form 5 17-10-2016 Dy No. 1670 Rs 20,000 17-10-2016 1*5's 1*10's As per SRO	MHRA-UK approved Symol Injection of M/s Indus Pharma Last inspection report 9-2-2016 Confirms GMP.
2.	M/s Vision Pharma Plot 22-23 Industrial triangle, Kahuta road, Islamabad	Zytec 50 mg Injection Each 2ml ampoule contains: Ranitidine hydrochloride eq. to ranitidine ….. 50 mg Histamine H2 Receptor Antagonist (U.S.P. Specifications)	Form 5 17-10-2016 Dy No. 1669 Rs 20,000 17-10-2016 1*5's 1*10's As per SRO	MHRA-UK approved Anine Injection of M/s Nexus Pharma Last inspection report 9-2-2016 Confirms compliance to GMP.

Registration Board in its 270th deferred for clarification regarding confirmation of date of submission of registration applications.

Now firm has submitted a letter regarding withdrawal of replacement letter and requested to issue registration letter of the product Tramax 50mg/ml Injection.

Decision: - Registration Board deferred for further deliberaton with complete case

Case No.13 Registration of Drug(s) M/s. Candid Pharmaceuticals, Lahore.

M/s. Candid Pharmaceuticals Opp. Eden Avenue Extension Airport Road, Lahore was granted the registration of following products:-

Old Reg. numbers issued			
S.No.	**Old Reg. No.**	**Name of Drug(s) & Composition**	**Remarks**
1.	028384	Ozone Injection Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone …… 250mg	The firm was granted registration vide letter No.F.3-3/2002-Reg-II (M-171) dated 21-08-2002 but the contract manufacturing condition was not mentioned initial letter of registration. Brand name was changed to Efxone vide letter dated 05-10-2002. These products contract manufacturing permission was extended vide letter No.F.3-1/2008-Reg-II-South(M-212) dated 18-09-2008 till 30-06-2010.
2.	028385	Ozone Injection Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone …… 500mg	
3.	028386	Ozone Injection Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone …… 1gm	

New Reg. numbers issued in 275th meeting			
4.	087354	Efxone Injection 250mg IV Each vial contains: Ceftriaxone (as sodium)..…….250 mg (USP Specifications)	The firm was granted registration of these products vide letter No.F.8-11/2017-Reg-III(M-275) dated 29-12-2017 after the approval of Ceph. Injectable section by Licensing Division.
5.	087355	Efxone Injection 250mg IM Each vial contains: Ceftriaxone (as sodium)…….250 mg (USP Specifications)	
6.	087356	Efxone Injection 1gm IV Each vial contains: Ceftriaxone (as sodium)……1000mg (USP Specifications)	

Registration Board in its 275th meeting approved transfer of registration from contract manufacturing to their own facility but due to typographical error firm was granted registration of Ceftriaxone 250mg Injection (IM) (Reg.No.087355) instead of Ceftriaxone 500mg Injection (IV). The firm has requested to correct the strength/rout of administration from "Efxone (Ceftriaxone) 250mg Injection IM (Reg.No.087355) to "Efxone (Ceftriaxone) 500mg Injection IV (Reg.No.087355).

Firm has also provided copies of application receiving which shows that the firm had applied "Efxome (Ceftriaxone) 250mg & 500mg Injection IV.

Decision:- Registration Board deferred for confirmation of manufacturing status of the product.

Case No.14 Registration of Drug(s) M/s. Arreta Pharmaceuticals (Pvt.) Ltd; Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi (Formerly M/s. Tayyab Laboratories, Islamabad)

Registration Board in its 276th meeting approved following products in the name of M/s. Tayyab Laboratories (Pvt) Ltd.) Islamabad, The details is given as under:-

Sr. No.	Drugs Composition	Demanded pack & Price	Approved MRP, Pack size with reference of meeting	Decision	Remarks
1.	Lymotil tablet 2.5mg/0.025mg Each tablet contains: Diphenoxylate hydrochloride ……..… 2.5mg Atropine sulphate … 0.025mg USP	Diary No:8797, 14/07/2017, Rs. 20,000/- 100's, 500's / As per SRO	Rs.205/50x 10's	Approved with change of brand name.	The firm has now requested to change the brand name to **Loqotil**.
2.	Tylgyl 400mg Tablet Each film coated tablet contains: Metronidazole…….. 400mg USP	Diary No:8799, 14/07/2017, Rs. 20,000/- 20's, 100's, 200's, 500's / As per SRO.	Rs.300/20x 10's Rs.150/100's Rs.30/20's	Approved with change of brand name.	The firm has now requested to change the brand name to **Bydin**.

Registration Board in its 277th meeting approved the following product of M/s. Tayyab Laboratories, Islamabad. The details are given as under:-

3.	DOXIVA TABLET Each Tablet Contains Doxofylline ….. 400 mg (Manufacturing Specs) Antiasthmatic	As per SRO 100s	Rs.138/10's	Approved with innovator's specifications.	BN ok

Title of the firm has been changed from "M/s. Tayyab Pharmaceuticals (Pvt.) Ltd; Plot No. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi" to M/s. Arreta Pharmaceuticals (Pvt.) Ltd; Rawalpindi. Furthermore, Registration Board in its 290th meeting endorsed the decision of DRAP Authority that "***In case of change of title of the firm, relevant fee will be applicable and case shall be processed at Division level, Director (PE&R) being the Chairman, Registration Board shall issue approval letter for change in registration status of products within 10 working days***". The Registration Board decided to follow the above decision of DRAP Authority.

Firm has submitted fee or Rs.20000/- for each product and Registration letters of above mentioned products have been issued on the new title of the firm i.e., M/s. Arreta Pharmaceuticals (Pvt.) Ltd; Rawalpindi.

Decision: - Registration Board noted the information.

Case No.15 Registration for the drug(s) of M/s. Allmed (Private) Limited. Lahore.

Registration Board in 237th meeting considered the products of M/s. Allmed (Private) Limited Lahore. as per detailed below:-

S.No	Name of the drugs with composition	Pack Size	Proposed Price	Date of Submission	Remarks
1.	Isoflo Oral Solution Each 100ml contains:- Isoflurane….100ml (Anesthesia)	100ml	As per SRO	10-11-2011 Fee.8000 11-10-2012 Fee.12000 Fast track fee submission Fee.40000	USFDA approved formulation is intended for inhalation route *Firm has clarified that applied formulation is as per reference product approved by USFDA with strength Isoflurane 99.9% Also corrected brand name as Isoflo Solution*
2.	Sevoflo Solution Each ml contains:- Sevoflurane ..250ml (anesthesia)	250ml	-do-	10-11-2011 Fee.8000 11-10-2012 Fee.12000 Fast track fee submission Fee.40000	USFDA approved formulation is intended for inhalation route *Firm has clarified that applied formulation is as per reference product approved by USFDA with strength sevoflurane 100%*

Firm has submitted following documents:-

i. Application for this purpose.
ii. Copy of GMP conducted on 12.11.2018 (panel recommends DML renewal)
iii. Evidence of section (inhalants) approval by CLB not provided by the firm

Registration Board in its 287th meeting decided to confirm manufacturing facility for above mentioned formulations from Licensing division.
Accordingly Licensing Division was requested to confirmed the manufacturing facility of the above said product. Licensing Division has forwarded a letter of concerned FID which states that;

> "The representative of the firm informed that they will be manufacturing these products in syrup section (General) (Already Approved). However, a vessel in syrup manufacturing section was dedicated for these anesthetic inhalants. A separate syrup filling machine was also installed in a separate room for filling of these inhalant anesthetics. The filling machine was covered to avoid the accumulation of fumes in the room. The room had HVAC facility with separate AHU for this area. For the purpose of testing of these solutions, the firm had purchased GC apparatus of Agilent company."

Decision: Registration Board rejected the application as firm does not have approved section for manufacturing of anesthetic inhalants.

Case No.16 Brand name approval for the product of M/s. Rotex Pharma, Islamabad.

M/s. Rotex Pharma, Islamabad, registration letter was not prepared due to MRP clarification/fixation by Costing & Pricing Division. The Costing & Pricing vide SRO 1608 has fixed the MRP. The firm has requested to grant them different brand name for Everolimus 10mg Tablet due to different indication as said strength, which is used in anticancer therapies while strengths of 0.25mg & 0.75mg, for which firm holds registration with brand name of certimus, are used as an immunosuppressant. Registration Board in its 282nd meeting while considering the case of M/s. Schazoo Pharmaceuticals, Lahore decided to grant different brand names to same molecule (Bimatoprost) bearing different therapeutic indications. Furthermore, in MHRA different brand names are registered for Everolimus of different strengths i.e Afinitor 2.5mg, 5mg & 10mg and Certican 0.25mg & 0.75mg. Details are given as under:-

Sr. No.	Drugs Composition	Demanded pack & Price	Approved MRP, Pack size	Decision	Remarks
1.	Primus 10mg tablet Each tablet contains: Everolimus……..10mg Mfg	10's, 30's, 50's, 60's, 90's, As per SRO	Rs.111947 Rs.55973 Rs.18657 Rs.93285 / 60's 30's 10's 5x10's	Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	The firm has requested to change the brand name to **Evnor**.

Decision: Registration Board was apprised that that presently same brand names are issued to a manufacturer/importer having same formulations. Now various applications have been received for issuance of same brand name under different scenario as follows:

a) **Issuance of same brand names to same formulations of different manufacturer/importer.**
b) **Issuance of diffeeferent brand names for different dosage forms of same formulation**
c) **Issuance of same brand names for different similar formulation**
d) **Issuance of different brand names for different dosage form/ strength and indications**
e) **Issuance of same brand name to same/similar formulation of product registered as drug and enlisted as HOTC product.**

Registration Board decided to seek guidance from DRAP Authority on above points.

Case No.17 Transfer of Registration from M/s. Obsons Pharma Lahore to M/s. Synchro Pharma Lahore.

Registration Board in its 246th Meeting canceled the registration of following products from M/s. Obson Pharma Lahore and registered in the name of M/s. Synchro Pharma Lahore for the following products and decision was taken as follows:-

S.No	Name of drugs with composition	Reg. No	Initial date of Registration and valid date
1.	Obdin Tablet 5mg Each tablet contains:- Desloratadine …….. 5mg	059991	10-09-2009 Valid until 9-9-2014
2.	Azrocin Suspension Each 5ml contains:- Azithromycinm dihydrate eq. to Azithromycin …….. 200mg	025404	11-11-1999 Valid until 10-11-2014

3.	Obflox Tablet Each tablet contains:- Levofloxacin Hemihydrate equivalent to Levoflocaxin …500mg	054157	19-02-2009 Valid until 18-02-2014
4.	Obflox Tablet Each tablet contains:- Levofloxacin Hemihydrate equivalent to Levoflocaxin ……. 250mg	030488	5-5-2003 Valid until 29-09-2015
5.	Obpra Capsule 40mg Each capsule contains:- Enteric coated pellets of Esomeprazole magnesium trihydrate eq. to Esomeprazole …… 40mg	054166	19-2-2009 Valid until 18-2-2009
6.	Vincam Capsule 20mg Each capsule contains:- Piroxicam …… 20mg	029834	6-3-2003 Valid until 5-3-2013
7.	Rubinol Tablet Each tablet contains:- Flurbiprofen …….. 100mg	025406	11-11-1999 Valid until 10-11-2014
8.	Azrocin Capsule Each capsule contains:- Azithromycin dehydrate ……. 250mg	025403	11-11-1999 Valid until 10-11-2014
9.	LevortizinTablet Each tablet contains:- Leocetirizine dihydrate …….. 5mg	054153	19-02-2009 Valid until 18-02-2014
10.	Obpra Capsule Each capsule contains:- Esomeprazole magnesium trihydrate enteric coated pellets equivalent to Esomeprazole ……. 20mg	054165	19-02-2009 Valid until 18-02-2014

Decision: Registration Board decided as follows:

i. Cancellation of above registrations from name of manufacturer (column II) except item at S.No.45 as it is case for change of contract manufacturer, which is deferred for processing in light of contract manufacturing policy.

ii. Grant of above registrations in name of manufacturer (column III). Chairman, Registration Board will permit issuance of registration letter after evaluation /completion of Form 5A as per check list approved by Registration Board, renewal status and comments of Cost & Pricing Division about MRP of the drug.

The CEO of M/s. Obson Pharma Lahore has now submitted an application and stated that they had issued an NOC in 2013 in favor of M/s Scynchro Pharma for transfer of products. Since their agreement has been cancelled during this period therefore they withdraw NOC issued in favor M/s. Scynchro Pharma Lahore. He has requested to stop proceeding in this regard.

Meanwhile, M/s Synchro Pharmaceuticals, Lahore has submitted an application and stated that after cancellation of registration M/s. Obsons Pharmaceuticals are still manufacturing the same product while we are waiting for the issuance of transfer letter till to date.

The case was discussed in 257th meeting of the board wherein board decided to summon representative of the both firms to explain their position. Accordingly letter for personal hearing have been issued.

In 258th meeting of registration, Mr.Abbas Butt GM and Shams Mehmood of M/s Synchro Pharma, Lahore and Mr. Naeem Shakeel of M/s Obsons Pharma, Lahore appeared before the Board and presented their point of view. Representative of M/s Obson admitted that he had given NOC to M/s. Synchro for transfer of registration previously but later on he has withdrawn NOC as he has settled his matter by other means. Both parties failed to present any written agreement regarding the matter

Registration Board noticed that NOC issued by M/s Obson Pharma, Lahore in respect of M/s Synchro Pharma, Lahore was accepted and approved in 246th meeting of the Board. It was purely an internal arrangement between the two parties through an agreement as to the status of assests and liabilities of the transfer. The terms and agreements may be looked into by the parties to resolve the issue. Thus, M/s Obson Pharma, Lahore is not authorized to submit application before the Board for cancellation of NOC at this moment. Therefore, Registration Board decided to process the case as per decision of 246th meeting.

In the meanwhile, M/s. Obson Pharmaceuticals, 209-S Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, filed writ petition in the Islamabad High Court, Islamabad, against Federation of Pakistan through Secretary M/o. NHRSR, Drug Regulatory Authority of Pakistan and M/s. Synchro Pharmaceuticals, 77 Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore and no further action was taken in the case as per decision of 258th meeting of Registration Board being sub-judice in the Honorable Court.

The Islamabad High Court, Islamabad decided on 22-02-2017 as "the instant petition is without merit and is, therefore, accordingly, dismissed.

M/s. Obson again submitted an intra court appeal and Islamabad High Court, Islamabad has decided as "Despite repeated calls, no one has appeared for or on behalf of the appellant. The case is reflected in the cause list. There is no application for adjournment, therefore, the instant Intra Court Appeal is dismissed for non-prosecution on 13-11-2019.

Decision: **Registration Board deferred the case for seeking opinion of Legal Affair Division, DRAP for further processing of case.**

Case No.18 **Transfer of Registration from M/s. Wnsfield, Hattar to M/s. Horizon Pharma Lahore.**

Regisration Board in its 287th meeting cancelled the registration of following 16 products from the name of M/s. WnsField Pharmaceuticals, Hattar and registered in the name of M/s. Horizon Healthcare (Pvt.) Ltd; Plot No. 33, Sundar Indusrial Estate, Lahore on contract manufacturing by M/s. WnsField Pharmaceuticals, Hattar.

S.#	Reg. No.	Brand Name with Generic
1.	083140	Ridomide 50mg Tablet Each film coated tablet contains:- Lacosamide 50mg
2.	083142	Ridomide DS 100mg Tablet Each film coated tablet contains:- Lacosamide 100mg
3.	084220	Profitam 250mg Tablet Each film coated tablet contains:- Levetiracetam ..... 250mg (USP Specification)
4.	084221	Profitam 500mg Tablet Each film coated tablet contains:- Levetiracetam ..... 500mg (USP Specification)

5.	084227	Delpoflex 4mg tablet Each tablet contains:- Tizanidine as HCl ..... 4mg (USP Specification)
6.	064337	Endtron Injection Each 4ml contains:- Ondansetron (as HCl) ..... 8mg (USP Specification)
7.	064338	Respivant 1mg Tablet Each tablet contains:- Risperidone ..... 1mg (USP Specification)
8.	064339	Respivant 2mg Tablet Each tablet contains:- Risperidone ..... 2mg (USP Specification)
9.	064340	Moxofin 400mg Tablet Each tablet contains:- Moxifloxacin (as HCL)..... 50mg
10.	080877	Moxofin 400mg Infusion Each 250ml vial contains:- MoxifloxacinHCleq to:- Moxifloxacin 400mg
11.	087031	Mytodone 4mg Tablet Each film coated tablet contains:- Risperidone ..... 4mg (USP Specification)
12.	046813	Delpoflex Tablet Each tablet contains:- Tizanidine as HCl 2mg
13.	060052	Lewdes 5mg tablet Each tablet contains:- Desloratadine 5mg
14.	075596	Endtron 8mg tablet Each tablet contains:- Ondansetron (as HCldihydrate) ..... 8mg (USP Specification)
15.	075577	Zolfenac 50mg tablet Each coated tablet contains:- Diclofenac Sodium ..... 50mg Misoprostol ..... 200µg (USP specification)
16.	080244	Olaway tablet 8mg Each film coated tablet contains:- Lornoxicam 8mg

It was observed that M/s. Horizon Healthcare (Pvt.) Ltd; Plot No. 33, Sundar Indusrial Estate, Lahore has 03 approved section and they can avail registration of 15 products as per Rule 20(a) of Drugs (Licesing, Registering & Advertising) Rules, 1976. M/s. Horizon healthcare (Pvt.) Ltd; Lahore intended to withdraw following 04 products for which registration has already been cacncelled from the name of M/s. Wnsfield, Hattar.

S.#	Reg. No.	Brand Name with Generic
1.	064338	Respivant 1mg Tablet Each tablet contains:- Risperidone ..... 1mg (USP Specification)

2.	064339	Respivant 2mg Tablet Each tablet contains:- Risperidone ..... 2mg (USP Specification)
3.	080877	Moxofin 400mg Infusion Each 250ml vial contains:- MoxifloxacinHCleq to:- Moxifloxacin 400mg
4.	087031	Mytodone 4mg Tablet Each film coated tablet contains:- Risperidone ..... 4mg (USP Specification)

Furthermore, M/s. Wnsfield, Hattar has submitted a letter stating that;

"We have withdrawn 04 products (mentioned above) from transferring to Horizon Pharma. So, it is requested to your good self to please cancel the transfer of registartion of these 04 products."

Decision: Registration Board deferred the case for seeking opinion of Legal Affair Division, DRAP for further processing of case.

Case No. 19 Registration of Drug(s) M/s. Himont Pharmaceuticals Lahore.

M/s. Himont Pharmaceuticals (Pvt) Ltd., 17th Km, Ferozpur Road, Lahore has requested for registration of following additional flavors and they already have registration of same molecule without flavor under the brand name VC-Cal Sachet (Reg.No.018060)

Sr. No.	Drugs Composition	Diary No. Date of R& I & fee	Diary Date Demanded pack & Price	Approval status of product in Reference Regulatory Authorities	Remarks
1.	VC-Cal Sachet (Lemon Honey Flavor) Each sachet contains: - Calcium Carbonate … 600mg Ascorbic Acid …….. 1000mg	Dy. No. 8658 dated 26-02-2019 Rs.20,000/- 25-02-2019	As Per SRO 10's	RRA status Not confirmed Me-too status not confirmed	Firm has submitted 18th months stability with this flavor
2.	VC-Cal Sachet (Cola Flavor) Each sachet contains: - Calcium Carbonate … 600mg Ascorbic Acid …….. 1000mg	Dy. No. 8659 dated 26-02-2019 Rs.20,000/- 25-02-2019	As Per SRO 10's	RRA status Not confirmed Me-too status not confirmed	Firm has submitted 18th months stability with this flavor

The firm has submitted following documents:-

i. Form-5
ii. GMP Compliance inspection report dated 04 & 05th October, 2018.
iii. Approval of concerned manufacturing facility.

Decision: Registration Board acceded to request of the firm and approved the registration of above product in the name of M/s. Himont Pharmaceuticals Lahore.

Case No.20 Registration of Drug(s) M/s. BJ Pharma, 19 km Mandiali Stop, Lahore.

Registration Board in 237th meeting deferred the following case of M/s. BJ Pharma, Lahore. In 293rd meeting deferred the product due to confirmation of international availability

S. No.	Name of Drug(s)	Demanded pack size	Demanded MRP	Decision of Registration Board.	Remarks
1.	B-Compound Tablets Each tablet contains:- Vitamin B1…..1mg Vitamin B2…..1mg Nicotinamide…..15mg (vitamin)	1000's 10x100's	As per SRO	Deferred for international availability M-293	MHRA approved

Firm has submitted photocopies of fee challan of Rs. 8000/- and Rs. 12000/- for each product.

Decision: Registration Board acceded to request of the firm and approved the registration of above products in the name of M/s. BJ Pharma, 19 km Mandiali Stop, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.

Case No.21 Registration of Drug(s) M/s. BJ Pharma, 19 km Mandiali Stop, Lahore.

Registration in its 237th meeting approved the following product of M/s. BJ Pharma, 19 Km, Mandiali Stop, Lahore but the firm has informed that registration letter was not issued:-

S. No.	Name of Drug(s)	Demanded pack size	Demanded MRP	Decision of Registration Board.
1.	Be-Koff Syrup Each 5ml contains:- Ammonium chloride…..100mg Sodium citrate….58mg Chlorpheniramine maleate….2mg (expectorant/antihistamine)	60ml 120ml 400ml 450ml	As per SRO	Approved.

The product of the firm named Be-Koff Syrup was presented in 237th meeting of the Board and approved with following composition:-

Each 5 ml contains Ammonium Chloride …. 100 mg Sodium Citrate …….. 58mg Chlorphenarmine maleate 2mg	Approved

Later on, firm informed that due to typographical mistake, they missed one of the active ingredient of the product i.e. menthol 1mg/5ml. Now firm has submitted revised dossiers to be considered by the Board with composition as under:-

Each 5 ml contains

i. Ammonium Chloride …….. 100mg
ii. Sodium Citrate …… 58mg
iii. Chlorphenarmine maleate …… 2mg
iv. Manthol …….. 1mg

The dossier of the proposed product has been re-evaluated and found upto date with respect to evaluation guidelines approved in 256th meeting of the Board.

S #	Name and address of Manufacturer / Applicant	Brand Name (Proprietary name + Dosage form + Strength) Composition Pharmacological Group Finished product specification	Type of Form Initial date, diary. Fee including differential fee Demanded Price / Pack size	International status in stringent regulatory agencies Me-too status	Decision
1.	M/s BJ Pharmaceuticals, 19 km, Mandiali Stop, Lahore – Sheikhupura Road, Lahore	BE-Koff Syrup Each 5 ml contains Ammonium Chloride 100 mg Sodium Citrate 58mg Chlorphenarmine maleate 2mg Manthol 1mg Expectorant / Antihistamine (BP Specification)	Form 5 Rs. 8,000/- + Rs. 12000/- =20,000/- dated 22-06-2012 & 04-02-2013 Pack size / as per SRO	---------- Amrid -Jawa	Approved

Decision of 291st meeting: -

Registration Board deferred the product for evidence of approval status of formulation in the reference regulatory authorities.

Now firm has submitted registered products of other firms with following composition without Menthol.

Each 5 ml contains:-
Ammonium Chloride …..... 100 mg
Sodium Citrate ……. 58mg
Chlorphenarmine maleate … 2mg

Decision of 293rd meeting: -

Registration Board deferred the product for evidence of approval status of formulation in the reference regulatory authorities.

Now firm has submitted a request to grant them registration without Menthol for which me-too products are available.

Decision: - Registration Board deferred the case with following comments;

i. Submission of evidence of reference regulatory agencies.
ii. Status of Innovator's product.
iii. Submission of revised Form-5

Case No.01:- **Request of M/s. U.M Enterprises, Karachi for change of local address for their already registered veterinary drugs.**

M/s. U.M Enterprises, Karachihas requested for change of local address for their following registered imported products as per following details:-

S. No	Reg. No.	Name of Drug(s)	Name & Address of Importer (as per Registration Letters)	Name & Address of Importer (as per New DSL)	Initial date of Registration & date of last renewal
1.	012886	Coliprim Suspension	M/s. U.M. Enterprises, State Life Building No.4, Shahrah-e-Liaquat, Karachi.	M/s. U.M. Enterprises, Plot No.12 Sector 15 Korangi Industrial Area, Karachi.	02-11-1991 19-10-2016
2.	012888	Coccidiopan Powder	-do-	-do-	02-11-1991 19-10-2016
3.	014164	Colimycin Powder	M/s. U.M. Enterprises, 03-3D, State Life Building, No.4, Shahrah-e-Liaquat, New Challi, Karachi.	-do-	01-08-1993 Registration Board acceded the request of firm and decided to grant the renewal w.e.f 01-08-2018 to 31-07-2023 subject to prevailing import policy for the manufacturer abroad vide Renewal Section letter No.F.3-8/2018-RRR (M-286) dated 21st January, 2019.
4.	014165	Aviquil Plus Powder	-do-	-do-	01-08-1993 Registration Board acceded the request of firm and decided to grant the renewal w.e.f 01-08-2018 to 31-07-2023 subject to prevailing import policy for the manufacturer abroad vide Renewal Section letter No.F.3-8/2018-RRR (M-286) dated 21st January, 2019.
5.	014166	Avitryl Oral Solution	-do-	-do-	01-08-1993 Registration Board acceded the request of firm and decided to grant the renewal w.e.f 01-08-2018 to 31-07-2023 subject to prevailing import policy for the manufacturer abroad vide Renewal Section letter No.F.3-8/2018-RRR (M-286) dated 21st January, 2019.
6.	016219	Avitryl 5% Injectable Solution	-do-	-do- Renewal status	19-10-1994 04-03-2019

7.	016220	Avinide Suspension	-do-	-do- Renewal status	19-10-1994 04-03-2019
8.	017986	Avicycline 5% Injection	-do-	-do-	02-10-1995 17-04-2015
9.	017987	Avixavit Powder	-do-	-do-	02-10-1995 17-04-2015
10.	017988	Tylosin 20% Injection	-do-	-do-	02-10-1995 17-04-2015
11.	018419	Avixim Oral Solution	-do-	-do-	22-08-1996 17-04-2015
12.	019028	Provimi Broiler Pack Powder	-do-	-do-	22-08-1996 22-03-2016
13.	019029	Provimi Layer Pack Powder	-do-	-do-	22-08-1996 22-03-2016
14.	019031	Avimec Injection	-do-	-do-	11-08-1996 22-03-2016
15.	020776	Avinazene Powder	-do-	-do-	04-12-1997 17-11-2017
16.	021250	Viamine Liquid	-do-	-do-	09-05-1998 26-04-2018
17.	021251	Permacol-500 Granule	-do-	-do-	09-05-1998 26-04-2018
18.	021256	Aviprate Liquid	-do-	-do-	09-05-1998 26-04-2018
19.	021447	Try-Ban Powder for Injection	-do-	-do-	07-09-1998 04-09-2018
20.	027433	Nicarmix Premix	M/s. U.M. Enterprises, 18-C, 3rd Floor, Dolmen Estate Building, Block 7-8, Shaheed-e-Millat Road, Karachi.	-do-	21-03-2002 30-01-2017
21.	031513	Monensin 20% Powder	-do-	-do-	07-10-2003 04-11-2018
22.	032218	Coxistac 12% Granular	-do-	-do-	06-09-2004 29-08-2019
23.	034508	Maduramicin Ammonium Premix Powder	-do-	-do-	27-11-2004 30-09-2019
24.	034509	Camectin 1% Injection	-do-	-do-	27-11-2004 30-09-2019
25.	039954	UFLO 20% Injection	-do-	-do-	03-09-2005 17-04-2015
26.	039955	OXLA 20% Injection	-do-	-do-	03-09-2005 17-04-2015
27.	039956	Compen 20% Injection	-do-	-do-	03-09-2005 17-04-2015
28.	057153	Gentamycin Sulfate 10% Injection	-do-	-do-	03-06-2009 29-04-2019
29.	057154	Ivermectin 2% Injection	-do-	-do-	03-06-2009 29-04-2019

The firm has deposited fee of Rs.5000x 29 = Rs.145,000/- and submitted following documents: -

a) Copies of initial Registration letters.
b) Copies of renewal status.
c) Copy of new Drug Sale License.

Current Name of Firm with Proprietor Name	Proposed Name of Firm with Proprietor Name
M/s. U.M. Enterprises,Karachi. Mr. Muhammad UmerS/O Mr. BadarUddin	No change
Premises Address on old DSL with Proprietor Name	**Premises Address on New DSL**
(i)M/s. U.M. Enterprises, State Life Building No.4, Shahrah-e-Liaquat, Karachi. (Mr. Muhammad Umer S/O Mr. BadarUddin) **(ii)**M/s. U.M. Enterprises, 03-3D, State Life Building, No.4, Shahrah-e-Liaquat, New Challi, Karachi. (Mr. Muhammad Umer S/O Mr. BadarUddin) **(iii)**M/s. U.M. Enterprises, 18-C, 3rd Floor, Dolmen Estate Building, Block 7-8, Shaheed-e-Millat Road, Karachi. (Mr. Muhammad UmerS/O Mr. BadarUddin)	M/s. U.M. Enterprises, Plot No.12 Sector 15 Korangi Industrial Area, Karachi.

Decision:- **Registration Board approved firm's request for change of local storage facility address *"Plot No.12 Sector 15 Korangi Industrial Area, Karachi"* for above mentioned imported veterinary products in accordance with new DSL, on same terms and conditions. Approval letter shall be issued after verification of new local storage facility site.**

Case No.02:- **Request of M/s. Vigilant Veterinary Services (Pvt) Ltd, Lahore for change of local address for their already registered veterinary drugs.**

M/s. Vigilant Veterinary Services (Pvt) Ltd, Lahorehas requested for change of local address for their following registered imported products as per following details:-

S. No	Reg. No.	Name of Drug(s)	Name & Address of Importer (as per Registration Letter)	Name & Address of Importer (as per New DSL)	Initial date of Registration & date of last renewal
1.	017912	Enrosol-S Oral Solution	M/s. Vigilant Veterinary Services (Pvt) Ltd., A-3, 24-Jail Road, Lahore.	M/s. Vigilant Veterinary Services (Pvt) Ltd., Flat No.1, First Floor, Sultan Plaza, Main Bani Gala Road, Islamabad.	23-07-1995
2.	039948	Neomycin-25 Water Soluble Powder	-do-	-do-	03-09-2005 20-01-2020
3.	039949	Bromexan Oral Solution	-do-	-do-	03-09-2005 20-01-2020
4.	035109	Tylosin Water Soluble Powder	-do-	-do-	13-12-2004 20-01-2020
5.	035110	Amoxycol Water Soluble Powder	-do-	-do-	13-12-2004 20-01-2020
6.	035111	Mycoplasmin Water Soluble Powder	-do-	-do-	13-12-2004 20-01-2020
7.	035112	Colistin-600 Water Soluble Powder	-do-	-do-	13-12-2004 20-01-2020
8.	035113	Vermizole-Forte Suspension	-do-	-do-	13-12-2004 20-01-2020

9.	035114	Vazuril Solution	-do-	-do-	13-12-2004 20-01-2020
10.	018813	Heparenol Powder	-do-	-do-	07-04-1996 06-04-2016
11.	018814	Albendazine Bolus	-do-	-do-	07-04-1996 06-04-2016
12.	018815	Amprolium -60 Powder	-do-	-do-	07-04-1996 06-04-2016
13.	018816	Ciprosol Solution	-do-	-do-	07-04-1996 06-04-2016

The firm has deposited fee of Rs.5000 x 13 = Rs.65,000/- and submitted following documents:-

a) Copies of initial Registration letters.
b) Copies of renewal status.
c) Copy of previous Drug Sale License.
d) Copy of new Drug Sale License.

Current Name of Firm with Proprietor Name	**Proposed Name of Firm with Proprietor Name**
M/s. Vigilant Veterinary Services (Pvt) Ltd, Lahore. Mr. Muhammad Azam Chohan S/O Mr. Bashir Ahmed Chohan.	No change
Premises Address on old DSL	**Premises Address on New DSL**
M/s. Vigilant Veterinary Services (Pvt) Ltd., A-3, 24- Jail Road, Lahore.	M/s. Vigilant Veterinary Services (Pvt) Ltd., Flat No.1, First Floor, Sultan Plaza, Main Bani Gala Road, Islamabad.

Decision:- **Registration Board approved firm's request for change of local storage facility address from "A-3, 24- Jail Road, Lahore" to "Flat No.1, First Floor, Sultan Plaza, Main Bani Gala Road, Islamabad" for above mentioned imported veterinary products in accordance with new DSL, on same terms and conditions. Approval letter shall be issued after verification of new local storage facility site.**

Case No.03:- **Request of M/s. Vety-Care (Pvt) Limited, Islmabad for change of local address for their already registered veterinary drugs.**

M/s. Vety-Care (Pvt) Limited, Islamabad has requested for change of local address for their following registered imported products as per following details:-

S.No.	Reg. No.	Product Name(s)	Previous Address	New applied Address
1.	008690	Ampicillin 20%	M/s. Vety-Care (Pvt) Ltd., 864, N.W. Murree Road, Opp. Old Passport Office, Rawalpindi.	M/s. Vety-Care (Pvt) Ltd., Distributors, Plot No.77, Street No.6, I-10/3, Islamabad.
2.	008698	Gentamast	-do-	-do-
3.	008692	Trimethosulf	-do-	-do-
4.	016254	Supersept Liquid for Disinfectant	M/s. Vety-Care (Pvt) Ltd., 59-C, Satellite Town, Murree Road, Rawalpindi.	-do-
5.	013218	Amoxicillin Trihydrate 11.5% Powder for Oral Administration	M/s. Vety-Care (Pvt) Ltd., 2nd Floor, Allied Commercial Plaza, ChandaniChowk, Rawalpindi.	-do-

6.	027458	Brema® mectin Solution for Injection	M/s. Vety-Care (Pvt) Ltd., 4-A, Satellite Town, Murree Road, Rawalpindi.	-do-
7.	023426	Amoxinject L.A. Suspension for Injection	M/s. Vety-Care (Pvt) Ltd., 4-A, Satellite Town, Murree Road, Rawalpindi.	-do-
8.	023427	Synchromate Solution for Injection	-do-	-do-
9.	017150	Gentamicin 10% Injection	M/s. Vety-Care (Pvt) Ltd., 2nd Floor, Allied Commercial Plaza, ChandaniChowk, Rawalpindi.	-do-

The firm has deposited fee of Rs.5000 x 9 = Rs.45,000/- and submitted following documents: -

a) Copies of initial Registration letters.
b) Copies of renewal status.
c) Copy of previous Drug Sale License.
d) Copy of new Drug Sale License.

Current Name of Firm with Proprietor Name	**Proposed Name of Firm with Proprietor Name**
M/s. Vety-Care (Pvt) Limited, Islamabad. Dr. Muhammad Amjad S/O Ch. Sardar Muhammad.	No change
Premises Address on old DSL	**Premises Address on New DSL**
(i)M/s. Vety-Care (Pvt) Ltd., 864, N.W. Murree Road, Opp. Old Passport Office, Rawalpindi. (Dr. Muhammad Amjad S/O Ch. Sardar Muhammad). **(ii)**M/s. Vety-Care (Pvt) Ltd., 59-C, Satellite Town, Murree Road, Rawalpindi. (Dr. Muhammad Amjad S/O Ch. Sardar Muhammad). **(iii)**M/s. Vety-Care (Pvt) Ltd., 2nd Floor, Allied Commercial Plaza, ChandaniChowk, Rawalpindi. (Dr. Muhammad Amjad S/O Ch. Sardar Muhammad). **(iv)**M/s. Vety-Care (Pvt) Ltd., 4-A, Satellite Town, Murree Road, Rawalpindi. (Dr. Muhammad Amjad S/O Ch. Sardar Muhammad).	M/s. Vety-Care (Pvt) Ltd., Distributors, Plot No.77, Street No.6, I-10/3, Islamabad.

Decision:- **Registration Board approved firm's request for change of local storage facility address "Plot No.77, Street No.6, I-10/3, Islamabad" for above mentioned imported veterinary products in accordance with new DSL, on same terms and conditions. Approval letter shall be issued after verification of new local storage facility site.**

Case No. 04:- Request of M/s. Ghazi Brothers, Karachi for Change of Name of Manufacturer/ Manufacturer Site for their registered products.

M/s. Ghazi Brothers, Karachi has applied for change of name of manufacturer/manufacturing site for their already registered products as per details mentioned alongside each:-

S. No	Reg. No.	Name of Drug(s)/Composition as per Registration letter	Name of Drug(s)/Composition as per new CoPP	Existing Name of Manufacturer	Request in 2015 for Change of Name of Manufacturer	Request in 2017 for Change of Manufacturing Site
(I)	(II)	(III)	(IV)	(V)	(VII)	(VIII)
1.	029685	Lincocin 40% Soluble Powder Each gm contains:- Lincomycin Hydrochloride (corresponding to Lincomycin …400mg)	Lincocin 40% Soluble Powder Each gm contains:- Lincomycin base as Lincomycn Hydochloride…..0.4000 gram activity Colloidal Silicon Dioixde…….0.0012 gram Lactose Monohydrate…..qs to 1 gram	M/s. Pfizer Suzhou Animal Health Products Co. Ltd., China.	M/s. Zoetis Suzhou Manufacturing Co., Ltd, No.180, Zhu Yuan Road, Suzhou New District, Jiangsu Province, P.R. China.	M/s. Zoetis Suzhou Manufacturing Co., Ltd, 690, Jian Lin Road, Suzhou New District Jiangsu Province, P.R. China.
2.	009990	Lincomix Premix Powder Each Kg contains:- Lincomycin Hydrochloride…110gm	Lincomix 110 Premix Each Kg contains:- Lincomycin base as Lincomycin Hydrochloride..0.11 gram activity Light Liquid Paraffin…0.01 gram Rice Husk…….qs to 1 gram	-do-	-do-	-do-
3.	017935	Lincomix 44 Premix Powder Each Kg contains:- LincomycinHCl…44gm	Lincomix 44 Premix Powder Lincomycin base as Lincomycin Hydrochloride…0.044 gram activity	-do-	-do-	-do-
4.	009991	Linco-Spectin Powder Containing:- Lincomycin Hcl 42.19gm (equivalent to Lincomycin base 33.3gm) Spectinomycin Sulphate 103.71gm (equivalent to Spectinomycin base 66.7gm)	Linco-Spectin 100 Soluble Powder Contains:- Lincomycin base as Lincomycin Hydrochloride…0.222 gram activity Spectinomycin base as Spectinomycin Sulfate…0.445 gram activity. Sodium Benzoate……0.0107 gam Lactose Monohydrate…..qs to 1 gram	-do-	-do-	-do-

With reference to the instant case it is Animal Health Products Co. Ltd., China" to "M/s. Zoetis Suzhou Manufacturing Co., China" with submitted that the firm initially requested in 2015 for change of name of manufacturer from "M/s. Pfizer Suzhou full fee i.e. Rs.100,000/-for each product. For products 1-3 firm provided attested fee copy (from Allied Bank, Karachi Branch) for product at Sr.No. 4 original fee challan is available. Later, the firm also requested for change of manufacturing site for the said products from "M/s. Pfizer Suzhou Animal Health Products Co., Ltd, China" to "M/s. Zoetis Suzhou Manufacturing Co., Ltd, 690, Jian Lin Road, Suzhou New District Jiangsu Province, P.R. China".

Original request submitted by the firm is being traced, and fee challan alongwith undertaking and provided the following supporting documents. The renewal section has confirmed the renewal of above mentioned drugs. Furthermore, the firm has informed regarding change of brand in remarks column -IV as submitted free sale certificates.

a) Copies of initial Registration letters along with renewal status and post registration variations.
b) Original legalized and attested free sale certificate (issued by Chines Authority.
c) GMP certificate duly legalized by Consulate General of Pakistan for new manufacturing site.
d) Copy of Drug Sale License.
e) Site master file Suzhou.

Decision: Registration Board deferred for incorporation of complete background of the case.

Case No.05:- Registration of Drugs under the Drugs Act, 1976.

Registration Board in its 287th meeting approved registration of following veterinary product in the name of M/s. Punjnad Pharma (Pvt) Ltd, Lahore and cancellation of the same from the name of M/s. Vetaria Pharmaceuticals, Lahore.

S. No.	Regn. No.	Name of Drug(s) & Composition	Already pack sizes granted as per Regn. Letter.	Remarks
1.	034516	Promectine Injectable Solution Each ml contains:- Ivermectin…..10mg	10ml 50ml 100ml 250ml 500ml	Firm requested for grant of 500ml pack among the approved pack sizes.

The M/s. PunjnadPharma (Pvt) Ltd, Lahore has deposited fee of Rs.100,000 x 2 = Rs.200,000/- for Promectine Injectable Solution pack sizes 50ml & 100ml and submitted separate registration dossiers.The cancellation letter of the above product in the name of M/s. Vetaria Pharmaceuticals, Lahore and registration letter has already been issued for pack sizes 50ml & 100ml.

Decision:- The Board noted the above information.

Case. No.06:- Request of M/s. Bin Sadiq International, Lahore for correction in finished product specifications of registered products.

M/s. Bin Sadiq International, Lahore has requested for correction in finished product specification of their registered veterinary drugs as per following details;

S.No.	Product Name/Composition/ Reg.No.	Currently approved specification	Finished product specification demanded by the firm	Remarks
1.	Doxiciclina 50% Water Soluble Powder Each 100gm contains:- Doxycycline hyclate eq. to Doxycycline…50gm **Reg.No.088648**	USP specification	As per innovator's specification	Firm initially requested for European specification. Case was considered in 290th meeting wherein the Board decided not to accede firm's request because requested specification is not available.

2.	Amoxifarma Soluble Powder for Oral Solution 800mg Each 1gm of powder contains:- Amoxicillin trihydrate…….800mg (eq. to Amoxicillin base……696.80mg **Reg.No.088649**	B.P	-do-	Firm initially requested for European specification. Case was considered in 290th meeting wherein the Board decided not to accede firm's request because requested specification is not available.
3.	Amprosid Liquid Water Soluble 250mg/ml Each ml contains:- Amprolium HCL…….250mg **Reg.No.088650**	USP	-do-	The firm initially requested for change of specification from USP to "European pharmacopeia". Case was considered in 27th PRVC and committee did not acceded to firm request being available in USP.

The Post Registration Variation Committee in its 34th meeting evaluated the case and decided to place the case before Registration Board for further consideration of firm's request.

Decision:-Registration board deferred for confirmation from relevant pharmacopeias.

Case .No. 07:- Request of M/s. La-Vie Pvt. Ltd. Lahore for withdrawal of Registration Application.

M/s. La-Vie Pvt Ltd., Lahore has informed that their principal aborad has terminated market authorization of below mentioned approved product stating the reason as delay in registration process.

S. No.	Name of Importer/ Manufacturer	Name of Drug(s)/ Composition	Board Decision (M-282)
1.	M/s. La-Vie Pvt. Ltd. 53-A XX, Commercial Block, Phase II, Khayaban-e-Iqbal DHA, Lahore. **Manufacturer & Marketing Authorization Holder:-** M/s. Kolmar Korea Co., Ltd., 245 Sandan-gil, Jeonui-myeon, sejong-si, Republic of Korea.	DUKAY Topical Gel 1 g of gel contains:- Clindamycin as clindamycin phosphate…10mg Anhydrous benzoyl peroxide as hydrous benzoyl peroxide….50 mg	Approved as per Policy for inspection of manufacturer abroad.

Registration Board in its 291st meeting deferred the case for confirmation of me-too products of abovementioned formulations.As per available record same drug are already registered in various firms.

Decision:- Registration Board acceded to the firm's request.

Case.No.08:- Registration of Drugs

Registration Board in its 289th meeting approved following veterinary drugs in the name of M/s. Chakwal Pharma International, Lahore for import from M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands. Details are as follow;

S. No.	Approved Products of M/s. ChakwalPharma, Lahore/ Manufacturer	Details of Already Registered Products.	Regn. No.
	II	III	IV
1.	Alfamec1% Solution for injection Each ml contains:- Ivermectin…….10mg Manufactured By M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	Alfamec 1% Injectable Solution. Each ml contains:- Ivermectin…10mg M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured By M/s. Alfasan International B.V., The Netherlands.	048180

2.	Lincomycin-Spectinomycin 5/10 Solution for injection Each ml solution contains:- Lincomycin (as Hydrochloride)……..50mg Spectinomycin (as Hydrochloride)……..…….100mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	Lincomycin-Spectinomycin 5/10 Injectable Solution. Each ml contains:- Lincomycin (as HCl)……...50mg Spectinomycin (As HCl)...100mg M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	048182
3.	Xylazine 2% Solution for injection Each ml solution contains:- Xylazine (as Hydrochloride)…….20mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	Xylazine 2% Injectable Solution. Each ml contains:- Xylazine (as HCl)……20mg M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	048181
4.	Multivitamin Solution for injection Each ml solution contains:- Vitamin A…15,000 IU Cholecalciferol…1000 IU Alfa-Tocoferol Acetate…20mg Thiamine Hydrochloride…10mg Riboflavine Sodium Phosphate…6.85mg Pyridoxine Hydrochloride…3mg Cyanocobalamine….50mcg Nicotinamide….35mg D-Panthenol…..…25mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	Multivitamins Injectable Solution. Each ml contains:- Vitamin A (as Synthetic concentrate oily form) ....15000 IU. Cholecalciferol (as concentrate Oily form) …….1000 IU. Alpha Tocopheryl Acetate …..20mg. Thiamine Hydrochloride ……..10mg. Riboflavine Sodium Phosphate....6.85mg. Pyridoxin Hydrochloride…….3mg. Cyanocobalamin…50mcg. Nicotinamide…35mg. Dexpanthenol …25mg. M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	048185
5.	Amoxycilline 20% LA Suspension for Injection Each ml Suspension contains:- AmoxycillinTrihydrate……..…200mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JaWoerden Netherlands.	AmoxcinTrihydrate 20% Injectable Each ml contains: - AmoxycillinTrihydrate equivalent to 200mg amoxycillin base M/s. Shayan Traders Rawalpindi./ Manufactured by M/s. AlfasanInt Holland.	022144

While processing of registration letters it has been observed that the same products are already found registered in the name of other importers (M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi and M/s. Shayan Traders Rawalpindi). M/s. ChakwalPharma International, Lahore informed that their principle had already cancelled the agency agreement dated 06-03-2009 due to not reaching the agreed annual targets for several years and provided a copy of it.

The case was again discussed in 291st meeting the Registration Board decided to issue show cause to M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi and M/s. Shayan Trader, Rawalpindi as to why the registration of the abovementioned products may not be cancelled because of termination of their distribution agreement.

Accordingly show cause notices issued to both firms;

M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi Reply against show cause is as under:

(i) We strongly object to the cancellation of subject registrations since it is violation of their agreement with M/s. Alfasan, Netherlands. We never received notice of termination of ouragreement with M/s. Alfasan, Netherlands and reason behind this invalid termination.Prior to agreement with M/s. Alfasan, Netherlands, the products of this company are being counterfeited in Pakistan by their previous agent M/s. Lexicon Pharma. It was Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi that exposed M/s. Lexicon Pharma and its illegal counterfeit business and underwent extensive legal and operational costs in initiating legal proceedings against M/s. Lexicon Pharma.

(ii) M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachispent hugeamounts of money in getting Alfasan Netherlands out of the grips of counterfeiters M/s. Lexicon Pharma which is included legal costs, market surveys, travelling costs and products registration and transfer costs. Furthermore, Alina Combine pharmaceuticals has over the regularly paid the required DRAP fees to maintain the products registrations valid in Pakistan, hence they are asked to right to market these products in Pakistan given the extensive costs borne by us the effort and hardships faced by us in securing the interest of M/s. Alfasan in Pakistan.

(iii) Considering the above believe that DRAP should secure the interest of its genuine importers/manufacturers who have over the years exposed the counterfeit and spurious manufacturers and helped international manufactures as a result. They gone the extra length and paid exorbitant amounts in legal costs and various other expenses without any compensation to date from M/s. Alfasan Netherlands.

(iv) In lieu of above, we again submit that strongly object to the notion of consideration of cancellation of their registered products and hope that Board will give justified consideration to their case and not cancel our valid registration.

For product at Sr.No.5, show cause notice issued to M/s. Shayan Traders Rawalpindi but letter was undelivered. As per record the product has been transfer from M/s. Shayan Traders Rawalpindi to M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi vide letter No.F.2-2/2007-Reg-I (Vet) dated 16th April, 2007.

Decision:- Registration Board defer the case for provision of fresh sole agency agreement /authorization letter from the manufacturer abroad in the name of M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi.

Case.No.09:- Request of M/s. Breeze Pharma (Pvt.) Ltd., Islamabad registration of drugs.

M/s. Breeze Pharma (Pvt.) Ltd., Islamabad has requested for registration of following veterinary products for local manufacture in their name and cancellation of same from the name of M/s. Redex Pharmaceutical Industries (Private) Limited, Karachi.

S. No.	Reg. No.	Name of Drug(s)/ Composition	Already Approved Pack Sizes	Initial Date of Registration/ Remarks
1.	025349	Devermazole-CS Oral Solution Each ml contains:- Albendazole B.P……...…100mg Cobalt Sulphate B.P……0.382% Selenium Sulphide B.P……0.150%	100ml 500ml 1000ml	09-05-2000
2.	025350	Bovicin-20 Oral Solution Each ml contains:- Enrofloxacin Hcl…….200mg	100ml 500ml 1000ml	09-05-2000

M/s. Breeze Pharma (Pvt.) Ltd., Islamabad has deposited the required fee Rs. 20,000 x 2 = 40,000 and submitted following supporting documents:-

(i) Original NOC **dated 05-09-2018** from M/s. Redex Pharmaceutical Industries (Private) Limited, Karachi.
(ii) Copy of initial registration letter along with renewal status.
(iii) Copy of Drug Manufacturing License.
(iv) Undertaking.

(v) GMP inspection report conducted on 03-08-2017.
(vi) Applications on Form 5.

Decision:- Registration Board defer the case for provision fresh NOC as existing NOC is more than 2 years old.

Case No.10:- Request for Change of Proprietor/Change of Address (Local) for their already Registered Veterinary Drugsof M/s. Unicare Enterprises, Faisalabad.

M/s. Unicare Enterprises, Faisalabad has requested for Change in name of importer with change of proprietor/ change of address (Local) address for their following registered imported products as per following details:-

S. No.	Reg. No.	Name of Drug(s)	Initial date of Registration & date of last renewal
1.	081301	Lincosol 40% Oral Powder	22nd August, 2016
2.	081302	Amoxicilina 500 Karizoo	22nd August, 2016
3.	081715	Kariflox 10% Oral Solution	07th September, 2016
4.	-	Karidox 500mg/g Water Soluble Powder	Approved in (M-291)
5.	-	Flortek 100mg/ml (Solution for Oral administration)	Approved in (M-291)

Details of Firm

Current Name of Firm with Proprietor Name	Proposed Name of Firm with Proprietor Name
M/s. Unicare Enterprises, Faisalabad. Mr. Muhammad Laiq S/O Ch. Bashir Ahmad	M/s. Unicare Enterprises, Faisalabad. Dr. Munir Ahmad S/O Faiz Ahmad.
Premises Address on old DSL	**Premises Address on New DSL**
M/s. Unicare Enterprises, P.98/54, Street No.3, JamiaAmdadia Street, Al-Fayyaz Colony, Satiana Road, Faisalabad.	M/s. Unicare Enterprises, Plot No.587/1-B, Street No.03 Punjab Small Industrial Estate NalkaKohala Sargodha Road, Faisalabad.
Requirements (NO SOP is Available)	**Firms Response**
a) Applications with required fee as per relevant SRO (in case of similarity/ resemblance with drug, fee will not be required.	a) A fee of 5,000 x 5 = Rs.25000/-
b) Copy of registration letter.	b) Copy of registration letters.
c) Copy of Drug Sale License with new name.	c) Copy of Old Drug Sale License andCopy of New Drug Sale License No. 0011000 0001642 valid upto 10-04-2020 is submitted.
d) NOC from previous proprietor.	d) NOC on affidavit provided by Ex-proprietor (Mr. Muhammad Laiq).

Decision:- Registration Board decided to refer complete case to Legal Affair Division for their opinion as properiter of DSL has been changed.

Case.No.11:- M/s. A & K Pharmaceuticals, Faisalabad/Non Penicillin Section.

Federal Inspector of Drugs, Lahore has conducted routine GMP inspection of M/s. A & K Pharmaceuticals, Faisalabad was conducted on 09-11-2018 wherein it has been observed that the panel has not recommended Penicillin Dry Powder Section, as per available record firm has two registered penicillin products but has no separate penicillin manufacturing section. The Federal Inspector of Drugs recommended the renewal of Drug Manufacturing Section.

S. No.	Regn. No.	Name of Drug(s)/Composition
1.	035043	Moxis Oral Powder Each 100gm contains:- Amoxicillin Trihydrate……10gm ColistinSulphate..…. 50,000,000 IU
2.	049668	Colmox Powder Each 100gm contains:- Amoxicillin Trihydrate……...15gm ColistinSulphate…….…….50 MIU

Decision:- Registration Board decided to issue show cause notice to M/s. A & K Pharmaceuticals, Faisalabad for cancellation/suspension of registration of above mentioned products registered in the name of M/s. A & K Pharmaceuticals, Faisalabad for not possessing the penicillin manufacturing facility.

Case No. 12:- Request of M/s. U.M.Enterprises, Karachi for Grant of Additional Pack Size(s) for their already Registered Veterinary Drugs.

M/s. U.M. Enterprises, Karachi has requested for grant of additional pack size(s) for their following registered imported veterinary product. Details are mentioned below;

S. No.	Regn. No.	Name of Drug(s)/Composition	Already Pack Size Granted	Demanded Additional Pack	Initial registration with renewal	Justification
1.	016220	Avinide Suspension Each Litre contains:- Rafoxanide…..25gm	1000ml 4.5 Litre	100ml Plastic Bottles 500ml Plastic Bottles	19-10-1994 04-03-2019	*Due to different sizes, we require different pack sizes of our product "Avinide Suspension" as it would be more convenient for our end customers/ consumers. Smaller pack sizes would be more suitable for small farms and other pack sizes are needed accordingly to different capacity of frams.*

M/s. U.M. Enterprises, Karachi has deposited fee of Rs.5000 x 2 = Rs.10,000/- and submitted required supporting documents including.

(i) Copy of initial Registration letter.
(ii) Renewal status of above drug.
(iii) Copy of Drug Sale License.
(iv) Legalized free sale certificate issued by Ministry of Agriculture/ The Veterinary Department-Pharmacy and Drugs Control Division, Jordan wherein the demanded pack size(s) is mentioned.
(v) Undertaking.

The demanded pack sizes are not given to other firms.

Decision:- Registration Board approved M/s. U.M. Enterprises, Karachi request for grant of additional pack sizes of "100ml plastic bottle and 500mlplastic bottle" to their registered veterinary product Avinide Suspension (Reg.No.016220) on same terms and conditions.

Case No. 13:- Registration of Veterinary Drug under Drug Act, 1976.

Registration Board in its 237th meeting approved following product of M/s. Ghazi Brothers, Karachi for import from M/s. HebeiYuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China subject to inspection of manufacturer abroad as per import policy and verification of storage facility (where applicable) as per detailed mentioned against each:-

S. No.	Name of Importer/ Manufacturer	Name of Drugs/ Composition & Meeting	Decontrolled/ Packs Size	Shelf Life	Decision/ Remarks
1.	M/s. Ghazi Brothers, Karachi. / M/s. HebeiYuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China.	Sinomox LA Suspension for Injection Each ml contains:- Amoxicillin….150mg (15%)	10ml 50ml 100ml 250ml	2 years	Approved

While processing for issuance of registration letter it was observed that the said product is already registered in the name of M/s. Genome Pharma, Islamabad with brand name **"**Amoxygen LA Injection" (Reg.No. 057143) from the same manufacturer/product license holder. M/s. Ghazi Brothers was informed accordingly about the status of the case.

Now, M/s. Ghazi Brothers, Karachi has provided legalized and attested termination letter in favor of "*M/s. Genome Pharma, Islamababd-Pakistan*" from the manufacturer/principal M/s. HebeiYuanzheng Pharmaceutical Co., Ltd., No. 16 Liuyuan Road, Chang, An District, Shijiazhuang City, Hebei Province, China.

It is pertinent to mention that inspection of above mentioned manufacturer has already been carried out by nominated panel on 04th and 05th April, 2017 and rated the manufacturing facility as "Good".

The case was discussed in 291st meeting of Registration Board meeting, keeping in view the termination of distribution agreement of M/s. Genome Pharma, Islamabad for product "Amoxygen LA Injection" (Reg.No. 057143) by M/s. HebeiYuanzheng Pharmaceutical Co., Ltd., No. 16 Liuyuan Road, Chang, An District, Shijiazhuang City, Hebei Province-China, Registration Board decided to issue show cause notice to M/s. Genome Pharma, Islamabad as to why the registration of aforesaid product may not be cancelled because of termination of distribution agreement.

Accordingly show cause notice issued on 30thDecember, 2019 and reminder issued on11th February, 2019 to M/s. Genome Pharma, Islamabad. But reply is still awaited.

Decision:- Registration Board decided to issue final reminder to M/s. Genome Pharma, Islamabad. A copy of same will also be sent to concerned DRAP office for handing over to the firm.

Case No. 14:- Cancellation of distribution agreement of M/s. SS Associates, Lahore by their principal abroad (Turkey).

M/s. Medicavet, Turkey informed vide letter about termination of distribution agreement with M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, MozangChungi Jail Road, Lahore ***w.e.f. 18-01-2019*** and further informed about appointment of *M/s. Unicare Enterprises, Faisalabad* (Head Office: M/s. Unicare Enterprises, Commercial -06, 1st Floor, Block-A, Kazimabad, Model Colony, Karachi, Pakistan-75100) (Regd. Office: Reg. Office: Plot No. 587/1-B, Street No.3, Punjab Small Industrial Estate, NalkaKohala, Sargodha Road, Faisalabad) as their new distributor. M/s. Medicavet, Turkey also provided a copy of termination notice addressed to M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, MozangChungi Jail Road, Lahore.

Details of registration applications submitted by M/s. SS Associates, Lahore from the above mentioned principal is as follow:-

S.No	Name of Drugs/Composition / Meeting No.	Name of Manufacturer	Remarks
1.	Mediquinol 10% Oral Liquid Each ml contains:-	M/s. Medicavet, TarimHayvancilikIlacveKimya San. Tic. Ltd. Sti. ItosbEski	Inspection of the manufacturer abroad has been carried by the nominated panel on 27th& 28th

	Enrofloxacin……100mg **(M-277)**	Ankara AsfaltiUzeri 12. Cadde No: 1 34959 Tepeoren Tuzla Istanbul, Turkey.	September, 2018 and recommended the facility.
2.	Medicol 24% Oral liquid Each ml contains:- Colistin Sulfate…240mg **(M-277)**	-do-	-do-
3.	Nemason Water Soluble Powder Each gram contains:- Levamisole hydrochloride……150mg **(M-277)**	-do-	-do-
4.	Synercid Water Soluble Powder Each gm contains:- Amoxicillin (as trihydrate)……720mg ColistinSulphate...180 mg **(M-284)**	-do-	Panel for inspection of Penicillin Section of manufacturer has been constituted comprised of Mr. Abdullah and Mr. AjmalSohailAsif.

Keeping in view the termination of distribution agreement of M/s. SS Associates, Lahore by M/s. Medicavet, Turkey, Registration Board decided to issue show cause notice to M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, MozangChungi Jail Road, Lahoreas to why the approval for registration of veterinary products may not be cancelled because of termination of their distribution agreement.

Accordingly show cause notice issued to M/s. SS Associates, Lahore on 30th December, 2019 and letter is undelivered and again letter to the firm another company address but letter is again undelivered.

Decision:- Registration Board decided to issue final reminder to M/s. SS Associates, Lahore. A copy of same will also be sent to concerned DRAP office for handing over to the firm.

Case.No.15:- M/s. D-Maarson Pharmaceuticals, Rawat, Rawalpindi.

Secretary Central Licensing Board has forwarded the case of M/s. D-MaarsonPharmaeucticals, Rawat Rawalpindi wherein it has been informed that while considering the case of renewal of Drug Manufacturing License of M/s D-Maarson Pharmaceuticals Plot No. 17, SS-2, RCCI Rawat, Rawalpindi in 259th meeting of the Central Licensing Board, held on 29-30, March 2018, the Board observed that the firm have registration for following veterinary products which contains penicillin but firm does not possess section for manufacturing of these products.

i. Lox-20 (Reg. No.063514)
ii. Claumox-28 Powder (Reg. No. 072682)
iii. Moxibac-C Powder (Reg. No. 062175)

The Board was also informed that in addition to the above mentioned products identified by Central Licensing Board, the following product containing penicillin is found registered in the name of M/s. D-Maarson Pharmaceuticals, Rawat, Rawalpindi.

i. Salinobak Water Soluble Powder (Reg.No.063822)

Registration Board in its 282nd meeting decided to issue show cause notice to M/s. D-Maarson Pharmaceuticals, Rawat, Rawalpindi for cancellation/suspension of registration of above mentioned products registered in the name of M/s. D-Maarson Pharmaceuticals, Rawat, Rawalpindi for not possessing the manufacturing facilities.

Show Cause Notice issued to the firm. In response the firm has requested for personal hearing. Accordingly personal hearing letter has been issued to the firm.

Mr. Daulat Khan, CEO of M/s. D-Maarson Pharmaceuticals, Rawat appeared before the Board and informed the Board that they had already suspended the manufacturing of their registered penicillin containing products. He further informed that they are in process of developing a separate veterinary

penicillin manufacturing section and in the meantime arrangements will be made for contract manufacturing of these products from M/s. Farm Aid Group, Hattar.

The case was again discussed in 286th meeting of Registration Board suspended the registration of below mentioned products registered in the name of M/s. D-Maarson Pharmaceuticals, Rawat for not possessing the penicillin manufacturing facility till the firm make necessary arrangements for contract manufacturing of these products.

S. No.	Regn. No.	Name of Drug(s)/Composition	Remarks (if any)
1.	063514	LOX-20 Water Soluble Powder Each 100gm contains: AmoxycillinTrihydrate……..20gm ColistinSulphate…..……50MIU	
2.	072682	CLAU MOX-28 Water Soluble Powder Each 100g contains:- Amoxicillin Trihydrate……..20g Clavulinic Acid ……...4g ColistinSulphate …….....4g	**Initially approved composition are as under:-** CLAU MOX-28 Water Soluble Powder Each 100g contains:- Amoxicillin Trihydrate….20g Clavulinic Acid ……..…4g ColistinSulphate ……..4g **Firm applied for contract manufacturing composition are as under:-** Moxiwall Powder Each 100gm contains:- Amoxicillin Trihydrate BP eq. to Amoxicillin…….200mg Lincomycion HCL BP eq. to Lincomycion…….88mg SpectinomycinSulphate BP Vet eq. to Spectinomycin…….88mg Vitamin-E Acetate USP…30mg Shortcoming letter issued to the firm regarding change of composition. The applied product is different from one communicated to you vide letterNo.F.7-9/2018-Reg-I (M-286) Vet dated 12-07-2019 (i.e. Clau Mox-28 Water Soluble Powder) in the light of decision taken by Registration Board. In response the firm informed that Moxiwal Water Soluble Powder should be considered as fresh application for contract manufacturing on M/s. Farm Aid Group because our product Claumox-28 contains clavulanic acid on which DRAP has reservation for use in veterinary.
3.	062175	MOXIBAK-C Water Soluble Powder Each 100gm powder contains:- Amoxicillin as Trihydrate…….15gm ColistinSulphate……50MIU	
4.	063822	Salinobak Water Soluble Powder Each 100gm contains:- Lincomycin as HCl ……. 5gm Spectinomycin as HCl …….5gm Amoxicillin Trihydrate ……10gm	

M/s. D-Maarson Pharmaceuticals, Rawat has deposited the required fee Rs.50,000 x 4 = 200,000/- and submitted following supporting documents:-

(i) Agreement of toll manufacturing between M/s. D-Maarson Pharmaceuticals, Rawat& M/s. Farm-Aid Group, Hattar.
(ii) Original NOC from M/s. Farm-Aid Group, Hattar.
(iii) Copy of approved Section of M/s. Farm-Aid Group, Hattar.
(iv) Copies of registration letters.
(v) Copies of renewal status.
(vi) Copy of Drug Manufacturing License M/s. D-Maarson Pharmaceuticals, Rawat.
(vii) Copy of Drug Manufacturing License M/s. Farm-Aid Group, Hattar.
(viii) cGMP inspection report of M/s. Farm-Aid Group, Hattar.
(ix) Applications on prescribed Form -5.

Decision:- Registration Board directed to get clarification from applicant regarding relevant provision of rule applicable to their case.

Case No. 16:- Withdrawal of Veterinary Liquid Syrup Section and Veterinary Dry Powder Section of M/s. Legacy Pharmaceuticals (Pvrt) Ltd. Peshawar.

The case was placed before 273rd meeting of Central Licensing Board held on 15th January, 2020. The Central Licensing Board considered the facts and decided to accede the request of M/s. Legacy Pharmaceuticals (Pvt) Ltd., Peshawar for withdrawal of veterinary liquid syrup section and veterinary dry powder section in the name of M/s. Legacy Pharmaceuticals (Pvt) Ltd., Peshawar. Therefore said section stand cancelled being withdrawn. The manufacturing in the sections is prohibited and offense. The firm shall submit comprehensive plan for future utility of the section within 30 days positively. As per available record no drugs were registered in the name of M/s. Legacy Pharmaceuticals (Pvt) Ltd., Peshawar.

Decision:- Registration Board observed that as no product is registered for Veterinary Liquid Syrup Section and Veterinary Dry Powder Section of M/s. Legacy Pharmaceuticals (Pvrt) Ltd. Peshawar thus no action is required on its part.

Case No.17:- Request of M/s. Vet Line International, Lahore for change of address (Local) for their already registered veterinary drugs.

M/s. Vet Line International, Lahore has requested for change of local address for their following registered/approved veterinary products as per following details:-

S. No.	Reg. No.	Name of Drug(s)	Name & Address of Importer (as per Registration Letters)	Name & Address of Importer (as per New DSL)	Initial date of Registration & date of last renewal
1.	-	Sulphix Solution for Injection	M/s. Vet Line International, Flat # 55/5, First Floor, Shadman Market, Lahore.	M/s. Vet Line International, Plot No.939-A, Block-J, Phase-I, LDA Avenue-1, District Lahore. **Godown Address as per new DSL:-**Basement & Ground Floor, 939-A, Block-J, Phase-I, LDA Avenue-1, District Lahore.	Approved in (M-291)

The firm has deposited fee of Rs.5000/- and submitted following documents:-

a) Copy of previous Drug Sale License is submitted.
b) Copy of new Drug Sale License is submitted.

Current Name of Firm with Proprietor Name	Proposed Name of Firm with Proprietor Name
M/s. Vet Line International, Lahore. (Syed Zamirul Hassan Tirmazi S/O Syed MunirHussain)	No change
Premises Address on old DSL	**Premises Address on New DSL**
M/s. Vet Line International, Flat # 55/5, First Floor, Shadman Market, Lahore.	M/s. Vet Line International, Plot No.939-A, Block-J, Phase-I, LDA Avenue-1,

(Syed Zamirul Hassan Tirmazi S/O Syed MunirHussain)	District Lahore. **Godown Address as per new DSL:-**Basement & Ground Floor, 939-A, Block-J, Phase-I, LDA Avenue-1, District Lahore.

Decision:- **Registration Board approved firm's request for change of local storage facility address from "Flat # 55/5, First Floor, Shadman Market, Lahore" to "Plot No.939-A, Block-J, Phase-I, LDA Avenue-1, District Lahore. Godown Address as per new DSL:-Basement & Ground Floor, 939-A, Block-J, Phase-I, LDA Avenue-1, District Lahore" for above mentioned imported veterinary products in accordance with new DSL, on same terms and conditions. Approval letter shall be issued after verification of new local storage facility site.**

Case No. 18:- **Show Cause Notices issued to the firms having registration of products containing Norfloxacin.**

Registration Board in its 249th meeting while rejecting applications of veterinary drugs containing Norfloxacin due to development of resistance in human the Board also decided to issue show cause notice to already registered products for cancellation. Accordingly show cause notices were issued to the firms having registrations of aforementioned drug formulations. A number of firms have responded with their point of view including request for personal hearings.

The salient points, of the responses received are summarized as under:-

i) The drug is considered vital to combat stubborn bacterial infections faced by the poultry section.
ii) No scientific approval information regarding Norfloxacin resistance in human.
iii) Extensive study needs to be carried out before making a decision on this issue.
iv) Under Section 7 (11) of Drugs Act, 1976, detail of the information or enquiry conducted, on the basis of which the decision was taken, may be communicated for response.
v) The drug has no significant residual effect on human body.
vi) A few firms also agreed to withdraw the products.
vii) A number of the firm requested for opportunity for personal hearing.

The Board in 262nd meeting referred the case to Dr. Qurban Ali for further evaluation and recommendations. Dr. Qurban Ali in 265th meeting informed the Board that the case is under study for developing policy recommendations. The Board accordingly deferred the case in 265th and subsequent meetings.

The case was again discussed in 278th meeting decided that Dr. Qurban Ali, Member Registration Board informed that he will submit report after reviewing all relevant references and literature.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018wherein it has been decided as follow;

"The Group observed that Ciprofloxacin has already been banned for veterinary use so two antibiotics of Quinolone group i.e. Enrofloxacin and Norfloxacin may continue to be permitted for having more choice for controlling infections in veterinary practices"

Registration Board in its 289th meeting deferred the case for further deliberation on the matter in light of status in reference regulatory authorities.

Decision:- **Registration Board advised to present case with approval status of formulation in reference regulatory authorities and for veterinary.**

Case No.19:- **Show Cause Notices issued to the firms having registration of products containing Phenylbutazone.**

Registration Board in its 260th meeting while rejecting applications of veterinary drugs containing Phenylbutazone as drug is not recommended for use in food producing animals the Board also decided to issue show cause notices to all registered veterinary drug formulation containing Phenylbutazone. Accordingly show cause notices were issued to the firms having registrations of aforementioned drug formulations. A number of firms have responded with their point of view including request for personal hearings.

The salient points, of the responses received are summarized as under:-

i) The drug is used in equines like horse, donkeys etc. which is not meant for human consumption, therefore there is no problem of residual effect
ii) Extensive study needs to carry out before making a decision on this issue.
iii) Under Section 7 (11) of Drugs Act, 1976, detail of the information or enquiry conducted, on the basis of which the decision was taken, may be communicated for response.
iv) A few firms also agreed to withdraw the products

The Board in 262nd meeting referred the case to Dr. Qurban Ali for further evaluation and recommendations. Dr. Qurban Ali in 265th meeting informed the Board that the case is under study for developing policy recommendations. The Board accordingly deferred the case in 265th and subsequent meetings.

The case was again discussed in 278th meeting decided that Dr. Qurban Ali, Member Registration Board informed that he will submit report after reviewing all relevant references and literature.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018wherein it has been decided as follow;

"The Group, after deliberation, observed that since the Phenylbutazone is primarily used in equine animals so its use should be restricted to these animals only. Moreover, prominent warning on label of drugs containing Phenylbutazone, restricting its use in nonfood producing animals, should also appear in conspicuous manner."

Registration Board in its 289th meeting deferred the case for further deliberation on the matter in light of status in reference regulatory authorities.

Decision:- Registration Board advised to present case with approval status of formulation in reference regulatory authorities and for veterinary.

Case No.20:- Show cause notices issued to firms having registration of products containing Amantadine in combination with other antibiotics/ antibacterial.

Registration Board in its 249th meeting decided to issue show cause notices for cancellation of all the drug formulations having Amantadine in combination with antibiotic/ antibacterials for veterinary use for having drug interaction and resistance problem. Accordingly show cause notices were issued to the firms having registrations of aforementioned drug formulations. A number of firms have responded with their point of view including request for personal hearings.

The case was placed before the Registration Board in its 257th meeting and the Board directed to place comments of all firms / stake holders before the Board in its next meeting. Accordingly, the responses of the firms were placed before the Board in 258th meeting. The salient points, of the responses received are summarized as under:-

i) Huge financial losses to the firms /distributor as heavy investment have been made in the products.
ii) No complaints/information regarding interaction of Amantadine with antibiotic/ antibacterial, is reported.
iii) These combinations play very important role for treatment of diseases like Bird flu, Influenza.
iv) Extensive study needs to be carried out before making a decision on this issue.
v) Under Section 7 (11) of Drugs Act, 1976, detail of the information or enquiry conducted, on the basis of which the decision was taken, may be communicated for response.
vi) A few firms also agreed to withdraw the products and requested for grant of registration of other products instead.
vii) A number of the firm requested for opportunity for personal hearing.
viii) Pakistan Poultry Association has claimed that Amantadine based products are effective and safe for veterinary practices, that they have not received any complaint. The Association has requested for withdraw of the decision.
ix) Pakistan Veterinary Pharmaceutical Association has claimed that Amantadine based products are effective and safe for veterinary practices and they have received no complaint regarding such products. The Association has requested for withdrawal the decision.

Registration Board deferred the case in its 258th meeting due to paucity of time and took it again in 259th meeting. The following decision was taken.

Registration Board referred the matter to Dr. Muhammad Arshad, Member Registration Board, for giving his detail views (approval status of products by reference regulatory authorities, pharmacological and pharmaceutical compatibility etc) on the matter after consultation with other concerned experts in veterinary field.

Since no response was received from Dr. Muhammad Arshad so the Registration Board in its 262nd meeting decided to refer the matter to Dr. Qurban Ali, Director General, National Veterinary Laboratory, Islamabad/ Member Registration Board for expert views.

The Board in 262nd meeting referred the case to Dr. Qurban Ali for further evaluation and recommendations. Dr. Qurban Ali in 265th meeting informed the Board that the case is under study for developing policy recommendations.

The case was again discussed in 278th meeting decided that Dr. Qurban Ali, Member Registration Board informed that he will submit report after reviewing all relevant references and literature.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018 wherein it has been decided as follow;

"The group deliberated the matter in depth and in absence of any recognized scientific rational, regarding simultaneous use of antibiotic with antiviral drugs, all such combination are recommended to be withdrawn."

Registration Board in its 289th meeting deferred the case for further deliberation on the matter in light of status in reference regulatory authorities.

Decision:- Registration Board advised to present case with approval status of formulation in reference regulatory authorities and for veterinary.

Case No. 21:- Registration of Drugs under the Drugs Act, 1976-Inspection of Manufacturer Abroad.

Registration Board in 252nd meeting approved the following product of M/s. Ghazi Brothers, Karachi as per decision mentioned alongside;

S.No.	Name of Importer/Manufacturer	Product Name/Composition	Pack Size/shelf life	Decision/ Remarks
1	M/s. Ghazi Brothers, Karachi-75350 / **Product License Holder:-** M/s. Agrovet Market S.A., San Luis, Lima, Peru. **Manufacturer Under Product License Holder:-** M/s. Pharmadix Corp. S.A.C. Urbanizacion La Aurora-Ate Lima 3-Peru	Metri-CEF 3 Intrauterine Suspension Each 30ml contains:- Cephalexin monohydrate (Base)……600mg Neomycin sulfate (Base)……..1.02gm Cloxacillinbenzathine…1.50gm Vitamin A…30.000 IU	Decontrolled 30ml Pre-filled syringe 03 years	Approved

Inspection of manufacturer abroad was carried out by nominated panel, in accordance with the decision of Registration Board, on 03rd and 04th April, 2017. The panel was comprised of Dr. Amanullah Khan (Director-DTL, Quetta) and Ch. ZeeshanNazir (DD-QA, DRAP).

The nominated panel rated the "oral suspension" facility as good while "not recommended" the injection manufacturing facility of the said firm and the same was presented before Registration Board in its 287th meeting wherein the injection products were rejected by the Board in the light of recommendation of the inspection panel.

However, while processing for the issuance of registration letter of product "Metri-Cef intrauterine injection suspension" it has been observed that the said dosage form is pre-filled syringe (intrauterine injection) while the facility inspected was "oral suspension" which seems to be because of misunderstanding of the dosage form.

The case was discussed in 293rd meeting of Registration Board deferred the case for confirmation that whether the manufacturing of the said product is carried out aseptically or otherwise.

Firm has submitted that their product is intrauterine suspension and it is manufactured in non-sterile suspension area which is different from the aseptic section as Metri-Cef 3 is not intended to be injected parentally and this section is already inspected and approved by inspection panel. For further understanding manufacturing process is elaborated below:

(i) **Mixing of the Suspension Base:** In the stainless-steel reactor, Vaseline and peanut oil are heated to 100^{o}C for 15 minutes to dehydrate the mix, then passed through the sieve and later cool down.

(ii) **Addition of the API and Excipients:** then Cephalexin monohydrate, cloxacillinbenzathine, neomycin sulphate, vitamin A, aluminummonoesterate and chlorbutanol are mixed until these get the homogenized.

(iii) **Filling:** filling is performed with an adequate machine or through the gravity dispenser. Manufacturing process is also attached for your quick reference.

Decision:- **Registration Board rejected the application for registration of** Metri-CEF 3 **Intrauterine Suspension as panel in its report recommended oral liquid syrup/suspension section only for grant of registration and not recommended injection manufacturing facility of M/s. Pharmadix Corp. S.A.C. Urbanizacion La Aurora-Ate Lima 3-Peru and thus manufacturer does not have manufacturing facility for applied product.**

Case No. 22:- **Request of M/s. Evergreen Pharmaceuticals, Lahore for Grant o Additional Pack Size(s)for their already Registered Veterinary Drug.**

M/s. Evergreen Pharmaceuticals, Lahorehas applied for grant of additional pack of their followingregistered veterinary drug as per details mentioned against each:-

S. No.	Regn. No.	Name of Drug(s)/Composition	Already Pack Size Granted	Demanded Additional Pack	Initial registration with renewal	Diary No. /Justification
1.	081735	Emanta-98 Oral Powder Each gm contains:- Amantadine Hcl….0.98 Kg	100gm 500gm 1000gm	25Kg	03-03-2017	Dy. No. 2249-R&I dated 21-02-2020. Due to market requirements and demanded of breeders and hatcheries.
2.	081736	Tylotar-98 Oral Powder Each gm contains:- Tylosin Tartrate ...0.98 Kg	100gm 500gm 1000gm	25Kg	-do-	Dy. No. 2248-R&I dated 21-02-2020. Due to market requirements and demanded of breeders and hatcheries.
3.	089861	Mak Coli Powder Each Kg contains:- ColistinSulphate……5000,000IU	500gm 1Kg 5Kg 10Kg	25Kg	11-10-2018	Dy. No. 2251-R&I dated 21-02-2020. Due to market requirements and demanded of breeders and hatcheries.
4.	095642	Cloratec-20 Oral Powder Each gm contains:- Chlortetracycline Hydrochloride……20%	100gm 500gm 1000gm	25Kg	30-04-2019	Dy. No. 2251-R&I dated 21-02-2020. Due to market requirements and

						demanded of breeders and hatcheries.
5.	083240	Evedox Oral Powder Each gm contains:- Doxycycline ……0.5Kg	100gm 500gm 1000gm	25Kg	03-03-2017	Dy. No. 2247-R&I dated 21-02-2020. Due to market requirements and demanded of breeders and hatcheries.

M/s. Evergreen Pharmaceuticals, Lahorehas deposited the required fee of Rs.5,000 x 5 = Rs.25,000/- and submitted following supporting documents:-

(i) Copy of initial registration letters.
(ii) Details of previously granted pack size.
(iii) Justification of proposed change.
(iv) GMP inspection conducted by DRAP during last 12 months.
(v) Undertaking that the provided information/documents are true/correct.

The demanded pack sizes are not given to other firms.

Decision:- **Registration Board advised to present case with approval status of applied packs in reference regulatory authorities and for veterinary.**

Case No.23: Request of M/s. Aptly Pharmaceuticals, Faisalabad for change of composition of veterinary drug(s).

Registration Board in its 285th meeting approved following veterinary drugs in favor of M/s. Aptly Pharmaceuticals, Faisalabad. Registration letters has already been issued to the firm. The firm has requested to change the compositions are as under:-

S. No.	Name of Manufacturer	Name of drug(s) / Composition & Regn.No.	Composition requested by the firm	Approved Packs Size	Remarks
I	II	III	IV	V	VI
1.	M/s. Aptly Pharmaceuticals, 5-Km Sargodha-Sidhar Bypass Road, Faisalabad.	Closul-4.8 Oral Powder Each gm contains:- **ColistinSulphate…….48MIU** (As per Innovator's Specification)* **(Regn.No. 093868)**	Closul-4.8 Oral Powder Each gm contains:- **ColistinSulphate……..4, 800,000IU**	500g 1Kg 2.5Kg 5Kg in plastic jar	Dy.No.11773-R&I DRAP dated 21-05-2020
2.	-do-	Closul-5 Oral Powder **Each Kg contains:-** ColistinSulphate……..5,000,000 IU (As per Innovator's Specification)* **(Regn.No. 093869)**	Closul-5 Oral Powder **Each gm contains:-** ColistinSulphate……..5,000,000 IU	500g 1Kg 2.5Kg 5Kg in plastic jar	Dy.No.11772-R&I DRAP dated 21-05-2020

M/s. Aptly Pharmaceuticals, Faisalabad has deposited fee of Rs.20,000 x 2 = Rs.40,000/- for the said purpose along with form-5 and requested to change the compositions. Furthermore, the requested composition has already been granted registration to various firms.

Decision:- **Registration Board advised to get justification for reason for change of composition and its approval status accordingly.**

Case.No.24:- Registration of Drugs under the Drugs Act, 1976.

Registration Board in its 289th meeting held on 14–16th May, 2019 deferred the following drug of M/s. Medi-Vet (Pvt) Limited, Lahore for confirmation of me-too status

S. #	Name of Drug(s)/Composition	Demanded Composition of the firm.	Pack Size	Shelf Life
1.	Floxivet-C Injection Each ml contains:- Enrofloxacin B.P Vet……..……..100mg/ml ColistinSulphate BP…….250000 iu/ml	Floxivet-C Injection Each 100ml contains:- EnrofloxacinBP Vet…10gm ColistinSulphate BP……....50,000,000IU	100ml 250ml 500ml 1000ml	02 years

The firm has deposited the fee of Rs.20,000/-. As per available record the above mentioned product is not registered in same composition. The firm has requested to change the composition me-too already registered product in various firms including M/s. Zakfas Pharmaceuticals (Pvt) Ltd. Multan ***"Encoras Injection Regn.No.057067"***.

Decision:- Registration Board advised to get justification for reason for change of composition and its approval status accordingly.

Case No. 25:- Request of M/s. Vet Line International, Lahore for grant of additional pack size(s) for already registered veterinary drug(s).

M/s. Vet Line International, Lahore has requested for grant of additional pack sizes for their following registered veterinary products. Details are mentioned alongside each product.

S.No.	Regn. No.	Name of Drug(s)/Composition/Manufacturer	Details as per Registration letter	Demanded Additional Pack
1.	093226	Pyanosid Powder Each gm contains:- LincomycinHydrochloride Monohydrate…..…258.01mg (eq. to 227.52mg Lincomycin) SpectinomycinSulphateTetrahydrate……689.11mg (eq. to 455.73mg Spectinomycin) **Manufacturer &Product License Holder:-** M/s. Bela-Pharm GmbH & Co. KG Lohner Str. 19, 49377 Vechta, Germany.	Already granted pack sizes 146gm 1.46Kg Date of Reg: 02-11-2018	300g 1Kg 3Kg

M/s. Vet Line International, Lahore has deposited fee of Rs.5,000 x 3 = Rs.15,000/- and submitted required supporting documents including;

(i) Copy of initial registration letter. Renewal not due.
(ii) Copy of Drug Sale License.
(iii) Original legalized CoPP shows demanded pack size.

Decision:- Registration Board approved M/s. Vet Line International, Lahore request for grant of additional pack sizes of "300g, 1Kg&3Kg" to their registered veterinary product Pyanosid Powder (Reg.No.093226) on same terms and conditions.

Case No.26:- **Request for Change the Salt Form of "OxytetracyclineDihydrate" to "Oxytetracycline Hydrochloride" in Composition of Registered Veterinary Products of M/s. Nawan Laboratories (Pvt) Ltd, Karachi.**

M/s. Nawan Laboratories (Pvt) Ltd, Karachi has requested for change of composition of their following registered drug as per detail mentioned against each:-

S. No.	Regn. No.	Product Granted Composition	Demanded Composition
I	II	III	IV
1.	021303	Nawacin-100 Injection Each 100ml contains:- OxytetracyclineDihydrate equivalent to 10gm Oxytetracycline base.	Nawacin-100 Injection Each 100ml contains:- Oxytetracycline (as Hydrochloride)……10gm
2.	020800	Nawacin L.A. Injection Each 100ml contains:- OxytetracyclineDihydrate equivalent to 20gm Oxytetracycline base.	Nawacin L.A. Injection Each 100ml contains:- Oxytetracycline (as Hydrochloride)…….20gm
3.	023417	Nawacin-50 Injection Each 100ml contains:- OxytetracyclineDihydrate equivalent to 5gm Oxytetracycline base.	Nawacin-50 Injection Each 100ml contains:- Oxytetracycline (as Hydrochloride)…….5gm
4.	081321	Nimtol Injection Each ml contains:- Oxytetracycline as dehydrate…….300mg Flunixin as Meglumine..20mg	Nimtol Injection Each ml contains:- Oxytetracycline(as Hydrochloride) ……300mg Flunixin as Meglumine…..20mg

The firm has deposited fee of Rs.5,000 x 4 = Rs.20,000/- and submitted following supporting documents:-

(i) Copies of initial registration letters.
(ii) Copy of renewal status.
(iii) Copy of Drug Manufacturing License.
(iv) Copy of CRF.
(v) Locally and internationally available brands with composition of "Oxytetracycline Hydrochloride".
(vi) Summary of product characteristics.
(vii) Undertaking.

The firm submitted the following reason for change of composition of above stated products:-

They are producing injectable form of veterinary drug therefore in the base of freely solubility in water, so therefore they are going to change the ***"Salt Form"*** of OxytetracyclineDihydrate to Oxytetracycline Hydrochloride in composition of their already registered above mentioned veterinary drugs.

They are clarify that the change of Salt Form in composition will not affect in fill volume of their already registered packs sizes i.e. 30ml,50ml & 100ml vial.

Remarks of Evaluator:
Submitted fee is 5000/- but salt form is changed.

Decision:- **Registration Board advised to present case with approval status of salts in reference regulatory authorities and generic status as well.**

Case No.27:- **Request of M/s. Tec-Man Internationl, Rawalpindi for change of local address for their already registered veterinary drugs.**

M/s. Tec-Man Internationl, Rawalpindi has requested for change of local address for their following registered imported products as per following details:-

S. No	Reg. No.	Name of Drug(s)	Name & Address of Importer (as per Registration Letters)	Name & Address of Importer (as per New DSL)	Initial date of Registration & date of last renewal
1.	044991	Fosbac Plus-T Powder	M/s. Tec-Man International, 1200, Block-B, Satellite Town, Rawalpindi.	M/s. Tec-Man International, 226 Race Course Road, Westridge-1, Rawalpindi.	21-06-2007 19-06-2017
2.	009616	Colisol Powder	-do-	-do-	05-07-2010 10-03-2015
3.	012995	Oxyject 20% LA Injection	-do-	-do-	05-07-2010 10-03-2015
4.	011124	T.S.O Liquid	-do-	-do-	05-07-2010 10-03-2015
5.	014184	T.S.O Suspension	-do-	-do-	05-07-2010 10-03-2015
6.	017902	Gentaject 10% Injection	-do-	-do-	05-07-2010 10-03-2015
7.	017903	Flumequine 50% Water Soluble Powder	-do-	-do-	05-07-2010 10-03-2015
8.	081303	Phenoxypen Water Soluble Powder	-do-	-do-	29-08-2016
9.	023494	Pharmasin-100	-do-	-do-	13-08-1999 06-08-2014
10.	028589	Fosbac Powder	-do-	-do-	21-08-2002 18-08-2017

The firm has deposited fee of Rs.5000 x 10 = Rs.50,000/- and submitted following documents:-

a) Copies of initial Registration letters.
b) Copies of renewal status.
c) Copy of previous license.
d) Copy of new Drug Sale License No. 0011000 0000985 valid upto 15-01-2020 is submitted. Firm has submitted copy of renewal slip.
e)

Current Name of Firm with Proprietor Name	Proposed Name of Firm with Proprietor Name
M/s. Tec-Man Internationl, Rawalpindi. (Mr. SaqibDaud S/O Daud Ahmed)	No change
Premises Address on old DSL	**Premises Address on New DSL**
M/s. Tec-Man International, 1200, Block-B, Satellite Town, Rawalpindi.	M/s. Tec-Man International, 226 Race Course Road, Westridge-1, Rawalpindi.

Decision:- **Registration Board approved firm's request for change of local storage facility address from "1200, Block-B, Satellite Town, Rawalpindi" to "226 Race Course Road, Westridge-1, Rawalpindi" for above mentioned imported veterinary products in accordance with new DSL, on same terms and conditions. Approval letter shall be issued after verification of new local storage facility site.**

Case No.28:- Cancellation of Drug Manufacturing Licensesby Central Licensing Board.

Central Licensing Board in its 271st meeting held on 12th September 2019 cancelled the Drug Manufacturing License (DML 0003530 (Formulation) of M/s. Kakasian Pharmaceuticals (Pvt) Ltd., 29-Km, Ferozpur Road, Lahore.

The case is submitted for consideration of Registration Board with regard to status of drugs registered with this firm after cancellation of their Drug Manufacturing License.

Decision:- Registration Board defer the case for seeking status from Legal Division whether the firm has challenged decision of CLB or otherwise..

Case.No.01: **CORRECTION IN MINUTES FOR ALREADY APPROVED PRODUCT DAXOTEL CONCENTRATE INJECTION 20MG/ML OF M/S ATCO PHARMA (PVT) LTD, KARACHI.**

The following product of M/s Atco Pharma (Pvt) Ltd, Karachi has been approved in 259th meeting of Registration Board as under: -

Importer & Manufacturer	Brand Name & Composition	Dy. No. & Fee	Reference	Documents
M/s Atco Pharma International Pvt Ltd, B-18 S.I.T.E Karachi. Manufactured By M/s Fresenius Kabi Oncology Ltd, Villege Kishanpura, P.O Guru Majra, Tehsil Nalagarh, District Solan, India (168)	Daxotel Concentrate Injection 20mg/ml Each ml contains:- Docetaxel Anhydrous eq to Docetaxel ……20mg Anticancer Manufacturer's Specifications	Form 5A 30-10-2013 vide diary No. 274 Rs. 100,000. Rs.1200/Vial.	MHRA. Docetaxil 20mg/ml, 80mg/4ml, 160mg/8ml by M/s Dr. Reddy Local. Docetax 20mg, 80mg, 120mg by M/s A.J Mirza.	COPP valid upto 02-01-2015. GMP valid upto 02-10-2015.
Decision of 259th Meeting Approved. Firm will provide valid legalized CoPP and Chairman will permit issuance of registration letter				

The demanded MRP Rs.1200/vial mentioned in minutes is a typographically error as the demanded MRP by the firm is Rs.12000/- as per Form-5A submitted by the firm.

The case is submitted for correction of demanded MRP i.e. Rs.12000/- instead of Rs.1200/-

Decision:- **Registration Board deferred the case for confirmation of firm's request from original dossier.**

Case.No.02:- **REQUEST OF M/S MUKHTAR ENTERPRISES, LAHORE FOR CHANGE OF ADDRESS (LOCAL) FOR THEIR REGISTERED PRODUCTS.**

The firm has requested for change of their office and store address. Details are as under:-

S.No.	Name of Document	Details as per old DSL	Details as per New DSL
1.	**Proprietor Name**	Mr. Farooq Ahmed S/o Mukhtar Ali	-do-
2.	**Head Office address**	Ground Floor 55 Block B, Faisal Town Lahore	151-C Block Faisal Town, Lahore
3.	**Godown Address**	-do-	-do-

Details of registered products as per approval		
S.No.	**Reg. No.**	**Name of Product**
1.	085257	Vancomycin 500mg Injection powder for concentrate for solution for IV infusion. Each vial contains: Vancomycin (as hydrochloride)……500mg
2.	085258	Vancomycin 1000mg Injection powder for concentrate for solution for IV infusion. Each vial contains: Vancomycin (as hydrochloride)……1000mg
3.	093937	Colistimethate Sodium Powder for Solution for IV injection/infusion Each 10ml vial contains: Colistimethate Sodium…1MIU
4.	094757	Colistimethate Sodium powder for solution for IV injection / infusion Each vial contains: Colistimethate Sodium…….. 2MIU

The firm has deposited fee of Rs.5000/- for each product and submitted the following supporting documents: -

a. Total fee of Rs.20,000/-
b. Copies of Initial registration letters & post registration variation (Renewal are valid)
c. Copy of previous and new drug sales license.

Decision: **Keeping in view the new Drug Sale License; Registration Board approved the change of address of importer from M/s Mukhtar Enterprises, Ground Floor 55 Block B, Faisal Town Lahore to M/s Mukhtar Enterprises, 151-C Block Faisal Town, Lahore for above products subject to storage facility verification report of new address.**

Case.No.03:- REQUEST OF M/S BIOCARE PHARMACEUTICA, LAHORE FOR CHANGE OF ADDRESS (LOCAL) FOR THEIR REGISTERED PRODUCTS.

The firm has requested for change of their office and store address with change of proprietor. Details are as under:-

S. No.	Name of Document	Details as per Old DSL	Details as per New DSL
1.	**Proprietor Name**	Mr. Salah-ud-Din Haider	Mr. Ali Haider
2.	**Head Office address**	108-B New Muslim Town, Lahore	807 Shadman-1, District Lahore
3.	**Godown Address**	-do-	8-C, Street No.3, Near LGS School, Shah Jamal District Lahore

Details of registered products as per approval		
S. No.	**Reg. No.**	**Name of Product**
1.	072552	Neocyspin Soft Gelatin Capsule 50mg. Each capsule contains: - Microemulsion Cyclosporin A 50mg.
2.	052214	Hisun (Vancomycin Hydrochloride) for Injection. Each vial contains:- Vancomycin…….500mg
3.	052215	Hisun (Vancomycin Hydrochloride) for Injection. Each vial contains:- Vancomycin……1000mg
4.	053887	Neocyspin Oral Solution 5gm/50ml. Each 5ml contains:- Microemulsion Cyclosporin A…….. 500mg.
5.	053888	Neocyspin Soft Gelatin Capsule 25mg. Each capsule contains:- Micro Emulsion Cyclosporin A 25mg.
6.	053889	Neocyspin Soft Gelatin Capsule 100mg. Each capsule contains:- Micro Emulsion Cyclosporin A 100mg.
7.	053890	Cycopin Dispersible Tablets 250mg. Each dispersible tablet contains:- Mycophenolate Mofitil 250mg
8.	053891	Cycopin Dispersible Tablets 500mg. Each dispersible tablet contains:- Mycophenolate Mofitil 500mg.
9.	053892	Cymusi Oral Solution 50mg/50ml. Each 50ml contains:- Sirolimus……. …….50mg.
10.	053893	Secomep (Lyophilized) Powder for Injection 40mg. Each vial contains:-

		Omeprazole Sodium….. 40mg
11.	053894	Zithrax 250mg Injection. Each vial contains:- Azithromycin...250mg.
12.	053895	Zithrax 500mg Injection. Each vial contains:- Azithromycin...500mg
13.	053897	Flurane Liquid for Inhalation. Contains:- Isoflurane…… 99.9%
14.	028470	CERON-α 3MIU Injection. Each vial contains:- Interferon Alpha 2b (Human Recombinant) 3MIU
15.	028471	CERON-α 5MIU Injection. Each vial contains:- Interferon Alpha 2b (Human Recombinant) 5MIU.
16.	028468	Sulzone 1.0gm Injection. Each vial contains:- Cefoperazone as Sodium Salt 500mg. Sulbactam as Sodium Salt 500mg.
17.	028469	Sulzone 2.0gm Injection. Each vial contains:- Cefoperazone as Sodium Salt 1.0gm. Sulbactam as Sodium Salt 1.0gm.
18.	043063	Solvent for CERON-α Injections. (Sterile Water for Injection 1ml).
19.	079235	Penitrax for Injection Each vial contains:- Piperacillin Sodium equivalent to Piperacillin……..….2gm Tazobactam Sodium equivalent to Tazobactam……..0.25gm
20.	079236	Penitrax for Injection. Each vial contains:- Piperacillin Sodium equivalent to Piperacillin……..….4.0gm Tazobactam Sodium equivalent to Tazobactam……0.5gm
21.	081771	Cyonse Capsule 1mg Each Capsule contains:- Tacrolimus……..1mg

The firm has deposited fee of Rs.105,000/- for above 21 products and submitted the following supporting documents: -

a. Total fee of Rs.105,000/-
b. Copies of Initial registration letters & post registration variation (Renewals are valid)
c. Copy of previous and new drug sales license.
d. NOC in the name of new proprietor from previous proprietor.

It is stated that in 285th meeting of Registration Board approved the product (Colistate 150 Injection Powder for solution for injection) of the firm with new DSL (new Head office & Godown) as mentioned above. Details of approved product as under: -

Name of Firm / Manufacturer	Name of product / composition	Remarks
M/s Biocare Pharmaceutica, 807 Shadman -1, Lahore. **Manufacturer & Product License Holder:** M/s Atlantic Corporation, Ltd. 111 Moo 7, Bang Phli Noi, Bang Bo, Samut Prakan 10560 Thailand	Colistate 150 Injection (Powder for solution for injection) Each vial constains: Colistimethate sodium eq. to Colistin….150mg	The proposed brand name resembled with already registered brand name i.e. Colistat Reg. No.076160. the firm has submitted following three alternate brand names: a. CBA 150. b. Colibase.

		c. ColiActive.

The inspection of new storage facility of the firm is already conducted and recommended on 31-01-2018 with remarks *"the facility was found suitable for storage of the applied products".*

The firm has now requested to change the address as per new DSL for their above products.

Decision: Registration Board decided to refer complete case to Legal Affair Division for their opinion as properiter of DSL has been changed

Case.No.04:- REQUEST OF M/S ALHABIB PHARMACEUTICALS, KARACHI FOR CHANGE OF TITLE OF COMPANY NAME & ADDRESS (LOCAL) FOR THEIR REGISTERED PRODUCTS.

The firm has requested for change of title of company name, office and godown address. Details are as under:-

S. No.	Name of Document	Details as per Old DSL	Details as per New DSL
1.	**Name of Importer**	M/s Al Habib Corporation	M/s Al Habib Pharmaceuticals
2.	**Proprietor Name**	Azeemullah Khan S/o Habib Ullah Khan	Azeemullah Khan S/o Habib Ullah Khan
3.	**Head Office address**	D-26 Block-A SMCHS, Karachi	81-B Block B, SMCHS, Karachi
4.	**Godown Address**	81, Block-B SMCHS, Karachi	1. Plot No. 10, Sector 25, KIA, Karachi 2. HT-8, Landhi Industrial Area Karachi

Details of Registered Products as per Approval					
S. No	**Reg. No.**	**Name of Product**	**S. No**	**Reg. No.**	**Name of Product**
1.	031378	Bleonco-S for Injection 15 I.U. Each vial contains:- Bleomycin sulfate 15 I.U	2.	031334	Ucetam Injection 1gm. Each 5ml ampoule contains:- Piracetam 1000mg.
3.	027388	Unitaxel IV Injection Each vial contains:- Paclitaxel…….. 6mg	4.	027317	Purinetone tablets Each tablet contains:- Mercaptopurine 50mg
5.	027316	Azafrine tablets Each tablet contains: Azathioprine 50mg	6.	020661	Unistin injection Each vial contains:- Cisplatin…… 50mg
7.	020662	Unistin injection Each vial contains:- Cisplatin….. 10mg	8.	020663	Tamooex tablets 10mg Each tablet contains:- Tamoxifen citrate… 10mg
9.	020664	Tamooex tablets 20mg Each tablet contains:- Tamoxifen citrate… 20mg	10.	020665	Duticin injection Each vial contains: - Dacarbazine… 200mg
11.	020666	Kunyrin tablets Each tablet contains:- leucoverin….. 15mg	12.	021045	Utoral injection 500mg Each vial 10ml contains fluorouracil 500mg
13.	021046	Utoral injection 250mg Each vial 5ml contains fluorouracil 250mg	14.	021047	Carbotinol Injection 450mg Each vial 45ml contains Carboplatin 450mg
15.	021048	Carbotinol Injection 150mg Each vial 15ml contains: Carboplatin 150mg	16.	021955	Ucetam 400mg Capsules Each capsule contains: piracetam 400mg
17.	021956	Ucetam 800mg Tablet Each tablet contains: piracetam 800mg	18.	023648	Daunocin injection Each vial contains: - daunorubicin hcl 20mg

19.	021041	Kunyrin injection 50mg Each 5ml contains:- leucovorin calcium 50mg	20.	021042	Kunyrin injection 15mg Each 5ml contains: leucovorin calcium 15mg
21.	021043	Unitrexate injection 50mg Each 2ml contains: methotrexate 50mg	22.	021044	Unitrexate Tablet Each tablet contains: methotrexate 2.5mg
23.	021049	Carbotinol injection 50mg Each vial 5ml contains carboplatin 50mg	24.	021050	K.U. Doxorubicin HCL injection 50mg Each vial contains doxorubicin HCL 50mg
25.	021051	K.U. Doxorubicin HCL injection 10mg Each vial contains doxorubicin HCL 10mg	26.	021052	Vinracine Injection Each vial 1ml contains vincristine sulfate 1mg
27.	022623	Vinracine Injection Each vial 2ml contains vincristine sulfate 2mg	28.	022622	Etopul Injection Each ampoule 5ml contains etoposide 100mg
29.	025232	K.U. Mitomycin C injection Each vial contains Mitomycin C 10mg	30.	023643	Mitomycin Injection Each vial contains: - Mitomycin C 2mg
31.	022637	K.U. Thioguanine tablets Each tablet contains Thioguanine 40mg	32.	022625	Hydrine capsules Each capsule contains: hydroxyurea 500mg
33.	022626	Unitrexate injection 25mg/ml Each 1ml contains methotrexate 25mg	34.	022624	K.U. Dactinomycin injection Each vial contains Dactinomycin 0.5mg

The firm has deposited fee of Rs.5000/- for each product and submitted the following supporting documents: -

a. Total fee of Rs.170,000/-
b. Copies of Initial registration letters & post registration variation with last renewal status.
c. Copy of previous and new drug sales license.

Decision: **As title of the firm is also changed thus the Board advised to evaluate the case in light of decision of DRAP's Authority in 63rd meeting and 290th meeting of Registration Board.**

Case.No.05: **CORRECTION IN MINUTES FOR ALREADY APPROVED PRODUCT DAXOTEL CONCENTRATE INJECTION 20MG/ML OF M/S ATCO PHARMA (PVT) LTD, KARACHI.**

Registration Board in its 292nd meeting approved the following product of M/s Himmel Pharmaceuticals (Pvt) Ltd, House#793-D, Block -C, Faisal Town, Lahore.

As per CoPP & Inspection report abroad manufacturer is Product License Holder. Details are as under;

Manufacturer & Product License Holder (M-292)	Manufacturer & Product License Holder as per COPP & Inspection Report
Manufacturer:- M/s Onk Ilac Sanayi ve Tacaret A.S Gebze Organize Sanayi Bolgesi, 1700 Sokak, No: 1703 Gebze, Kocaeli, Turkey. **Product License Holder:** M/s Onko Ilac Sanayi ve Tic. A.S. Kosuyolu, Istanbul, Turkey	**Manufacturer & Product License Holder:-** M/s Onko İlaç Sanayi ve Ticaret A.Ş Gebze Organize Sanayi Bölgesi, 1700 Sokak, No: 1703 Gebze, Kocaeli, Turkey

Registration letter is processed as per CoPP.

Decision: **Registration Board noted the information.**

Case. No.06: CORRECTION OF BRAND NAME IN REGISTRATION LETTER – FROM "PEYONA SOLUTION FOR INFUSION" TO "PEYONA SOLUTION FOR INFUSION & ORAL SOLUTION" (REG. NO. 079619).

The subject case was presented in 293rd meeting of Registration Board as under: -

M/s Chiesi Pharmaceuticals (Pvt) Ltd, 60/1A, XX, Phase-III, Commercial Zone, Khayaban-e-Iqbal, DHA, Lahore has stated that their product Peyona solution for infusion (Reg. No.079619) granted on 26th November, 2015 (M-243).

Submitted COPP (issued by EMA) by the firm the product name mentioned as "Peyona Solution for infusion and oral solution". In minutes of meeting 243rd held on 8th & 9th May, 2014 mentioned product name as "Peyona Solution for Infusion."

Now the firm has requested with a fee of Rs.5000/- that there was a typographic error in issued letter i.e. "Peyona Solution for Infusion" is mentioned while it is "Peyona Solution for Infusion and Oral solution" as per COPP. The firm has now submitted following supporting documents to rectify the typographic mistake as proposed.

Requirements as per SOP	Firms Response
Corrigendum for Correction in Registration Letter.	
a) Application with required fee as per relevant SRO, if error is on part of firm.	a) Fee of Rs.5,000/-.
b) Copy of registration letter and last renewal status.	b) Copy of initial registration letter with renewal trail.
c) Document in support of proposed correction.	c) Original & legalized COPP (issued by EMA) and Form-5A (previously submitted).
d) Undertaking that the provided information/ documents are true/ correct.	d) Not provided.

Decision of 29th PRVC Meeting: The Committee has advised to take up the case in upcoming Registration Board meeting along with the Original legalized COPP.
Fresh Proceedings

The original legalized COPP mentions the following Brand name:

"Peyona *Solution for Infusion & Oral Solution"*

Decision of M-293:
Deferred for submission of undertaking as per SOP approved in 283rd Registration Board Meeting.

Fresh Proceedings:

The firm has submitted undertaking as required

Decision: Registration Board approve the complete name of product (Reg. No.079619) as "Peyona Solution for Infusion & Oral Solution".

Case. No.07: <u>ADDITION OF BATCH RELEASING SITE IN THE CHANGE OF SOURCE LETTER OF OXALIPLATIN MEDAC 50MG & 100MG INJECTION.</u>

M/s Amgomed, Islamabad has stated approval of source / manufacturer of Oxaliplatin Medac 50mg Reg. No. 045746 & Oxaliplatin Medac 100mg Reg. No. 045747 has been granted on 28th July, 2016. The firm has requested that in said approval letter Product License Holder is not mentioned and Product License Holder is also a batch releasing site. Details are as under:

Sr. No.	Name of Product / Reg. No.	Manufacturer & PLH as per Reg. Letter/Post Registration Variation letter	Manufacturer / Product License Holder (PLH)as per CoPP	Remarks
1.	Oxaliplatin Medac 100mg Injectable. Each ml reconstituted solution for infusion contains:- Oxaliplatin… 5mg Reg. No. 045746	**Manufacturer**: M/s. Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau RoBlau, Germany.	**Product License Holder & Batch release:** Medac Gesellschaft fur klinische Spezialpraparate mbH Theaterstraβe 6 22880 Wedel / Germany **Manufacturer**: Oncotec Pharma Produktion GmbH Am Pharmapark 06861 Dassau-RoBlau/ Germany	Firm has deposited a Fee of Rs. 5000/- Request for **addition** of Product License holder & batch release
2.	Oxaliplatin Medac 50mg Injectable. Each ml reconstituted solution for infusion contains:- Oxaliplatin……5mg Reg. No. 045747	-do-	-do-	Firm has deposited a Fee of Rs. 5000/- Request for **addition** of Product License holder & batch release
3.	Oxaliplatin Medac 150mg Injectable. Each vial contains:- Oxaliplatin……150mg Reg. No. 080400	**Product License Holder:** Medac Gesellschaft fur klinische Spezialpraparate mbH Fehlandtstrasse 3 20354 Hamburg/Germany **Manufacturer**: Oncotec Pharma Produktion GmbH Am Pharmapark 06861 Dassau-Rosslau/ Germany	-do-	Firm has deposited a Fee of Rs. 5000/- and request for correction in product license holder.
4.	Irinotecan medac 100mg Injection Each ml of sterile concentrate contains: Irinotican Hydrochloride trihydrate …20mg (eq. to 17.33mg Irinotecan)	**Product License Holder:** Medac Gesellschaft fur klinische Spezialpraparate mbH Fehlandtstrasse 3 20354 Hamburg/Germany **Batch release:** Medac Gesellschaft fur klinische Spezialpraparate mbH Theaterstraβe 6 22880 Wedel / Germany **Manufacturer**: Oncotec Pharma Produktion GmbH Am Pharmapark 06861 Dassau- Rosslau / Germany	-do-	Firm has deposited a Fee of Rs. 5000/- and request for correction in product license holder.
5.	Topotecan Medac 4mg Injection Each 4ml vial of sterile concentrate contains: Topotecan as Hydrochloride…4mg	**-do-**	**-do-**	Firm has deposited a Fee of Rs. 5000/- and request for correction in product license holder.
6.	Paclitaxel medac 100mg/16.7ml Injection Each vial contains:	**-do-**	**-do-**	Firm has deposited a Fee of Rs. 5000/- and request for

	Paclitaxel…100mg			correction in product license holder.
7.	Paclitaxel medac 300mg/50ml Injection Each vial contains: Paclitaxel…300mg	**-do-**	**-do-**	Firm has deposited a Fee of Rs. 5000/- and request for correction in product license holder.

Decision 30TH PRVCon product at sr. 1 & 2:

The Chairman Registration Board has advised to take up the case in upcoming Registration Board meeting along with the Original legalized COPP and sole agency agreement between M/s Amgomed, Islamabad and M/s Medac Gesellschaft fur klinische Spezialpraparate mbH TheaterstraBe 6 22880 Wedel / Germany.

Decision: Registration Board approved as follows:

- **Addition of Product License Holder and Batch Release site for product at S.No 1-2.**
- **Correction in Product License Holder for product at S.No. 3-7.**

Case. No.8 Request of M/s Pfizer Pakistan Limited Karachi for change in specification of Lipitor tablet 10mg (Reg# 023620) , Lipitor tablet 20mg (Reg# 023621) & Lipitor tablet 40mg (Reg# 023622)

M/s Pfizer Pakistan Limited 12-Dockyard Road west wharf Karachi has submitted request that for change in finished product specifications to USP of their imported product. Specifications were not mentioned in initial registration letter dated 11-05-1999. The firm has submitted following documents: -

Change of Finished Product Specifications		
a)	Application with required fee as per relevant SRO.	Fee of Rs. 5000/- for each product.
a)	Copy of registration letter and last renewal status.	yes
a)	Document in support of proposed change.	yes
b)	Analytical reports as per monograph of FPP.	yes
c)	Undertaking that : i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum / court of law regarding this product. iii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. iv. The provided information/ documents are true/ correct**.**	yes

Decision: Registration Board approve the specification as "USP Specification" for the products Lipitor tablet 10mg (Reg. No. 023620), Lipitor tablet 20mg (Reg. No. 023621) & Lipitor tablet 40mg (Reg. No. 023622). Other terms and conditions will remain the same.

Case. No.9 **REQUEST OF AJM PHARMA (PVT) LTD, KARCHI FOR CHANGE IN SPECIFICAITON (PEMSOH 500MG).**

M/s AJM Pharma (Pvt) Ltd, Karachi has submitted request that there are changes made in finished product specifications from as per innovator's to USP of their imported product Pemsoh 500mg Powder for Injection by their principal Jiangsu Hansoh Pharmaceutical Group Co. Ltd. The firm has submitted following documents: -

Change of Finished Product Specifications	
a) Application with required fee as per relevant SRO.	Covering letter with a fee of Rs.5000/-.
b) Copy of registration letter and last renewal status.	Copy of registration letter issued on 20-05-2019.
d) Document in support of proposed change.	YES
e) Analytical reports as per monograph of FPP.	YES
f) Undertaking that : i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum / court of law regarding this product. iii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. iv. The provided information/ documents are true/ correct**.**	i. YES

Decision: **Registration Board approve the specification from "As per Innovator" to "USP Specification" for the product Pemsoh 500mg Powder for Injection (Reg. No. 095569). Other terms and conditions will remain the same.**

Case No.10 **REQUEST OF M/S ZAM ZAM CORPORATION, KARACHI FOR EXEMPTION OF URDU LABELING, MRP & IMPORT OF INTERNATIONAL PACKING FINISHED IMPORTED PRODUCT HEPARIN LEO INJ. 5000IU/ML**

M/s Zam Zam Corporation, Karachi has stated that their manufacturer produces bulk to cater the need of more than 50 countries this becomes difficult for the manufacturer to make specialized pack for Pakistan only as quantity of import is small on yearly business hence, principal has informed that in future only international pack would be exported, which will have no Urdu version.

The firm is requested to allow them sticker pasting of registration no. and MRP on the international pack on their license premises before sale / market. exemption of Urdu labeling, MRP & Import of international Packing finished imported product as under; -

S. No.	Product(s) Description	Reg.No.	Registered Source
1.	Heparin LEO injection Heparin sodium 5000IU/ml	000854	Denmark

The firm has provided the following documents along with the application: -

a. Fee challan of Rs.5000/-.
b. Copy of registration letter with post registration variation trial.
c. Copy of valid Drug Sale License (No.1051).

Decision: **Registration Board referred the case to Biological Division being biological drug.**

Case.No.11: REQUEST OF M/S CHIESI PHARMACEUTICALS (PVT) LTD, LHORE FOR DE-REGISTRATION/ CANCELLATION OF REGISTERED PRODUCT.

M/s Chiesi Pharmaceuticals (Pvt) Ltd, Lahore has submitted request for de-registration/cancellation of following registered imported products as per details mentioned alongside.

S. No	Product(s) Name	Reason for De-Reg (stated by firm)	Alternative registered product
1.	Atimos Pressurized Inhalation Solution. Each 100ml actuation contains: - Formoterol Fumarate 12mcg Reg. No. 045717	Its registration is being withdrawn because of its manufacturing in the country of origin i.e. Parma, Italy, has been dismantled as this product is of no more interest in the country of origin.	No alternate brand available as mentioned by firm
2.	Budiair Inhaler. Each 100ml actuation contains/delivers: - Budesonide……200mcg Reg. No. 053877	-do-	Brand Name. Budeform Ms Highnoon Laboratories Limited, Lahore

The firm has provided the following supporting documents:-

a. Copy of registration letter with last renewal status.
b. Justification (for de-registration/cancellation of registration).
c. An undertaking that no case is pending at any forum/court of law.

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case.No.12: Request of M/s. Amgomed, Islamabad for Registration of Drug.

The case was presented in 287th meeting of Registration Board held on 3rd & 4th January, 2019 as under:-

Registration Board in its 262nd meeting approved the following products of M/s. Amgomed, Islamabad for import from Korea as per details mentioned alongside;

S.No	Name of importer / manufacturer	Name & Composition of Drug(s)	Demanded Pack size & Price	Decision of Board
1.	M/s Amgomed, Islamabad. **Manufacturer:** M/s Dong Kook Pharmaceutical Co. Ltd. 33-19, yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Republic of Korea.	Diluent for Lorelin depot 3.75 mg Each ampoule (2ml) contains: D-Mannitol..100mg Sodium Carboxymethylcellulose…10mg Polysorbate 80……2mg Water for Injection…..q.s.	Free of Cost.	Approved
2.	M/s Amgomed, Islamabad. **Manufacturer:** M/s Dong Kook Pharmaceutical Co. Ltd. 33-19, yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Republic of Korea.	Lorelin depot 3.75 mg Injection Leuprolide acetate 3.75mg Injection	As per SRO	Approved

While issuance of registration letter it has been observed the above mentioned product "Lorelin Depot 3.75mg injection" has already been granted registration in favor of M/s. Medisure Pharma International, Karachi from the same source having registration number ***027357***.

Accordingly M/s. Amgomed, Islamabad was informed about the above stated position. The firm informed that the principle has already cancelled/terminated the sole agency agreement from the name of

M/s. Medisure Pharma International, Karachi in 2013 (provided copy of that cancellation letter dated 16-03-2013) for the reasons that M/s. Medisure Pharma International, Karachi *has never imported a single vial since the time of registration i.e 2002* and *violation of conditions of agreement*.

It is pertinent to mention that the inspection of the above mentioned manufacturer has been carried out dated 21st -22nd June, 2018 by nominated panel comprised of Mr.Malik Irshad Hussain (Member Policy Board), Mr.Sayyad Hussain (Deputy Director, DRAP).

Decision of 287th meeing:-

Registration Board decided to issue show cause notice to the firm M/s. Medisure Pharma International, Karachi as to why not the registration of product *Lorelin depot 3.75 mg Injection* may not be cancelled because of the termination of their sole agency agreement by M/s. Dong Kook Pharmaceutical Co. Ltd, Korea, as reported by M/s. Amgomed, Islamabad.

Fresh Proceedings:

In the light of Registration Board decision a Show Cause Notice has been served to the firm on 21st June, 2019 but no reply has been received. Furthermore, a reminder (No.F.1-40/2007-Reg-I-Pt) through registered post has been issued on on 26th August, 2019 to the firm (C-145, K.D.A. Scheme No.1 Off Karsaz Road, Karachi) with advised to submit reply within seven days after issuance of this letter, the same has been received back with failed delivery status. Afterwards, on 18th September 2019 the reminder letter handed over to firm's representative (Mr. Atta) & till the date no reply from M/s Medisure Pharma Internatinal, Karachi has been reiceved.

Decision of M-292:

Registration Board advised to issue final showcase notice to M/s Medisure Pharma International Karachi and in case of no reply, case will be considered by Registration Board.

Fresh Proceedings:

M/s Medisure Pharma International has submitted their reply as under: -

M/s Medisure Pharma International is a respectable commercial pharmaceutical organization committed to provide best quality products registered and accredited from all concerned departments of Government of Pakistan.

M/s Medisure Pharma International is fully honored and respects the land of laws, to fulfil the Pakistan regulations and fully comply with the Drug Laws. Accordingly, a per mandate and requirements of Drugs Act, 1976 and Drugs (Licensing, Registration & Advertising) Rules, 1976, the Medisure Pharma International entirety is to follow the regulations.

The aforesaid product is currently registered with M/s Medisure Pharma International and has a valid registration number. Subsequent to registration, we are regularly maintaining its registration and last renewal was filed in DRAP in June 2017.

We are not aware about the letter of cancellation of sole agency agreement whit M/s Dong Kook Pharmaceutical Co., Ltd, 33-19, Yongso 2-gil, Gwnghewon-myeon, Jincheon-gun, Chungcheongbuk –do, Republic of Korea and even not have been officially informed regarding termination of sole agency agreement from M/s Dong Kook Pharmaceutical Co., Ltd.

We are also wondering that how DRAP pharmaceutical evaluation cell accepted and included the case in Drug Registration Board (M-287) meeting without taking consideration of No Objection Certificate (NOC) from existing Marketing Authorization Holder which is the basic requirement of DRAP Post Registration Variation SOP of Marketing Authorization transfer from one importer to another importer.

Decision: **Registration Board advised to M/s Medisure Pharma International to submit fresh Sole Agency Agreement/Authorization Letter in their name from Product License holder for above mentioned products.**

Case.No.13: CORRECTION IN LOCAL STORAGE FACILITY ADDRESS OF M/S GHAZALI BROTHERS KARACHI.

The Registration Board in its 270th meeting approved the following product of M/s Ghazali Brothers, 1st floor Azzainab Court, Campbell Street, Karachi as per decision mentioned below: -

Name of importer / Manufacturer	Name of Drug(s) / Composition	Demanded Pack size / Price	Board Decision / Remarks
M/s Ghazali Brothers, 1st floor Azzainab Court, Campbell Street, Karachi. **Manufacturer: -** M/s. Nephron Pharmaceuticals Corporation, 4500 12th Street Ext, West Columbia, SC 29172 USA. **Marketing Authorization Holder:** M/s. Nephron Pharmaceuticals Corporation 4121 SW 34th Street, Orlando, FL 32811 USA	Ipratropium Bromide 0.5mg and Albuterol Sulfate 3mg Vial (Inhalant) Each Vial contains: Ipratropium Bromide… 0.5mg Albuterol Sulfate…….3mg. Anticholinergic Agent In House 2 years	3ml vial Rs.100/- per vial	Approved with Import Policy for Finished Drugs and with innovator's specifications. Reference will be sent to Budget & Accounts Division for verification of fee challan and authorized Chairman for issuance of registration letter.

The local storage facility of "M/s Ghazali Brothers, "1st floor Azzainab Court, Campbell Street, Karachi" has already been verified by concerned area FID**.** Details of address of local storage facility is as under:

Address as per Minutes	Address as per Inspection report	Address as per DSL
1st floor Azzainab Court, Campbell Street, Karachi	1st floor Azzainab Court, Campbell Street, Karachi	19-SR-7, Campbell StreetAzzainab Court Complex, Karachi.

M/s Ghazali Brothers Karachi has submitted Drug Sale License (No.1162) valid upto 28th October, 2021 and provided an undertaking that:-

> *The DSL "19-SR-7, Campbell Street, Azzainab Court, Karachi license validity 29-Oct-2019 to 28-Oct-2021 there is an addition of the plot no only. Therefore the premises are the same as in the previous DSL issued. There is no change in the office premises*

According to submitted previous DSL & new DSL there is no change in proprietor (i.e. Ahmed Ghazali S/o Nawab Ahmed)

Decision: Registration Board noted the information.

Case.No.14: REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF OLD IMPORTED PRODUCTS.

S. No	Firm Name	Product Name	Validity of Renewal & Reg. No	Reason for De-Reg	Alternative Registered Products	
1.	M/s GSK Pakistan Limited, 35 Dockyard Road, West Wharf, Karachi	Hepsera Tablet Each Tablet Contains: - Adefovir Dipivoxil 10mg	25-07-2019 031383	• Suitable therapeutic alternatives & advance therapies are available in the market. • Better / new molecules to cater the same portfolio are also available in the market.	**Product Name**	**Firm**
					Defovir	M/s English Pharma
					Adgen	M/s Wnsfeild

				• Virtually there is no demand of this product in local market.	Adeowin	M/s Orta
2.	-do-	Imigran FDT 50mg film coated tablet. Each tablet contains: - Sumatriptan Succinate 50mg	16-09-2020 041158	-do-	Sumatec	M/s Platinium
					Sumig	M/s Hilton
					Sumtan	M/s Shrooq

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case No.15: REQUEST OF M/S MEDIPAK LIMITED, LAHORE FOR ONE TIME IMPORT OF FINISHED PRODUCT

The subject case was presented in 293rd meeting of Registration Board as under:-

M/s Medipak Limited, Lahore has stated that their firm was registered as authorized importer from Fresenius Kabi Austria Germany since, 2002. Fresenius Kabi Germany has setup their offices at Pakistan and the product was transferred to M/s Fresenius Kabi Pakistan, Lahore and same was cancelled from the name of M/s Medipak Limited, Lahore. Details of the products are as under: -

S. No.	Name of Product / Reg. No	Manufacturer / Product License Holder	Remarks
1.	Nephrosteril solution for infusion Each litre contains: - L-Isoleucine…5.10gm L-Leucine…10.30gm L-Lysine Monoacetate…10.01gm eq to L-Lysine..7.1g L-Methionine…2.80gm Acetyl Cysteine...0.50gm eq to L-Cysteine…0.37gm L-Phenylalanine…3.80gm L-Threonine…4.80gm L-Tryptophan…1.90gm L-Valine…6.20gm L-Arginine…4.90gm L-Histidine…4.30gm Aminoacetic acid…3.20gm L-Alanine…6.30gm L-Proline…4.30gm L-Serine…4.50gm L-Malic Acid…1.50gm Acetic acid 99%...1.382gm (As per Innovator's Specification)* Reg. No. 095879	**Manufacturer** M/s. Fresenius Kabi Austria GmbH, Hafnerstrasse 36, A-8055 Graz, Austria. **Marketing Authorization Holder.** M/s. Fresenius Kabi Deutschland GmbH D-61346 Bad Homburg v.d.H. (Germany)	Product was transfer to M/s. Fresenius Kabi Pakistan Lahore on 30th May, 2019 &cancelled from M/s Medipak Limited, Lahore
2.	Fresofol 1% Emulsion for intravenous injection Each ml emulsion contains: - Propofol……10mg (BP Specifications) Reg. No. 099009	-do-	Product was transfer to M/s. Fresenius Kabi Pakistan Lahore on 22nd October, 2019 &cancelled from M/s Medipak Ltd, Lahore

M/s Medipak Limited, Lahore has now requested to allow one time import of the consignments that had already been manufactured at their name before transfer / cancellation. Details of products batch number are as under: -

Nephrosteril solution for infusion	Fresofol 1% Emulsion for intravenous injection
Batch number: 16 NE4358 16 NE4359 **Date of Manufacture:** 23.05.2019 **Date of Expiry:** 23.05.2022 Shelf life = 85% **Particulars of the premises where manufacturringis carried on.** Fresenius Kabi / Austria Gmbh, Hafnerstrasse 36, 8055 Graz, Austria	Batch number and Quantity as follows: 16NK5499 ..... 61.200 bottles 16NK5500 ..... 61.200 bottles 16NK5510 ..... 28.500 bottles **Date of Manufacture:** 10.2019 **Date of Expiry:** 10.2022 Shelf life = **97%** **Particulars of the premises where manufacturringis carried on.** Fresenius Kabi / Austria Gmbh, Hafnerstrasse 36, 8055 Graz, Austria

The firm has submitted following supporting documents:

- Application with a fee of Rs.5000/- for each product.
- Copy of registration letter at their name with post registration variation.

Decision of 293rd: Registration Board deferred the case for submission of rule position under the provisions of Drug Act, 1976 and DRAP Act 2012.

Fresh Proceedings: -

The firm has submitted their reply as per following points: -

Shortage of product.

We have learned of numerous product shortage complaints from the market, leading institutions, and M&P (Fresenius Kabi Pakistan distributor) as Fresenius Kabi has not yet been able to import a fresh consignment manufactured on their label.

COVID-19 Emergency.

Fresofol (propofol 1%) is a short acting intravenous general anesthetic agent that is therapeutically indicated for:

- Induction and maintenance of general anesthesia and
- Sedation of ventilated patients receiving intensive care.

Various scientific literatures have been attached for your reference.

Furthermore, we are enclosing herewith DGHS KPK tender enquiry list highlighting procurement of propofol (serial # 29) as a required item for COVID-19 stage 2 emergency escalation. Other provinces & key institutional demands are expected in coming weeks

Given the current nationwide epidemic it will only be prudent to have stocks already arrived at Lahore airport cleared and in the market available for ICU usage.

Storage charges.

The consignment is at Lahore airport since November 2019and with further prolonged storage under warming weather conditions we would not want to risk quality of the product to be negatively impacted.

Furthermore, there are immense storage charges already accumulated and further compounding on daily basis

Humble request.

We therefore request your kind consideration:

1. For urgent DRAP approval of our one time import request for the consignments especially Fresofol, which will be critically required under imminent emergency circumstances.
2. Along with the above referred approval for DRAP formal advice to Gerry's cargo shed operations at Lahore airport for waiver of storage charges under present situation on humanitarian grounds.

Decision: Registration Board referred case to Legal Affair Division for their opinion on firm's request.

Case.No.16: **REQUEST OF ZAM ZAM CORPORATION, KARACHI FOR DE-REGISTRATION/ CANCELLATION OF REGISTERED PRODUCT.**

The subject case was presented in 293rd meeting of Registration Board as under:-

M/s Zam Zam Corporation, Karachi has submitted requested for de-registration/ cancellation of following registered imported product as per details mentioned alongside.

M/s Zam Zam Corporation, Karachi
DE-REGISTRATION OF DRUG ON FIRM'S REQUEST

S. No	Firm Name	Product Name	Reg. No.	Reason for De-Reg	Alternative registered product
1.	M/s Zam Zam Corporation, Karachi	One Alpha Each ml contains: Alfacalcidol 2mcg	016155	**Firm States as under:-** 1. Commercial reason from supplier side. 2. No margins due to the price reduction by the DRAP in SRO 1610. 3. Exchange rate fluctuation is very high since past one and half years.	Kibon (Calcitriol 1mcg/ml) of M/s RG Pharma. Indrop D (Cholecalcifero 5mg) of M/s Neutro Pharma.

Furthermore, firm has informed that they have total 35,000/- packs of one alpha injection in their existing stock which will consume firmnot import this product anymore.

SOP Requirement	Firms Response
a) Application. b) Copy of registration letter and last renewal status. c) Justification d) List of alternatives brands/ FPPs available in the country. e) An undertaking that: i. No case is pending at any forum / court of law regarding this product. ii. Provided information/ documents are true/ correct.	a. Application dated 26-12-2019 b. Copy of registration letter with last renewal status.(Dec 21,2018) c. Justification (for de-registration/cancellation of registration). d. Provided and mentioned on above table e. An undertaking that no case is pending at any forum/court of law & and information / documents are true / correct

Decision of 293rd meeting: The Registration Board deferred the case for further deliberation.

Decision: **Registration Board referred the case for views of DRAP's availability committee.**

Case.No.17: **REQUEST OF M/S BAYER PAKISTAN (PVT) LTD, KARACHI FOR DE-REGISTRATION/ CANCELLATION OF REGISTRATION REGISTERED PRODUCT.**

The subject case was presented in 293rd meeting of Registration Board as under:-

The case was presented in 289th, 290th & 292nd meeting of Registration Board of M/s Bayer Pakistan (Pvt) Ltd, Karachi for de-registration/cancellation of registrations of following registered imported products as per details mentioned alongside.

S. No	Firm Name	Product(s) Name	Reg. No	Reason for De-Reg (stated by firm)	Alternative registered product
1.	M/S Bayer Pakistan (Pvt) Ltd, Karachi	Dopergin Tablet Each Tablet Contains: - Lisuride Hydrogen Maleate……0.2mg	009882	TEVA CZECH Republic was the single qualified source of Lisuride Hydrogen maleate worldwide & our parent company Bayer AG Germany procure this	Other product containing Lisuride Hydrogen Maleate as an

				API from the same manufacturer. M/s Medipharm (Pvt) Ltd (now merged with M/s Bayer Pakistan) was getting same API from our principal Bayer AG Germany. Bayer AG has stopped the production / marketing of this product in Europe since 2013. To continue with this product in Pakistan we directly approached TEVA & based on our very less requirement of this API (i.e. less than 1kg) TEVA has shown his inability to produce API batches solely for Pakistan due to big production batch sizes.	active ingredient is not available in Pakistan.
2.	-do-	Qlaira Tablet, Each wallet (28 film coated tablets) contains: - Part I (2 dark yellow film coated tablets-Core) Estradiol valerate ……3.000 mg. Part II (5 medium red film-coated tablets-Core) Estradiol valerate ……2.000 mg Dienogest…….2.000 mg Part III (17 light yellow film-coated tablets-Core) Estradiol valerate …..….2.000mg Dienogest…….3.000mg Part IV (2 dark red film-coated tablets-Core) Estradiol valerate …….1.000 mg Part V (2 white film-coated tablets-Core) None	088370	• The business of this product is not viable. • Due to delayed registration, globally our principal has taken decision to not market this product. • Therefore, we are applying for cancellation / De-registration of this product to avoid unnecessary workload of life cycle management at both ends DRAP & Company.	Qlaira contains two APIs: • Estradiol Valerate. • Dinogest (not available in pakistan). Company provided brands containing Estradiol Valerate as. Estranor, M/s Saffron Pharma Norestra, M/s British Pharma ltd, Orgyluton, M/s Hansel Pharma, Progyluton, M/s Bayer Health care. Ovlogyn M/s Zafa.

The firm has also provided the following supporting documents:-

a. Copy of registration letter with last renewal status..
b. Justification (for de-registration/cancellation of registration).
c. An undertaking that no case is pending at any forum/court of law.

Decision of 289th meeting:

Registration Board deferred the case for confirmation of alternative registered products.

With reference to above products firm states as under: -

S. No. 1 (Dopergin Tablet),

Teva Czech republic ws the single qualified source of Lisuride Hydrogen Maleate worldwide & our parent company Bayer AG Germany procure this API from the same manufacturer. Medipharm Pvt Ltd (now merged with Bayer pakistan) was getting same API from our principal Bayer AG Germany. Bayer AG has stopped the production / marketing of this product in Europe since 2013. To continue with this product in Pakistan we directly approached TEVA & based on our very less euirment of this API (less than 1kg/year) TEVA has shown his inability to produce API batches solely for Pakistan due to big production batch sizes.

S.No.2 Qlaira Tablet

Qlaira contains two APIs:

- Estradiol Valerate.
- Dinogest (not available in pakistan).

Company provided brands containing Estradiol Valerate as.

1. Estranor, M/s Saffron Pharma.
2. Norestra, M/s British Pharma ltd,
3. Orgyluton, M/s Hansel Pharma,
4. Progyluton, M/s Bayer Health care.
5. Ovlogyn M/s Zafa.
6. Star-gest, M/s Mass Pharma

Decision of 290th meeting:

Registration Board deferred the case for confirmation/provision of alternative registered products in Pakistan.

Decision of 292nd meeting:

Registration Board referred the case for views of DRAP's availability committee.

Fresh Proceedings:

Firm's response.

Firm has submitted that Qlaira Tablet (Reg. No. 088370) was applied for registration in 2013 and registration letter issued in 2018 and still company is not marketing the product just because the global decision. Therefore, it is not viable for company to retain the registration in their portfolio. Therefore, firm is requested to de register Qlair Tablet.

Decision of 293rd meeting: The Registration Board deferred the case for further deliberation.

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case.No.18: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LTD, KARACHI FOR DE-REGISTRATION/ CANCELLATION OF REGISTERED PRODUCT.

The subject case was presented in 293rd meeting of Registration Board as under:-

M/s Novartis Pharma (Pakistan) Ltd, Karachi has submitted request for de-registration/cancellation of following registered imported product as per details mentioned alongside.

S. No	Product(s) Name	Reg. No	Reason for De-Reg (stated by firm)	Alternative registered product
1.	Lopresor Ampoule Each 5ml Contains: - Metoprolol Tartrate…… 5mg	012846	Please note that Lopresor injections were manufactured and imported from Switzerland. We regret to inform you this product is nw de-registered n the country of origin and manufactured has now discontinued production. Consequently, we will not be able import, sale or maintain the registration of this product.	**Firm Name:** Atco Laboratores Ltd, **Brand Name:** Merol **Generic Name:** Metoprolol Tartrate **Strength/ form:** 1mg per ml Injection **Pack Size:** 5mlx5's

SOP Requirement	Firms Response
a) Application. b) Copy of registration letter and last renewal status. c) Justification d) List of alternatives brands/ FPPs available in the country. e) An undertaking that:	a. Application dated 07-10-2014 b. Copy of registration letter with last renewal status.(Oct 13,2014) c. Justification (for de-registration/cancellation of registration). d. Merol by Atco Laboratories

iii. No case is pending at any forum / court of law regarding this product. iv. Provided information/ documents are true/ correct.	e. An undertaking that no case is pending at any forum/court of law.

Decision of 293rd meeting:
The Registration Board deferred the case for further deliberation.

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case. No.19. REQUEST OF M/S AGP LIMITED, KARACHI FOR PERMISSION TO ONE TIME IMPORT CLOZARIL TABLET 100MG & 25MG

M/s AGP Limited B-23-C, SITE, Karachi has submitted request for one time import of Clozaril Tablet 100mg & 25mg due to the pandemic situaiton of COVID-19, manufacturer in Tueky is also affected and their production has gone slowdone. Therefore, they are unable to supply as per requirments. The firm has stated that they have discussed with their Principal to aragne the product by any means and made them agree to share some stocks from Malaysia order to fulfill our need. the packing materials are in English language. Details of product is as under:-

S.No.	Name of Product	Reg. No.	Demanded Quantity
1	Clozaril Tablet 25mg	097361	600 packs (50's)
2	Clozaril Tablet 100mg	097362	10,800 packs (50's)

The firm has submitted following for approval.

a. Application with a fee of Rs.10,000/-.
b. Propsoed artworkis
c. Copy of registratio letter (issued on 23-08-2019)

The firm has mentioned that they will print the **MRP, Registration number and name of their company** by over printing on packs.

Submitted for consideration of PRVC Committee.

Decision of 40th PRVC:
Advised firm to quote rule position in support of their request.

Decision: Registration Board advised to the firm to quote rule position in support of their subject request.

Case. No.20 REQUEST FOR CHANGE IN ADDRESS OF M/s Angelini Pharmaceuticals (Pvt) Ltd, Lahore.

M/s Angelini Pharmaceuticals (Pvt) Ltd, Lahore has submitted requested for change in address and they have shifted to new premises with no change in proprietor The details of registered drug, company name, Godown address etc as per DSL are as under: -

Details of firm

Current Name of Firm / Proprietor.	Proposed Name of Firm / Proprietor.
M/s Angelini Pharmaceuticals (Pvt) Ltd, Lahore Mr. Raza Masud S/o Masud Akhtar	No change
Previous address as per old DSL	**Proposed address as per New DSL**
221-CCA, Phase 4, DHA, District Lahore	Basement 44 Commercial Imperial Block Paragon City Barki Road, Lahore

Details of Product

S. No.	Name of Drug (s), Composition & Reg. No. (as per approval)	S. No.	Name of Drug (s), Composition & Reg. No. (as per approval)
1.	Monurol Sachet, Each 3gm Sachet contains: - Fosfomycin Tromethamel 5.631gm (equivalent to Fosfomycin 3gm) Reg. No. 022663	2.	Brumixol Cream Each 100gm contains: - Ciclopiroxolamine 1gm Reg. No. 043074

3.	Brumixol Ovules Each ovule contains: - Ciclopiroxolamine 0.1gm Reg. No**.** 043075	4.	Lantigen B Suspension Each ml contains:- Streptococcus penumonial type 63.2 Antigenic units. Streptococcus pyogenes group A 126.2 Antigenic units. Branhamella Catarrhalis 39.9 Antigenic units. Staphylococcus aureus 79.6 Antigenic units. Haemonhilus influengae type B 50.2 Antigenic units. Klebsiella pneumonia 39.8 Antigenic units. Reg. No**.** 018229
5.	Fluimucil 200mg Sachets Each 1gm sachet contains:- Acetylcysteine 200mg. Reg. No**.** 021174	6.	Spasmex Injection IM/IV Each 4ml vial contains:- 1,2,3 Trihydroxybenzene dehydrate (phlereglucine dehydrate) 51.43mg. (equal to waterless phleroglucine 40mg) Reg. No**.** 021929
7.	Spasmex Tablet Each 4ml vial contains:- 1,2,3 Trihydroxybenzene dehydrate (phlereglucine dehydrate 102,850 (equal to waterless phleroglucine 80mg) - 1,2,3 Trihydroxybenzene 80mg. Reg. No**.** 021930		

Requirements (No SOP is Available)	**Firms Response**
a) Application with required fee as per relevant SRO (in case of similarity / resemblance with drug, fee will not be required). b) Copy of registration letter and last renewal status. c) Copy of Drug Sale License with new name.	a) A fee of Rs.5000/- for each product. b) Firm has submitted complete post registration variation detail. c) Copy of Old DSL & new DSL.

Decision: **Keeping in view the new Drug Sale License; Registration Board decided as follows:**

a) Approved firm's address from M/s Angelini Pharmaceuticals (Pvt) Ltd, 221-CCA, Phase 4, DHA, District Lahore to M/s Angelini Pharmaceuticals (Pvt) Ltd, Basement 44 Commercial Imperial Block Paragon City Barki Road, Lahore for products at S.No.1, 5,6 and 7. Inspection of storage facility will be conducted for new address/ site before processing of letter.

b) Deferred products at SNo.2 and 3 for confirmation of renewal status

c) Referred product at SNo.04 to Biological Division being biological product.

Case No. 21. **REQUEST OF M/S ELI LILLY PAKISTAN PRIVATE LIMITED KARACHIFOR CHANGE OF MANUFACTURING SITE OF THEIR REGISTERED PRODUCT.**

M/s Eli Lilly Pakistan Pvt. Ltd. 5A, 5TH Floor 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6 PECHS Karachi has applied for change of manufacturing site of their following already registered product as per details given below: -

S.No	Reg. No.	Name & Composition (as per initial reg. letter 02-12-2010)	Name & Composition (as new per CoPP)	Existing approved Site Manufacturing Site (as per initial reg. letter) (02-12-2010)	New Proposed Site / Manufacturer/ Product License Holder (asper COPP)
1.	066174	Alimta 100mg Injection Each vial contains: Pemetrexed Disodium	Alimta Powder for concentrate for	M/s Eli Lilly and Company Indiana USA Packing by:	**Product License Holder:** M/s Eli Lilly

		Heptahydrate…151.7mg equivalent to Pemetrexed Free Acid 100mg	solution for infusion Each vial contains: Pemetrexed Disodium Heptahydrate 151.7mg equivalent to Pemetrexed Free Acid (with 8.5% overage) 100mg (108.5mg)	M/s Lilly France S.A.S. F-67640 Fegersheim France **Change of Site** (M/s Eli Lilly and Company Indianapolis, IN 46285, USA) by DRAP dated 01-01-2014	Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Manufacturer by:** M/s Vianex S.A. Plant C, 16th km Marathonos Avenue, Pallini Attiki, 15351, Greece Packaging site: Lilly France S.A.S., 2 rue du Colonel Lilly, 67640 Fegersheim, France
2.	043068	**(as per initial reg. letter 12-9-2006)** Alimta 500mg Injection Each vial contains: 500mg Pemetrexed (as pemetrexed disodium)	Alimta Powder for concentrate for solution for infusion Each vial contains: Pemetrexed Disodium Heptahydrate 713mg equivalent to Pemetrexed Free Acid (with 2% overage) 500mg (510mg)	**(as per initial reg. letter) (12-09-2006) M/s Lilly France S.A.S France Change of Site** (M/s Eli Lilly and Company Indianapolis, IN 46285, USA) by DRAP dated 01-01-2014	

The firm has submitted the following supporting documents: -

i. Fee of Rs.100,000x2=200,000/- dated 20-11-2019.
ii. Application on Form-5F
iii. Copy of initial registration letter of Alimta 100mg dated 02-12-2010 & Post Registration renewal dated 05-11-2015
iv. Copy of initial registration letter of Alimta 500mg dated 12-09-2006& Post Registration renewal dated 21-07-2016
d) Original & legalized COPP of Alimta 100mg (No. 09/19/128907 issued by EMA dated 19-02-2019showing the freely availability of product in exporting country and GMP compliant status of the product).
v. Original & legalized COPP of Alimta 500mg (No. 03/19/128896 issued by EMA dated 19-02-2019 showing the freely availability of product in exporting country and GMP compliant status of the product).
vi. Site master file (M/s M/s Vianex S.A. Greece)
vii. Undertakings that provided information are correct.

Decision: Registration Board approved the change of manufacturing site of above products from "M/s Eli Lilly and Company Indianapolis, IN 46285, USA" to "Product License Holder: M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. Manufacturing site: M/s Vianex S.A. Plant C, 16th km Marathonos Avenue, Pallini Attiki, 15351, Greece Packaging site: Lilly France S.A.S., 2 rue du Colonel Lilly, 67640 Fegersheim, France" subject to policy for imported finished drug registration. Other terms and conditions will remain the same.

Case No. 22. <u>REQUEST OF M/S ELI LILLY PAKISTAN PRIVATE LIMITED KARACHI FOR REGISTRATION OF ALREADY REGISTERED PRODUCT FROM M/S ALI GOHAR AND COMPANY PVT. LIMITED KARACHI TO THEIR NAME.</u>

M/s Eli Lilly Pakistan Pvt. Ltd. 5A, 5TH Floor 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6 PECHS Karachi has applied for Registration of already registered Product from M/s Ali Gohar and Company Pvt. Limited Karachi to their name. The details given below: -

S.No	Reg. No.	Name & Composition (as per initial letter) (issued on 11-05-1999)	Name & Composition (as new per CoPP)	Existing approved Manufacturing Site (as per approval letter) (11-05-1999)	Manufacturer/ Product License Holder (asper new COPP)
1.	023614	Zyprexa Tablet 5mg Each tablet contains: Olanzapine….5mg	Zyprexa **coated** Tablet Each tablet contains: Olanzapine….5mg	M/s Eli Lilly and Company Limited England. Change of Source (M/s Lilly S.A., Spain) of Zyprexa Tablet 5mg & 10mg letter issued by DRAP dated 11th July 2007	**Product License Holder:**M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands **Manufacturer:**M/s Lilly S.A., Avda. De la Industria 30, 28108 Alcobendas, Madrid, Spain
2.	023616	Zyprexa Tablet 10mg Each tablet contains: Olanzapine….10mg	Zyprexa **coated** Tablet Each tablet contains: Olanzapine….10mg		

Firm has submitted following documents:

i. Application on Form 5F with Rs. 100,000x2=200,000/- fee dated 13-05-2019. Copy of registration letter dated 11-05-1999 and last renewal (submission dated 04-05-2017) status.
ii. Original termination letter from M/s Eli Lilly and Company Nederland B.V for M/s Ali Gohar and Company Pvt. Limited Karachi.
iii. Authority letter/sole agent letter from M/s Eli Lilly and Company Nederland B.V in the name of M/s Eli Lilly Pakistan Pvt. Ltd. Karachi.
iv. Copy of NOC (dated 13-02-2020) from existing registration holder M/s Ali Gohar and Company Pvt. Limited Karachi.
v. Original and legalized Certificate of Pharmaceutical Product of Zyprexa coated 10mg tablet (No. 02/19/127974) dated 05-02-2019 issued by EMA showing the free sale of applied product in exporting country and GMP compliant status of manufacturer.
vi. Undertaking that the provided information/ documents are true/ correct

Decision:- Keeping in view the above position, Registration Board decided as follow;

a. Approved the cancellation of registration of Zyprexa Tablet 5mg (Reg.No. 023614) and Zyprexa Tablet 10mg (Reg.No. 023616) from the name of M/s Ali Gohar and Company Pvt. Limited Karachi.
b. Approved the registration of Zyprexa Tablet 5mg and Zyprexa Tablet 10mg in the name of M/s Eli Lilly Pakistan Pvt. Ltd. 5A, 5TH Floor 10th Building Floor, Al-Tijarah Centre 32-1-A, Block 6 PECHS Karachi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).
c. A reference shall be sent to Costing & Pricing Division for their comments regarding MRP of the said products.

Case.No.23 <u>REQUEST OF M/S MARTIN DOW LIMITED, KARACHI FOR REGISTRATION OF DRUGS TO THEIR NAME.</u>

M/s Martin Dow Limited, Karachi has submitted an application for Registration of following already registered products from M/s Hilton Pharma (Pvt) Ltd, Karachi to their name. Detail of each proposed product is as under:

Product-1: Enflor Sachet 250mg (Reg.No.022071)		
Sr.#	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	**As per approval** Enflor Sachet 250mg Each sachet contains: - Lyophilised Saccharomyces Boulardii…..282.5mg

		(Corresponding to 250mg of yeat per sachet (Biological) **As per COPP (France)** Saccharomyces Boulardii, strain CNCM I-745, …….282.50mg (mixture of 250mg of lyophilized yeast cells with 32.50mg of lactose)
	Name and address of Applicant (transferee)	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Name of Transferor	M/s Hilton Pharma (Pvt) Ltd, Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi
	Detail of Drug Sale License	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. **Godown address:** Plot No. 32, Sector 16, K.I.A, Karachi
	Name and address of manufacturer.	**As per approval:** N/A **As per COPP:-** Biocodex 1 avenue Blaise Pascal 60000 Beauvais -France.
	Name and address of product license holder (as per COPP)	Biocodex 7 avenue Gallieni, Gentilly, 94250 Gentilly, France.
	Name of exporting country	France
	Diary No. & Date of R& I	Dy. No. 14900 Dated 19/08/2019.
	Finished Product Specification	
	Shelf life	3 Years (as per CoPP)
	Pack Size	10's (as per approval)
	Remarks: - • The firm has provided termination letter from M/s Hilton Pharma (Pvt) Ltd, Karachi instead of PLH of product. • The product is not freely available in the provided COPP.	
Product-2: Enflor Capsules 250mg (Reg.No.022072)		
2.	**Name / detail of documents**	**Documents / information provided by firm**
	Product Name / Composition	**As per approval** Enflor 250 Capsules Each capsule contains: - Lyophilised Saccharomyces Boulardii…..282.5mg (Corresponding to 250mg of yeat per sachet (Biological) **As per COPP (France)** Lyophilized Saccharomyces Boulardii, strain CNCM I-745, …….282.50mg (mixture of 250mg of lyophilized yeast cells with 32.50mg of lactose)
	Name and address of Applicant (transferee)	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Name of Transferor	M/s Hilton Pharma (Pvt) Ltd, Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi
	Detail of Drug Sale License	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. **Godown address:** Plot No. 32, Sector 16, K.I.A, Karachi
	Name and address of manufacturer.	**As per approval:** N/A **As per COPP:** Biocodex 1 avenue Blaise Pascal 60000 Beauvais-France.
	Name and address of product	Biocodex 7 avenue Gallieni, Gentilly, 94250 Gentilly, France.

	license holder (as per COPP)	
	Name of exporting country	France
	Diary No. & Date of R& I	Dy. No. 14901 Dated 19/08/2019.
	Finished Product Specification	3 Years (as per CoPP)
	Shelf life	10's (as per approval)
	Pack Size	

Remarks:

- The firm has provided the termination letter from M/s Hilton Pharma (Pvt) Ltd, Karachi instead of PLH of product.
- The product is not freely available in the provided COPP.

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Fee of Rs.200,000/- (100,000/- for each product)
b) Applications on Form-5F.
c) Registration letters with complete renewal status.
d) Original legalized CoPP issued by Sweden.
e) NOC for transfer of registration by M/s Hilton Pharma (Pvt) Ltd (issued on 30-0-2019).
f) Letter of authorization in the name of M/s Martin Dow ltd, Karachi by Biocodex.
g) Termination letter from M/s Hilton Pharma (Pvt) Ltd.
h) An undertaking that annexed documents is correct and true.

Decision of 292nd meeting of Registration Board:

Registration board deferred the above 2 products for:

a) Submission of termination letter of above products from M/s Hilton Pharma (Pvt) Ltd, Karachi.
b) Submission of free sale certificates as the products are not freely available in the provided COPP.
c) Advised the evaluator to evaluate CTD of above products.

Remarks of Evaluator:

Submitted dossier shows that Applied product is Biological in nature (yeast production is biological process, fermentation) so case may be referred to Biological Drug Division for further processing at their end.

Decision:- Keeping in view the above position, Registration Board decided as follow;

a. **Approved the cancellation of registration of Enflor Sachet 250mg (Reg.No. 022071) and Enflor 250 Capsules (Reg.No. 022072) from the name of M/s Hilton Pharma (Pvt) Ltd, Karachi.**
b. **Approved the registration of Enflor Sachet 250mg and Enflor 250 Capsules in the name of M/s Martin Dow Limited, Karachi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).**
c. **A reference shall be sent to Costing & Pricing Division for their comments regarding MRP of the said products.**

Case.No.24: **Request of M/s Roche Pakistan Limited, Karachi For Change Of Manufacturing Site & Marketing Authorization Holder Of Their Registered Product Xeloda 500mg FC tablet.**

M/s Roche Pakistan Limited, 1st Floor, 37-B, Block-6, PECHS, Karachi has applied for change of manufacturing site & marketing authorization holder of their following already registered product as per details given below: -

S. No	Reg. No.	Name & Composition (as per initial letter) (issued on 27-11-2011)	Existing approved Site Manufacturing Site (as per approval letter) (18-01-2018)	New Proposed Site / Manufacturer (as per COPP)
1.	027375	Xeloda Tablet Each tablet contains:- Capecitabine…500mg	**Manufacturer:** M/s. Shanghai Roche Pharmaceuticals Ltd., 1100 Long Dong Avenue, Pudong New Area, Shanghai 201203, China. **Product License Holder:** M/s. Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City AL7 1TW, United Kingdom. **Exporting Site:** M/s. F.Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH 4070 Basel, Switzerland.	**Product License Holder:-** Roche Registration Gmbh, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany. **Manufacturer:** Excella GmbH & Co. KG Nuernberger Str. 12 90537 Feucht Germany.

The firm has submitted documents as per following details: -

a) Fee of Rs.100,000/-.
b) Application on Form-5F
c) Copy of initial registration letter & Post Registration renewal trail.
d) Original & legalized COPP (Issued by EMA).
e) Sole Agency Agreement between F.Hoffmann La-Roche and MAH.
f) Proof / evidence of the contract between product license holder and manufacturer.
g) Undertaking.

Decision: **Registration Board approved the change of Product License Holder & Manufacturing site of following product subject to policy for imported finished drug registration. Other terms and conditions will remain the same.**

Reg. No.	Name & Composition	Previously approved Manufacturing Site, PLH & Exporting Site	New Approved Product License Holder & Manufacturing Site
027375	Xeloda Tablet Each tablet contains:- Capecitabine…500mg	**Manufacturer:** M/s. Shanghai Roche Pharmaceuticals Ltd., 1100 Long Dong Avenue, Pudong New Area, Shanghai 201203, China. **Product License Holder:** M/s. Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City AL7 1TW, United Kingdom. **Exporting Site:** M/s. F.Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH 4070 Basel, Switzerland.	**Product License Holder:-** Roche Registration Gmbh, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany. **Manufacturer:** Excella GmbH & Co. KG Nuernberger Str. 12 90537 Feucht Germany.

Case.No.25: REQUEST OF M/S MEDINET PHARMACEUTICALS, RAWALPINDI FOR REGISTRATION OF DRUGS.

Registration Board in its 223rd meeting approved the following products of M/s Medinet Pharmaceuticals, Rawalpindi as per details given below:-

M/s. Medinet Pharmaceuticals Rawalpindi / M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina. **Manufactured by** M/s. Laboratorios IMA SAIC, Palpa Argentina	Anastrozol Coated Tablets Each Tablet contains; Anastrozole….1mg (Anticancer)	Pack of 28 tablets	2 year	Approved
M/s. Medinet Pharmaceuticals Rawalpindi / M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina. **Manufactured by** M/s. Laboratorios IMA SAIC, Palpa Argentina	Letrozol Tablets 2.5mg Each tablet contains; Letrozol….2.5mg (Anticancer)	28's Tablet	2 year	Approved

There is a typographic error by the respective evaluator in composition and the manufacturer of the above two products. The correct composition and manufacturer as per COPP is as follows:

As per M-223rd		**As per COPP**	
M/s. Medinet Pharmaceuticals Rawalpindi / M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina. **Manufactured by** M/s. Laboratorios IMA SAIC, Palpa Argentina	Anastrozol Coated Tablets Each Tablet contains; - Anastrozole….1mg (Anticancer)	M/s. Medinet Pharmaceuticals Rawalpindi / **Manufacturer & Product License Holder** M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina	Anastrozol Varifarma Coated Tablets Each Film Coated Tablet contains; - Anastrozole….1mg (Anticancer)
M/s. Medinet Pharmaceuticals Rawalpindi / M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina. **Manufactured by** M/s. Laboratorios IMA SAIC, Palpa Argentina	Letrozol Tablets 2.5mg Each tablet contains; - Letrozol….2.5mg (Anticancer)	M/s. Medinet Pharmaceuticals Rawalpindi / **Manufacturer & Product License Holder** M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina	Letrozol Varifarma Tablets 2.5mg Each Film Coated Tablet contains; - Letrozol….2.5mg (Anticancer)

The case was again discussed for the change of manufacturer in 258th meeting held on 25-04-2016 for M/s Medinet's other products, wherein they informed that they are not interested in the import of above two products.

Initially firm has deposited a Fee of Rs.15000/- (deposit slip Nos 21&22) for each product on 25th July, 2009 and firm deposited additional / remaining fee Rs.85,000/- (deposit slip Nos 0547530 & 0547531) for each product

Now the firm has submitted request for the grant of registration of above products.

Decision: Registration Board approved the above products subject to policy for imported finished drug registration.

Case.No.26: <u>Request Of M/S Ghazali Brothers, Karachi For Change Of Manufacturing Site Of Approved Products.</u>

Registration Board in its 275th meeting approved the following products of M/s Ghazali Brothers, 1st floor Azzainab Court, Campbell Street, Karachi. The firm has submitted request for change of manufacturing site for already approved products. Details are as under:-

S. No	Name & Composition (as approved in M-275)	Existing approved Manufacturing Site / MAH (as approved in M-275)	New Proposed Manufacturing Site / MAH (as per COPP)
1.	LUKOZE 5% in normal Saline 0.9% IV Injection Each bottle (250ml) contains: Glucose…..12.5g Sodium Chloride. 2.25g.	**Manufacturer:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy, **Market Authorization Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy,	**Manufacturer & Market Authorization Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd, Wuhu Green-food Economic Development Zone, Sanshan District, Wuhu City
2.	SODIOMIDE 0.9% INJECTION (IV). Each 500ml HDPE bottle contains: Sodium chloride… 4.5g.	**Manufacturer:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Sanshan Green-Food Industrial Park, Wuhu Economy & Technology Development Area, China **Market Authorized Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy, (form 5A and Sole agency)	**-do-**
3.	SOLAC RINGER's INJECTION (IV). Each HDPE bottle of 500ml Contains: Sodium Lactae……. 1,55g Sodium Chloride….. 3.0g Potassium Chloride. 0.15g Calcium Chloride... 0.1g	**Manufacturer:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Sanshan Green-Food Industrial Park, Wuhu Economy & Technology Development Area, China **Market Authorized Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy,	**-do-**
4.	LUKOZE 5% IV Injection. Each HDPE Bottle of 500ml contains: Glucose…. 25g.	**Manufacturer:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy. **Market Authorized Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy,	**-do-**

The firm has submitted documents as per following details: -

a) Fee of Rs.100,000/- for each product.
b) Application on Form-5A (submission date 23-12-2019)
c) Original & legalized COPP's for above products.
d) Sole Agency Agreement between Manufacturer / MAH and Importer.
e) Attested / legalized copy of GMP certificate.
f) Undertaking for each product.

Decision: Registration Board approved the change of Manufacturing site of following products subject to policy for imported finished drug registration. Other terms and conditions will remain the same.

S. No	Name & Composition	Previously approved Manufacturing Site/MAH	New Approved Manufacturing Site / MAH
1.	LUKOZE 5% in normal Saline 0.9% IV Injection Each bottle (250ml) contains: Glucose…..12.5g Sodium Chloride. 2.25g.	**Manufacturer:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy, **Market Authorization Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy,	**Manufacturer & Market Authorization Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd, Wuhu Green-food Economic Development Zone, Sanshan District, Wuhu City
2.	SODIOMIDE 0.9% INJECTION (IV). Each 500ml HDPE bottle contains: Sodium chloride… 4.5g.	**Manufacturer:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Sanshan Green-Food Industrial Park, Wuhu Economy & Technology Development Area, China **Market Authorized Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy, (form 5A and Sole agency)	**-do-**
3.	SOLAC RINGER's INJECTION (IV). Each HDPE bottle of 500ml Contains: Sodium Lactae……. 1,55g Sodium Chloride….. 3.0g Potassium Chloride. 0.15g Calcium Chloride... 0.1g	**Manufacturer:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Sanshan Green-Food Industrial Park, Wuhu Economy & Technology Development Area, China **Market Authorized Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy,	**-do-**
4.	LUKOZE 5% IV Injection. Each HDPE Bottle of 500ml contains: Glucose…. 25g.	**Manufacturer:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy. **Market Authorized Holder:** M/s Anhui Double-Crane Pharmaceutical Co., Ltd., Anhui Province Fanchang Economy,	**-do-**

Case No. 27. <u>Request Of M/s Novartis Pharma Karachi For Change Of Manufacturing Site Of Their Registered Product.</u>

M/s Novartis Pharma (Pakistan) Limited, 15 west Wharf Karachi has applied for change of manufacturing site of their following already registered product as per details given below: -

S. No	Reg. No.	Name & Composition (as per initial letter) (issued on 07-04-2017)	Existing approved Site Manufacturing Site (as per approval letter 07-04-2017)	New Proposed Site / Manufacturer/ Product License Holder (as per COPP)
1.	084160	Tykerb Tablet 250mg Each film coated tablet contains: Lapatinib ditosylate monohydrate, equivalent to 250mg lapatinib	Marketing authorization Holder: M/s Novartis Europharm Limited, Frimley Business Park, Camberley GU 16 7SR, UK Manufacturer: M/s Glaxo Operation UK Limited (trading as Glaxo welcome operations), Priority street, ware, hertfordshire SG12 ODJ, UK	Marketing authorization Holder: M/s Novartis Europharm Limited, Vista Building, Flm Park, Merrion Road, Dublin 4, Ireland. Manufacturer: M/s S.C. Sandoz S.R.L., Str. Livezeni nr, 7A, 540472 Targu Mures, Jud. Mures, Romania.

The firm has submitted the following supporting documents: -

i. Fee of Rs.50,000/- dated 22-11-2019.
ii. Application on Form-5F
iii. Copy of initial registration letter dated 07-04-2017.
iv. Sole agency agreement from marketing authorization Holder
v. Original & legalized COPP (No. 11/19/135140) dated 28-08-2019 issued by EMA showing the freely availability of product in exporting country and GMP compliant status of the manufacturer.
vi. Site master file (M/s Sandoz S.R.L., Str. Livezeni nr, 7A, 540472 Targu Mures, Jud. Mures, Romania).
vii. Undertakings that provided information are correct.

Decision: Registration Board approved the change of Product License Holder & Manufacturing site of following products subject to policy for imported finished drug registration. Other terms and conditions will remain the same.

Reg. No.	Name & Composition	Previously approved Marketing Authorization Holder & Manufacturer	New Approved Marketing Authorization Holder & Manufacturer
084160	Tykerb Tablet 250mg Each film coated tablet contains: Lapatinib ditosylate monohydrate, equivalent to 250mg lapatinib	**Marketing Authorization Holder:** M/s Novartis Europharm Limited, Frimley Business Park, Camberley GU 16 7SR, UK **Manufacturer:** M/s Glaxo Operation UK Limited (trading as Glaxo welcome operations), Priority street, ware, hertfordshire SG12 ODJ, UK	**Marketing Authorization Holder:** M/s Novartis Europharm Limited, Vista Building, Flm Park, Merrion Road, Dublin 4, Ireland. **Manufacturer:** M/s S.C. Sandoz S.R.L., Str. Livezeni nr, 7A, 540472 Targu Mures, Jud. Mures, Romania.

Case No. 28. Request of M/s Novartis Pharma Karachi for the extension in shelf life of their Registered Product.

M/s Novartis Pharma (Pakistan) Limited, 15 west Wharf Karachi apply for extension in shelf life of their registered product as per following details;

Sr. No.	Reg. No	MAH & Manufacturer (As per Reg. Letter 07-04-2017)	Brand Name and Composition (As per Reg. Letter)	Existing shelf life	New proposed shelf life
1	084160	Marketing Authorization Holder: M/s Novartis Europharm Limited, Frimley Business Park, Camberley GU 16 7SR, UK Manufacturer: M/s Glaxo Operation UK Limited (trading as Glaxo welcome operations), Priority street, ware, hertfordshire SG12 ODJ, UK	Tykerb Tablet 250mg Each film coated tablet contains: Lapatinib ditosylate monohydrate, equivalent to 250mg lapatinib	Two years	Three years

The firm has submitted the following supporting documents: -

i. Application on form-5F along with fee Rs. 5000/-
ii. Copy of registration letter dated 07-04-2017
iii. Proposed shelf-life, justification & data of long-term stability testing (as per conditions of zone IV-A)
iv. Original Legalized CoPP (No. 04/19/132175) dated 18-06-2019 issued by EMA showing 2-year shelf life of Blister packs and 3 years of Bottle pack Tykerb Tabler 250mg.
v. Undertaking that:
   - No change to the primary packaging type in direct contact with the FPP and to the recommended conditions of storage.
   - No change in formulation and specification either of finished product, API and excipients etc.
   - In case both the above conditions are involved then manufacturer will submit complete requisite information as per procedure.
   - provided information is true and correct

Decision: Registration Board approved has acceded to the request for the increase in the shelf life of Tykerb Tablet 250mg from 24 months to 36 months. Other terms and conditions will remain the same.

Case No: 29 M/s Sanofi-Aventis Pakistan request for Exemption of Labeling Text of Imported Product under registration namely: Aubagio 14mg Tablet (Teriflunomide)

M/s Sanofi-aventis Pakistan requested that Aubagio is indicated for a rare disease called Multiple Sclerosis and required to be imported in a limited quantity. Therefore, it is not possible for manufacturer to follow the Packaging and labeling rules of every country at the time of export plus production, packaging, quality controls of these sterile and temperature sensitive products require specialized methods and techniques of handling under highly controlled environment.

Keeping in view the above scenario we, sanofi-aventis Pakistan limited, would like to request for the exemption of **Urdu Text, Registration number and MRP on packs of above mentioned product and would request you to allow us to import the said product in Standard Export Packs**. We assure you that we will print the Urdu Text, Registration number and Maximum Retail Price (MRP) on each pack under cold chain process at our registered premises of sanofi-aventis Pakistan limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi before releasing the goods into the market and also undertake the same.

In light of the above, this is to kindly request you to grant us exemption from labeling text (Urdu Text, MRP and Registration Number) for Aubagio **at the time of importation** into Pakistan.

Firm submitted processing fee Rs. 5000/-

Decision: Registration Board acceded to the request for import of already registered above product (Aubagio 14mg Tablet) in Standard Export Packs. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at their Licensed Premises (DML No.000007) to comply requirement as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for one (01) year only after issuance of registration letter. The firm shall submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

Case No: 30 M/s Sanofi-Aventis Pakistan requested for Extension in exemption from labeling text on - Fludara 50mg (Reg. no. 088890) Powder for solution for Injection/Infusion

M/s Sanofi-aventis Pakistan requested that **Fludara** is indicated for the treatment of B-cell chronic lymphocytic leukaemia (CLL) in adult patients with sufficient bone marrow reserves and low-grade Non-Hodgkin's Lymphoma. Since Fludara is a highly specialized **Life Saving Medicine** and **critically needed essential drug** provided to institutes therefore, it is our social responsibility to make it available for patients in need.

Fludara is being manufactured and primarily packaged in large volume at the source point in Germany, then it is supplied to United Kingdom for Secondary Packaging from where supplies are made to various countries as per their needs.

SALES RECORD:

The sales record of Fludara is mentioned below since the transfer of its registration in name of sanofi-aventis Pakistan limited:

Product name	No of unit packs imported			No of unit packs sold		
Fludara	2018	2019	2020	2018	2019	Jan - Feb 2020
	-	**60**	-	-	**37**	**21**

***2 Packs used for QI sampling**

Fludara is purely used by the Government and Private institutes. Below is the list of institutions where Fludara Injection is being supplied;

S. #	Institutes	City
1	Armed Forces Bone Marrow Transplant Centre	Rawalpindi
2	Pakistan Institute of Medical Sciences	Islamabad
3	Hayatabad Medical Complex	Peshawar
4	IRNUM	Peshawar
5	MINAR	Multan
6	Shaukat Khanum Memorial Lahore	Lahore
7	Hameed Latif Hospital	Lahore
8	NIBD	Karachi
9	CENAR Quetta	Quetta

In light of the above, we would like to request the competent authority for extension in labeling exemption of the said product. We wish to continue the import of Fludara in Standard Export Packs and **locally print the Registration Number, Maximum Retail Price and Urdu Text on the packs once imported**.

Firm submitted processing fee Rs. 5000/-

Decision: Registration Board acceded to the request for import of already registered above product (Fludara 50mg Powder for solution for Injection/Infusion (Reg. no. 088890) in Standard Export Packs. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at their Licensed Premises (DML No.000007) to comply requirement as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for one (01) year only. The firm shall submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

Case. No.31 REQUEST FOR ISSUANCE OF PANEL INSPECTION REPORT OF FOREIGN MANUFACTURING FACILITY.

M/s Genix Pharma (Pvt) Ltd, Karachi has submitted request for copy of panel inspection report of Refent (Remifentanil Hydrochloride) Injection 1mg and Sufent (Sufentanil Citrate) Injection 50mcg manufactured by Yichang Humanwell Pharmaceutical Co., Ltd., No. 19 of Dallan road, Yichange Developing Zone, Hubei Province, China.

The firm has submitted a fee of Rs.5000/- for approval of their request.

Decision of 41st PRVC: The firm's request was refer to Registration Board.

Decision: Registration Board acceded and approved the firm's request.

Case No.01: Cases Referred by Post Registration Variation Committee. (38-PRVC.)

i. Similarity of Brand Name of Drug(s) of M/s. Ambrosia Pharmaceuticals, Rawat
(Page No.198 - 207/C)

The application of M/s. Ambrosia Pharmaceuticals, Rawat-Islamabad was considered in 25th meeting of PRVC (PR-I Section); wherein M/s. Karachi Chemicals Industries (Pvt.) Ltd, Karachi was advised to change the brand name of their product "Mukast [Montelukast (as sodium) 10mg tablet] (Reg.No.055831) vide letter No.F.25-PRVC/2019 (PR-I) dated 22nd March, 2019 subsequently followed by a reminder dated 13th January, 2020.

In pursuance of this authority's advices M/s Karachi Chemicals Industries (Pvt.) Ltd, Karachi is reluctant to change the brand name of their product and has requested to advise (Page No.242-273/C) M/s Ambrosia Pharmaceuticals, Rawat-Islamabad to the brand name of their product Mukast [Montelukast (as sodium) 10mg tablet] (Reg.No.056572).

Remarks:

Dates of registration letters were issued to the both firms for the same formulations are as under;

a. M/s. Ambrosia Pharmaceuticals, Rawat-Islamabad. 04th April, 2009.
b. M/s Karachi Chemicals Industries (Pvt.) Ltd, Karachi. 27th April, 2009.

Decision of 38-PRVC:

The Committee referred the case to Registration Board.

Decision: Registration Board decided to issue show-cause notice to M/s Karachi Chemicals Industries (Pvt.) Ltd, Karachi for the change of Brand Name of "Mukast [Montelukast (as sodium) 10mg tablet] (Reg.No.055831).

ii. M/s Ferozsons Laboratories Ltd, Nowshera (Page No.274 – 284 /C).

M/s Gilead Sciences Ireland UC through Meer & Hasan (Attorneys at Law), 306, Al-Faisal Plaza, 48-The Mall, Lahore-54000, Pakistan as Special Attorney; wherein the firm has complained that their following product being imported by M/s Ferozsons Laboratories Limited, Nowshera has close resemblance with the product of M/s Sami Pharmaceuticals (Pvt.) Ltd, Karachi.

Sr. No.	Name of Drug with Composition	Reg. No.	Date of Initial Registration	Name of Firm
1.	Truvada Tablets Each tablet contains: Emticitabine…….200mg Tenofovir Disoproxil Fumarate 300mg eq.to 245mg of Tenofovir Disoproxil	072544	20-Dec-12 (M-231)	**Importer:** M/s Ferozsons Laboratories Ltd, P.O.Ferozsons, Amangarh, Nowshera. **Manufacturer:** M/s Nycomed GmbH Plant Oranienburg Lehnitzstrasse 70-98, 16515 Oranienburg, Germany.
2.	Truva 10mg Tablets Each tablet contains: Atorvastatin Calcium Trihydrate eq.to Atorvastatin……..….10mg	036351	31-Dec-04 (M-188)	**Manufacturer:** M/s Sami Pharmaceuticals (Pvt.) Ltd, Karachi.

The firm i.e. M/s Gilead Sciences Ireland UC through Meer & Hasan (Attorneys at Law) has requested that M/s Sami Pharmaceuticals (Pvt.) Ltd, Karachi may be directed to change the brand name of their already registered drug as their product is being marketed in 123 countries around the world for over fifteen (15) years to treat and prevent HIV/AIDS with the trademark TRUVADA.

Remarks:

The product Truva of M/s Sami Pharmaceuticals (Pvt.) Ltd, Karachi has been registered 08 years earlier than the applicant's product with the different formulation.

Decision of 38-PRVC:

The Committee referred the case to Registration Board.

Decision: Registration Board advised to seek legal opinion from Legal Affairs Division.

ii. M/s Pfizer Pakistan Limited, Karachi (Page No. 503 – 676/C).

The application of M/s Pfizer Pakistan Limited, B-2, S.I.T.E., Karachi for the change of Name/Title of Manufacturers abroad of their following registered imported products (Bulk) **from Pharmacia NV/SA to Pfizer Manufacturing Belgium NV**; Rijksweg 12, 2870 Puurs, Belgium (site remains the same) and local repacking at M/s Pfizer Pakistan Ltd, B-2, SITE, Karachi was discussed in **37th meeting of PRVC** and the Committee deferred the same.

Sr. No.	Reg. No.	Name of Drug(s) with composition	Date of Initial Reg. & Renewal Status
1.	000604	Solucortef Injection 100mg/2ml (IM/IV) Each 2ml contains: Hydrocortisone Sodium Succinate.....100mg	Renewal confirmed in 279th meeting of Reg. Board
2.	000603	Solucortef Injection 250mg/2ml (IM/IV) Each 2ml contains: Hydrocortisone Sodium Succinate.……250mg	
3.	008253	Solucortef Injection 500mg/4ml (IM/IV) Each 4ml contains: Hydrocortisone Sodium Succinate….....500mg	
4.	005806	Solu Medrol Injection 1000mg (IM/IV) Each vial contains: Methylprednisolone eq.to (as Methylprednisolone sodium succinate)……..1000mg	One Reg.No. granted for both strengths
5.		Solu Medrol Injection 500mg (IM/IV) Each vial contains: Methylprednisolone eq.to (as Methylprednisolone sodium succinate)……..500mg	
6.	000599	Solu Medrol Injection 125mg/2ml (IM/IV) Each 2ml contains: Methylprednisolone eq.to (as Methylprednisolone sodium succinate)……..125mg	Renewal submitted within time
7.	000598	Solu Medrol Injection 40mg/ml (IM/IV) Each ml contains: Methylprednisolone eq.to (as Methylprednisolone sodium succinate)……..40mg	
8.	000606	Depo Medrol Injection 40mg/ml (IM/IV) Each ml contains: Methylprednisolone Acetate…….40mg	

The firm has submitted the following documents;

i. Application (14-Feb-14) for proposed change with fee Rs.100,000/- (Duplicate).
ii. Confirmation of change of title/name of Manufacturer Only (site remains same).
iii. Copies of CoPPs.
iv. Undertaking.

37-PRVC Decision:

The Committee deferred the request of firm for provision of evidence regarding change of Name/Title of the firm only (manufacturing site will remain same) from concerned Authority and original & legalized CoPP for the change of name only.

Updated Submission (Page No.286–313/C.): *Dy.No.3081 (R&I) dated: 28-Feb-20.*

Now, the firm has submitted the original/legalized CoPP for manufacturer of the above mentioned products; wherein the title of the manufacturer is written as **"Pfizer Manufacturing Belgium NV"**. However, manufacturing site is same i.e. Rijksweg 12, 2870 PUURS, Belgium.

Remarks: The Title/Name of manufacturer of products (imported in bulk and locally repacked) was changed on 17th October, 2005 and the firm submitted their application for the change of title of manufacturer on 11th February, 2014 (copies attached)

Decision of 39th meeting of PRVC:

The Committee referred the case to Registration Board.

Decision: Registration Board acceded to request of firm for change of title of manufacturer (abroad) from Pharmacia NV/SA to Pfizer Manufacturing Belgium NV; Rijksweg 12, 2870 Puurs, Belgium (site remains the same). Furthermore the Board also directed to allot separate registration number for product mentioned at Sr. No. 5 being different strengths.

iii. M/s. Pharmatec Pakistan (Pvt.) Ltd; Karachi. (Page No. 1496 – 1593/C)

Dy.No 3960 (R&I) dated: 9-Mar-20 & Dy.No. 6795 (R&I) dated: 10-Apr-20

M/s. Pharmatec Pakistan (Pvt.) Ltd; Karachi requested for change in primary packaging material of following products details are as under:

Sr.#	Reg. No.	Name of Product with composition	Existing Packaging	Proposed Packaging	Remarks
1.	019762	Reltus DM liquid Each 5ml contains: Dextromethorphan HBr ……. 10mg Pseudoephedrine HCl…….30mg Chlorphineramine Maleate……2mg	Amber glass bottle Alu cap 25mm with 1.8 WAD	Amber PET bottle Plastic cap PET bottle 60/120ml	RRA approval status not confirmed
2.	017570	Reltus cough expectorant Ammonium Chloride ……. 100mg Phenylephrine HCl…….5mg Chlorphineramine Maleate……2mg	Amber glass bottle Alu cap 25mm with 1.8 WAD	Amber PET bottle Plastic cap PET bottle 60/120ml	RRA approval status not confirmed

The stability data submitted by the firm **(accelerated=6months & Long-term= 6months).**

Details of Submission:

Firm has submitted the following documents as per SOP (approved in 283rd meeting).

Sr.#	Documents Required (as per SOP M-283)	Information Provided
1.	Application with required fee as per relevant SRO.	Date of applications 10-April-2020; Rs.5,000/- for each product.
2.	Copy of registration letter and last renewal status	Reg. No. 019762 (dated 07-08-1996) Last renewal dated 27.05.2015 (Rs.10,000/-) Reg. No. 017570 (dated 27-06-1995) Last renewal dated 27.05.2015 (Rs.10,000/-)
3.	Justification of proposed change including data on the suitability of the container-closure system (e.g. extractable/ leachable testing (where applicable), permeation testing, light transmission) demonstrating equivalent or superior protection compared to the current packaging system. For changes to functional packaging related to container closure (e.g. MDIs etc.), data to demonstrate the functioning of the new packaging	Data regarding suitability of proposed packaging material is provided from supplier i.e. Novatex Ltd. Following tests are performed: a) Leachable/extractable test as prescribed by FDA b) heavy metals determination
4.	If the container closure system of applied formulation is different from that of the reference product,	**Accelerated studies** (Temp 40◦C±2◦C/ RH 75%±5%)

	manufacturer will place first three lab scale batches or developmental scale batches as set by Registration Board in 276th meeting, at 3 months of accelerated and 3months of real time studies for compatibility of applied formulation with container closure system as directed by Pharmacopeia of Reference Regulatory Authorities. Registration Board shall be informed immediately and along with market withdrawal in case of any significant change about result of stability studies	Interval: 0,3,6 months **Long term studies** (Temp 30◦C±2◦C /RH 65%±5%) **Interval**: 0,3,6 months **Reltus DM liquid** **Testing parameters**: description, ph, assay (dextromethorphan, pseudoephedrine, chlorphineramine maleate, microbiological tests (total aerobic count, yeast and mold count, gas forming organism. Batch No: 0383, 0267, 0381 Type of container: Amber PET bottle with plastic cap **Reltus cough expectorant** **Testing parameters**: description, ph, assay (ammonium chloride, phenylephrine, chlorphineramine maleate, microbiological tests (total aerobic count, yeast and mold count, gas forming organism. Batch No: J67BH, J67B1,189PE Type of container: Amber PET bottle with plastic cap **Batch size:** 6000 bottles **Sample size**: 15 bottles for real time studies, 5 bottles for accelerated studies.
5.	Shelf life of the drug product supported with justification.	Provided
6.	Existing and proposed container closure system with differences (e.g. description, materials of construction of primary packaging components, specifications, if appropriate) highlighted in tabular form.	Comparison between Amber glass bottle and Amber PET bottle is provided in tabulated form.
7.	If the proposed change requires change in manufacturing section/ facility, then a new registration application with prescribed fee shall be submitted.	Not applicable
8.	An Undertaking that: • To perform stress studies. • In case of any quality complaint/OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. • Provided information is true & correct.	provided

A study report for container closure system performed by Smithers lab for Novatex Ltd. As follow:

Sr.#	Tests performed
1.	Specific migration of mono and diethylene glycol, terephtalic acid and antimony by total immersion into simulants.
2.	FDA extraction test as specified inUS FDA code of federal regulations CFR21
3.	Determination of levels of Pd, Cd, chromium and mercury

Certificate of Analysis by packaging material supplier i.e. Avutronics Limited submitted. Avutronics Limited buy raw material from Novatex Ltd**.**

Remarks:

Shortcomings	Reltus Cough Expectorant (Reg.No.017570)	➢ Validated analytical testing method/pharmacopeial reference not provided

	Reltus DM liquid (Reg.No.019762)	➢ Related substances were not tested ➢ Validated analytical testing method /pharmacopeial reference not provided ➢ Chromatograms are not submitted ➢ Certificate of analysis for each point of time is not provided ➢ Stability protocol not provided

Decision 39-PRVC:

The Chairman Registration Board referred the case to Registration Board after submission of shortcomings by the firm as mentioned above.

Updated Submission:

The firm has now submitted validated analytical testing method for product Reltus Cough Expectorant (Reg.No.017570); however, documents submitted for product Reltus DM liquid (Reg.No.019762) were not satisfactory.

Decision: Registration Board deferred the request of firm for confirmation of primary packaging material of same/similar formulation approved in any Reference Regulatory Authorities.

Case No.02: Extension in Contract Manufacturing of Registered Drugs.

The following firms have submitted applications for extension in manufacturing of registered drugs on contract basis.

Sr.#	Name of Drug(s) with composition; Reg.No. & Name of Contract Manufacturer / Dy.No.(R&I) & date	Date of Initial Reg. & Validity	Registration / Post Reg. Variation History	Documents submitted/ Remarks
I	**II**	**III**	**IV**	**V**
a.	**M/s Akhai Agencies, Akhai Arcade, 2nd Floor, 103-K, Block-2, PECHS, Shahra-e-Quaideen, Karachi. Contract Manufacturer: M/s ICI Pakistan Ltd, Hattar.** (Formerly: M/s Cirin Pharmaceutical (Pvt.) Ltd,**)**			
1.	Tricort 40mg Injection (IM) Each ml contains: Triamoinolone Acetonide……40mg (Reg.No.019478) *Dy.No.8653 (R&I) dt: 22-Apr-2020*	Initial Reg. 18-Aug-96 Validity **30-Jun-20**	Transfer of Reg. from import to local on contract manufacturing basis vide letter No.F.24-4/07-Reg-II (North) dated 10th April, 2007. Last Extension of Contract Manufacturing granted vide letter No.F.3-4/15-Reg-II (M-250) dated on 15th October, 2015 till 30th June, 2020.	• Fee Rs.50,000/-**(17-Mar-20)** for each product. • Copies of initial registration letter & extensions. • Undertaking. • Copy of agreement b/w contract giver/acceptor. • Copies of DSL/DML of contract giver/acceptor. • Copy of Section approval. • Name/Title of manufacturer has been changed from M/s Cirin Pharmaceuticals (Pvt.) Ltd., Hattar to M/s ICI Pakistan Ltd, Hattar vide letter No.F.3-4/92-Lic (Vol-III) dt: 18th & 20th Feb.2020. However, manufacturing site remains same.
2.	Nuphine 10mg Injection (IM/IV) Each ml contains: Nalbuphine HCl……10mg (Reg.No.021016) *Dy.No.8649 (R&I) dt: 22-Apr-2020*	Initial Reg. 25-Apr-98		
3.	Nuphine 20mg Injection (IM/IV) Each ml contains: Nalbuphine HCl……20mg (Reg.No.021017) *Dy.No.8654 (R&I) dt: 22-Apr-2020*	Validity **30-Jun-20**		
Decision: Registration Board observed that title of M/s Cirin Pharmaceuticals (Pvt.) Ltd. has been changed to M/s ICI Pakistan Ltd previously. The Board deferred and advised to confirm				

whether M/s Akhai has applied for change of title of manufacturer or otherwise and manufacturing status of these products during this period.

b. M/s Akhai Pharmaceuticals, Akhai Arcade, 4th Floor, 103-K, Block-2, P.E.C.H.S., Shahra-e-Quaideen, Karachi.
Contract Manufacturer: M/s ICI Pakistan Ltd, Hattar. (Formerly: M/s Cirin Pharmaceutical (Pvt.) Ltd,**)**

4.	S-Choline Injection Each 2ml contains: Suxamethonium Chloride….100mg (Reg.No.017411) *Dy.No.8648 (R&I) dt: 22-Apr-2020*	Initial Reg. 13-Jul-95 Validity **30-Jun-20**	Transfer of Reg. from import to local on contract manufacturing basis vide letter No.F.24-4/07-Reg-II (North) dated 10-Apr-07. Change of Brand Name: 6-Jun-97 (Product @ Sr.No.04) Last extension of contract manufacturing granted vide letter No.F.3-4/15-Reg-II (M-250) dated on 15th October, 2015 till 30th June, 2020.	• Fee Rs.50,000/-**(17-Mar-20**) for each product. • Copies of initial reg. letters & extensions. • Undertakings. • Copy of agreement b/w contract giver/acceptor. • Copies DSL/DML of contract giver/acceptor. • Copy of Section approval. • Name/Title of manufacturer has been changed from M/s Cirin Pharmaceuticals (Pvt.) Ltd., Hattar to M/s ICI Pakistan Ltd, Hattar vide letter No.F.3-4/92-Lic (Vol-III) dated 18th & 20th February, 2020. However, manufacturing site remains the same.
5.	Hydrocort 250mg Injection Each vial contains: Hydrocortisone (as Sodium succinate) …….250mg (Reg.No.015750) *Dy.No.8651 (R&I) dt: 22-Apr-2020*	Initial Reg. 7-Sep-94 Validity **30-Jun-20**		
6.	Hydrocort 100mg Injection Each vial contains: Hydrocortisone (as Sodium succinate) ……100mg (Reg.No.015751) *Dy.No.8652 (R&I) dt: 22-Apr-2020*			
7.	Flucate 25mg Injection Each ml contains: Fluphenazine Decanoate……25mg (Reg.No.016317) *Dy.No.8650 (R&I) dt: 22-Apr-2020*	Initial Reg. 8-Dec-94 Validity **30-Jun-20**		

Decision: Registration Board observed that title of M/s Cirin Pharmaceuticals (Pvt.) Ltd. has been changed to M/s ICI Pakistan Ltd previously. The Board deferred and advised to confirm whether M/s Akhai Pharmaceuticals has applied for change of title of manufacturer or otherwise and manufacturing status of these products during this period.

c. M/s Welwrd Pharmaceuticals, Plot No.3, Block A, Phase-I-II, Industrial Estate, Hattar.
Dy.No.10689 (R&I) dated: 12-May-2020
Contract Manufacturer: M/s WnsFeild Pharmaceutical, Hattar.

8.	Degrox Dry Suspension Each 5ml contains: Cefixime Trihydrate = Cefixime……..…..100mg (Reg. No.047374)	Validity **30-Jun-20**	***For Product @ Sr.No.8:*** Change of contract manufacturer from M/s Navegal Lab. to M/s WnsFeild Pharma vide letter No.F.1-25/06-Reg-II (S) dated 26-Aug-09 Change of Brand names: 12-Dec-19. Last extension of contract manufacturer granted vide letter No.F.13-6/15-Reg-IV (M-252) dated 3rd April, 2017 till 30-Jun-20	• Fee Rs.50,000/-**(30-Apr-20)** for each product. • Copies of initial registration letters & extensions. • Copies of agreement b/w contract giver/acceptor. • Copies of DMLs of contract giver/acceptor. **Remarks:** Initial registration letter & post registration variations for product @ Sr.No.08 was not provided. However, as per available record, product was registered with strength form of 200mg suspension.
9.	Degrox 400mg Capsules Each capsule contains: Cefixime Trihydrate = Cefixime……..…..400mg (Reg. No.053467)	Initial Reg. on contract Mfg. from M/s WnsFeirld 10-Jan-09 Validity **30-Jun-20**		

Decision: The Registration Board decided as under;

i. Deferred the product at Sr.No.08 for provision of initial registration letter & post registration variations of the same.

	ii. Acceded the request of firm for the product at Sr.No. 09 for extension in contract manufacturing period of their above registered drugs from M/s WnsFeild Pharmaceuticals, Plot No.122, Block A, Industrial Estate, Hattar till 30.06.2025 on the same terms and conditions.			
d.	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi.** *Dy.No.10002 (R&I) dated: 5-May-2020* **Contract Manufacturer: M/s Seraph Pharmaceutical, Islamabad**			
10.	Neogene 250mg IM injection Each vial contains: Ceftriaxone (as Sodium) 250mg (Reg.No.018301)	Initial Reg. 24-Sep-95 Validity **30-Jun-20**	***Products @ Sr.#10-15.*** Initially registered in name of M/s Ali Gohar Pharmaceutical vide letter No.F.3-4/95-Reg.II (M-115) dated 24.9.1995 Transfer of registration from M/s Ali Gohar Pharma to M/s AGP (Pvt) Ltd., Karadhi vide letter No.F.1-29/05 Reg.II dated 22-11-2005. Change of registration status from import to local manufacturing & Change of brand names from Tricef to Neogene on contract manufacturing from M/s UDL Pharma, Karachi vide letter No.F.3-9/16-Reg.II (M-262) dated 07-12-2016. Change of contract manufacturer from M/s UDL Pharma, Karachi to M/s Seraph Pharma, Islamabad vide letter No.F.3-9/18-Reg-II (M-286) (Misc) dt: 2-Jan-19.	• Fee Rs.50,000/-**(17-Apr-20)** for each product. • Copies of initial registration letters & extensions. • Copy of agreement b/w contract giver/acceptor. • Copies of DMLs of contract giver/acceptor. • Copies of Section approvals. • Undertakings.
11.	Neogene 500mg IM injection Each vial contains: Ceftriaxone (as Sodium).....500mg (Reg.No.018302)			
12.	Neogene 1gm IM injection Each vial contains: Ceftriaxone (as Sodium).....1gm (Reg.No.018303)			
13.	Neogene 250mg IV injection Each vial contains: Ceftriaxone (as Sodium).....250mg (Reg.No.018007)			
14.	Neogene 500mg IV injection Each vial contains: Ceftriaxone (as Sodium).....500mg (Reg.No.018008)			
15.	Neogene 1gm IV injection Each vial contains: Ceftriaxone (as Sodium).....1gm (Reg.No.018009)			
16.	Kefzol 500mg Injection Each vial contains: Cefazolin as sodium……..500mg (Reg.No.003755)	Transfer of Reg. 13-Feb-91 Validity **30-Jun-20**	***Products @ Sr.#16-17.*** Transfer of registration status from M/s Ali Gohar Pharma to M/s Elli-Lilly Gohar, Karachi alongiwth change in status from import to local manufacturing vide letter No.F.3-1/91-Reg.II (M-89) dated 13-Feb-91. Transfer of registration from M/s Eli Lilly Gohar (Pvt.) Ltd to M/s AGP (Pvt) Ltd. Karachi dated 13-10-03 Contract manufacturing permission by M/s PharmEvo (Pvt.) Ltd,	
17.	Kefzol 1g Injection Each vial contains: Cefazolin as sodium……1gm (Reg.No.003756)			

			Karachi vide letter No.F.3-7/07-Reg.II (S) (M-211) 15-Jul-08. Change of contract manufacturer & extension from M/s PharmEvo (Pvt.) Ltd to M/s UDL Pharma, Karachi vide letter No.F.3-4/16 Reg.II (M-257) 10th August, 2016. Change of contract manufacturer from M/s UDL Pharma to M/s Seraph Pharma, Karachi vide letter No.F.3-9/18-Reg-II (M-286) (Misc.) dated: 2-Jan-19.	
Decision:	**The Registration Board acceded to request of firm for extension in contract manufacturing period of their above mentioned registered drugs from M/s Seraph Pharmaceutical, Plot No.210, Industrial Triangle Kahuta Road, Islamabad till 30.06.2025 on the same terms and conditions.**			
e.	**M/s High-Q International, D-106, KDA-1, Karachi.** *Dy.No.8705 (R&I) dated: 22-Apr-2020*			
18.	Dayzone IV 1g Injection Each vial contains: Ceftriaxone as Sodium.....1gm (Reg. No.022646) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi	Initial Reg. 21-Nov-98 Validity **30-Jun-20**	Transfer from Import to local and manufacturing from M/s Pliva Pak (Pvt.) Ltd. Balochistan vide letter No.F.1-27/06-Reg-II (S) dated 3-Mar-09 Change of manufacturer from M/s Pliva to M/s Medicaids vide letter No.F.1-27/06-Reg.II (Vol-.II) dated 7-May-10. Extension granted vide letter No.F.3-2/13-Reg.II (M-238) dated 19-Sep-13 till 30-June-15. Extension & Change of manufacturer from M/s Medicaids to M/s High-Q Pharma, Karachi vide letter No.F.3-1/16-Reg.II (M-254) dated 3-Feb-16 till 30-June-2020.	• Fee Rs.50,000/-**(14-Apr-20)** for each product. • Copies of initial reg.letter & extensions. • Copy of agreement b/w contract giver/acceptor • Copies of DMLs of contract giver/acceptor. • Copies of Section approvals. • Undertaking.
19.	Dayzone IV 250mg Injection Each vial contains: Ceftriaxone as Sodium……250mg (Reg. No.022647) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi.			
20.	Daytaxime IM/IV 1gm Inj. Each vial contains: Cefotaxime as Sodium……1gm (Reg. No.022648) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi			
21.	Daytaxime IM/IV 500mg Inj. Each vial contains: Cefotaxime as Sodium…..500mg (Reg. No.022649) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi			
22.	Daytaxime IM/IV 250mg Inj. Each vial contains: Cefotaxime as Sodium……250mg (Reg. No.022650) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi			
23.	Fugacin 200mg Tablets Each film coated tablet contains: Ofloxacin……..200mg	Initial Reg. 1-Sep-94	Transfer of registration from Import to local manufacturing from M/s	

	(Reg. No.015589) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi	Validity **30-Jun-20**	High-Q Pharma, Karachi on contract basis vide letter No.F.3-2/14-Reg.II (M-243) dated 12-Sep-14. Last extension granted vide letter No.F.3-4/15-Reg.II (M-250) dated 15-Oct-15 till 30-June-2020.	
24.	Cycin 500mg Tablets Each film coated tablet contains: Ciprofloxacin (as hydrochloride) ……..500mg (Reg. No.019522) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi	Initial Reg. 17-Nov-96 Validity **30-Jun-20**		
25.	Cycin 250mg Tablets Each film coated tablet contains: Ciprofloxacin (as hydrochloride) ……....250mg (Reg. No.019523) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi			
26.	Hizone Injection 1gm IV Each vial contains: Ceftriaxone as Sodium…….1gm (Reg. No.018300) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi	Initial Reg. 5-Dec-95 Change of BN: 13-Nov-98 Validity **30-Jun-20**	Transfer of registration from finished import to bulk import & local repacking vide letter No.F.3-5/10-Reg.II (M-226) dated 29-Sep-2010. Transfer of registration from Import to local manufacturing by M/s Surge Lab. Sheikhupura vide letter No.F.3-2/14-Reg.II (M-243) dated 12-Sep-14 on contract basis. Last extension & change of manufacturer from M/s Surge Labs to M/s High-Q Pharma, Karachi vide letter No.F.3-1/16-Reg.II (M-254) dated 3-Feb-16 till 30-June-2020.	
27.	Hizone Injection 250mg IM Each vial contains: Ceftriaxone as Sodium…..250mg (Reg. No.022645) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi	Initial Reg. 21-Nov-98 Validity **30-Jun-20**		
28.	Cefapezone Inj. 1gm Each Vial Contains: Cefoperazone Sodium…….1gm (Reg. No.014947) **Manufacturer:** M/s High-Q Pharmaceutical, Karachi	Initial Reg. 19-May-94 Validity **30-Jun-20**		
29.	Remethan Injection 75mg Each 3ml contains:- Diclofenac Sodium……...75mg (Reg. No.018501) **Manufacturer:** M/s NovaMed Pharmaceutical (Pvt.) Ltd, Karachi	Initial Reg. 5-Dec-95 Validity **30-Jun-20**	Transfer of registration from Import to local manufacturing by M/s Surge Lab. Sheikhupura on contract basis vide letter No.F.3-2/14-Reg.II (M-243) dated 12-Sep-14. Last extension & change of manufacturer from M/s Surge Labs to M/s NovaMed Pharma (Pvt.) Ltd, Karachi vide letter No.F.3-1/16-Reg.II (M-254) dated 3-Feb-16 till 30-June-2020.	
30.	Cycin 100mg / 50ml Injection I.V Each vial contains:- Ciprofloxacin …….....100mg (Reg. No.019467) **Manufacturer:** M/s NovaMed Pharmaceutical (Pvt.) Ltd, Karachi	Initial Reg. 22-Aug-96 Validity **30-Jun-20**		
31.	Cycin 200mg/100ml Injection IV Each vial contains:- Ciprofloxacin …….....200mg (Reg. No.019468) **Manufacturer:** M/s NovaMed Pharmaceutical (Pvt.) Ltd, Karachi			

32.	Ruling 40mg Injection IV Each vial contains:- Omeprazole (as Sodium).....40mg (Reg. No.045616) **Manufacturer:** M/s English Pharmaceutical Industries, Lahore.	Initial Reg. 16-Apr-07 Validity **30-Jun-20**	Transfer of registration from finished import to bulk import & local repacking vide letter No.F.3-5/10-Reg.II (M-226) dated 29-Sep-2010. Transfer of registration from Import to local manufacturing by M/s Nabiqasim Industries, Karachi vide letter No.F.3-2/14-Reg.II (M-243) dated 12-Sep-14 on contract basis. Extension of contract manufacturing from M/s High-Q Pharma vide letter No.F.3-4/15-Reg.II (M-250) dated 15-Oct-15. Change of contract manufacturer from M/s Nabiqasim Industries to M/s English Pharma vide letter No.F.288-RB/19 (PR-I) dated 30-Apr-19 till 30-June-2020.	

Decision: Registration Board decided as follows;

i. **Approved the request of firm for extension in contract manufacturing of products at Sr.No.18 to 28 from M/s High-Q Pharmaceuticals, Karachi on the same terms and conditions till 30-June-2025.**

ii. **Approved extension in contract manufacturing of products at Sr.No.29 to 31 from M/s NovaMed Pharmaceuticals (Pvt.) Ltd., Lahore on the same terms and conditions till 30-June-2025.**

iii. **Approved extension in contract manufacturing of product at Sr.No.32 from M/s English Pharmaceutical Industries, Lahore on the same terms and conditions till 30-June-2025.**

f. M/s Getz Pharma (Pvt.) Ltd., 29-30/27, Korangi Industrial Area, Karachi.

33.	Cefiget 200mg Capsules Each capsule contains: Cefixime (as Trihydrate).....200mg (Reg. No.: 048776) **Manufacturer:** Opal Laboratories (Pvt.) Ltd., Karachi *Dy.No.10010 (R&I) dt: 5-May-20*	Initial Reg. 19-Jul-08 Validity **30-Jun-20**	Registered on contract manufacturing basis from M/s Opal Labs, Karachi vide letter No.F.3-1/08-Reg.II-South (M-212) dated 19-July-2008. Extension granted vide letter No.F.3-2/13-Reg-II (M-238) dated 19-Sep-13. Last extension granted vide letter No.F.3-1/08-Reg.II-South (M-212) dated 15-October-2015.	• Fee Rs.50,000/- **(25th; 26th & 31st March, 2020)** for each product. • Copies of initial registration letters & extensions for each product. • Copies of agreements b/w contract giver/acceptors. • Copies of DMLs of contract giver/acceptors. • Copies of Section approvals of contract manufacturers.
34.	Allerget Syrup 5mg/5ml Each 5ml contains: Loratadine ……5mg	Initial Reg. 7-Jul-01	Contract manufacturing permission granted from M/s Opal Labs, Karachi	

	(Reg. No.: 027212) **Manufacturer:** Opal Laboratories (Pvt.) Ltd., Karachi *Dy.No.10005 (R&I) dt: 5-May-20*	Brand Name Change 10-Jul-03 Validity **30-Jun-20**	vide letter No.F.3-1/08-Reg.II-South (M-212) dated 8-July-2008. Extension granted vide letter No.F.3-2/15-Reg.II (M-248) dated 18-Jun-15 till 30-Jun-15. Last extension granted vide letter No.F.3-4/15-Reg-II (M-250) dated 15th Oct-2015 till 30-Jun-20.	• Undertaking.
35.	Cefiget 200mg Tablets Each film-coated tablet contains: Cefixime (as trihydrate)……200mg (Reg. No.: 055746) **Manufacturer:** Opal Laboratories (Pvt.) Ltd., Karachi *Dy.No.10009 (R&I) dt: 5-May-20*	Initial Reg. 14-Apr-09 Validity **30-Jun-20**	Initially registered on contract manufacturing basis from M/s Opal Lab. Extension granted vide letter No.F.3-2/13-Reg-II (M-238) dt: 19-Sep-13 till 30-Jun-15. Last extension granted vide letter No.F.3-4/15-Reg-II (M-250) dated 15th Oct-2015 till 30-Jun-20.	
36.	Cefiget 400mg Capsules Each capsule contains: Cefixime (as trihydrate)….400mg (Reg. No.: 045118) **Manufacturer:** Opal Laboratories (Pvt.) Ltd., Karachi *Dy.No.10011 (R&I) dt: 5-May-20*	Initial Reg. 1-Feb-07 Validity **30-Jun-20**	Initially registered on contract manufacturing from M/s Opal Labs (Pvt.) Ltd., Karachi. Extension granted vide letter No.F.3-2/13-Reg-II (M-238) dt: 19-Sep-13 till 30-Jun-15. Last extension granted vide letter No.F.3-4/15-Reg-II (M-250) dated 15th Oct-2015 till 30-Jun-20.	
37.	Cefiget Powder for Oral Suspension 100mg/5ml Each reconstituted 5ml contains: Cefixime (as trihydrate).....100mg (Reg. No.: 045119) **Manufacturer:** Opal Laboratories (Pvt.) Ltd., Karachi *Dy.No.10012 (R&I) dt: 5-May-20*			
38.	Cefiget DS Powder for Oral Suspension 200mg/5ml Each reconstituted 5ml contains: Cefixime (as trihydrate).....200mg (Reg. No.: 045120) **Manufacturer:** Opal Laboratories (Pvt.) Ltd., Karachi *Dy.No.10013 (R&I) dt: 5-May-20*			
39.	Getofin 1g Injection (I.M.) Each vial contains: Ceftriaxone (as sodium).....1g (Reg. No: 024626) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore *Dy.No.10280 (R&I) dt: 7-May-20*	Initial Reg. 12-Mar-02 Validity **30-Jun-20**	Initially registered for manufacturing by M/s Bristol Myer Squibb, Karachi vide letter No.F.3-1/02-Reg-II (M-169) dated 12-03-2002. Change of manufacturer	

40.	Getofin 500mg Injection (IM) Each vial contains: Ceftriaxone (as sodium)……500mg (Reg. No: 024627) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore. *Dy.No.10278 (R&I) dt: 7-May-20*		from M/s Bristol Myer Squibb, Karachi to M/s Barrett Hodgson Pakistan (Pvt.) Ltd, Karachi vide letter No.F.3-8/02-R-II (M-176) dated 20-Jan-03. Change of manufacturer from M/s Barrett Hodgson Pakistan (Pvt.) Ltd to M/s NovaMed Pharmaceuticals, Lahore vide letter No.F.11-19/06 -Reg-II (North) dated 25th March, 2010. Extension granted vide letter No.F.3-2/13-Reg-II (M-238) dt: 19-Sep-13 till 30th June, 2015. Last extension granted vide letter No.F.3-4/15-Reg-II (M-250) dated 15th October, 2015 till 30th June, 2020.	
41.	Getofin 250mg Injection (I.M.) Each vial contains: Ceftriaxone (as sodium)……250mg (Reg. No: 024628) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore. *Dy.No.10276 (R&I) dt: 7-May-20*			
42.	Getofin 250mg Injection (I.V.) Each vial contains: Ceftriaxone (as sodium)… 250mg (Reg. No: 024629) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore. *Dy.No.10277 (R&I) dt: 7-May-20*			
43.	Alsef 250mg Injection (IM/IV) Each vials contains: Cefotaxime (as sodium).....250mg (Reg. No.: 019872) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore. *Dy.No.10006 (R&I) dt: 5-May-20*	Initial Reg. 4-Sep-96 Validity **30-Jun-20**	Grant of permission for contract manufacturing from M/s Bristol Myer Squibb, Karachi vide letter No.F.3-3/97-Reg.II dated 24-May-97 for 02 years. Extension in contract manufacturing granted vide letter No.F.3-11/99-Reg-II (M-149) dated 22nd January, 2000 for 01 year. Extension in contract manufacturing granted vide letter No.F.3-7/01-Reg-II (M-164) dated 15th Sep-2001 for 02 years. Extension in contract manufacturing & change of manufacturer from M/s Bristol Myer Squibb, Karachi to M/s Barrett Hodgson Pakistan (Pvt.) Ltd, Karachi vide letter No.F.3-8/02-R-II (M-176) dated 20-Jan-03 for 03 years.	
44.	Alsef 500mg Injection (I.M./I.V.) Each vials contains: Cefotaxime (as sodium).....500mg (Reg. No.: 019873) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore. *Dy.No.10007 (R&I) dt: 5-May-20*			
45.	Alsef 1gm Injection (I.M./I.V.) Each vials contains: Cefotaxime (as sodium).....1gm (Reg. No.: 019874) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore. *Dy.No.10008 (R&I) dt: 5-May-20*			
46.	Getofin 500mg Injection (I.V.) Each vial contains: Ceftriaxone (as sodium).....500mg (Reg. No.: 019875) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore. *Dy.No.10279 (R&I) dt: 7-May-20*			
47.	Getofin 1g Injection (I.V.) Each vial contains: Ceftriaxone (as sodium).....1g			

	(Reg. No.: 019876) **Manufacturer:** M/s NovaMed Pharmaceuticals(Pvt.) Ltd., Lahore. *Dy.No.10281 (R&I) dt: 7-May-20*		Extension in contract manufacturing & change of manufacturer from M/s Barrett Hodgson Pakistan (Pvt.) Ltd to M/s NovaMed Pharma, Lahore vide letter No.F.11-19/06-Reg-II (North) dated 25th March, 2010 till 30-6-10. Extension granted vide letter No.F.3-2/13-Reg-II (M-238) dt: 19-Sep-13 till 30th June, 2015. Last extension granted vide letter No.F.3-4/15-Reg-II (M-250) dated 15th October, 2015 till 30th June, 2020.	
48.	Lilac Syrup 67gm/100ml Each 5ml contains: Lactulose USP.....3.35g (together with other sugars such as galactose and lactose) (Reg. No.: 020590) **Manufacturer:** Herbion Pakistan (Pvt.) Ltd., Islamabad. *Dy.No.10275 (R&I) dt: 7-May-20*	Initial Reg. 23-Nov-97 Validity **30-Jun-20**	Permission of contract manufacturing from M/s Opal Labs., Karachi vide letter No.F.3-1/08-Reg-II -South (M-212) dated 8th July, 2008 till 30-6-2010. Extension of contract manufacturing granted vide letter No.F.3-2/15-Reg-II (M-248) dated 18th June, 2015 till 30-Jun-15. Extension of contract manufacturing granted vide letter No.F.3-4/15-Reg-II (M-250) dated 15th October, 2015 till 30th June, 2020. Change of manufacturer from M/s Opal Labs., to M/s Herbion Pakistan (Pvt.) Ltd., Islamabad vide letter No.F.3-5/18-Reg-II (M-282) (Misc.) dated 7th September, 2018 till 30th June, 2020 with the approval of fixation of following sources; ***Source of Lactulose:*** i. M/s Fresenius Kabi Austria GmbH. ii. M/s Danipharm A/S, Denmark.	

49.	Lactulose Solution 67gm/10mL Each 5mL contains: Lactulose USP……3.35g (Reg. No.: 000435-EX) **Manufacturer:** Herbion Pakistan (Pvt.) Ltd., Islamabad. *Dy.No.10274 (R&I) dt: 7-May-20*	Initial Reg. 30-Mar-06 Validity **30-Jun-20**	Extension granted vide letter No.F.3-2/13-Reg-II (M-238) dt: 19-Sep-13 till 30th June, 2015. Extension granted vide letter No.F.3-4/15-Reg-II (M-250) dt: 15th October, 2015 till 30th June, 2020. Change of contract manufacturer from M/s Opal Lab. to M/s Herbion Pakistan (Pvt.) Ltd., Islamabad vide letter No.F.3-5/18-Reg-II (M-282) (Misc.) dated 7th September, 2018 till 30th June, 2020 with the approval of fixation of following source; ***Source of Lactulose:*** i. M/s Fresenius Kabi Austria GmbH.	• Fee Rs.20,000/-(**20-Mar-20)** • Copies of initial registration letter & extensions. • Copy of agreement b/w contract giver/acceptor. • Copies of DMLs of contract giver/acceptor. • Copy of Syrup Section approval of contract manufacturer (No.F.6-3/14-Lic (M-234) dt: 27-3-14). • Undertaking.

Decision: The Registration Board decided as follows;

i. **Approved the request of firm for extension in contract manufacturing of products at Sr.No.33 to 38 from M/s Opal Laboratories (Pvt.) Ltd, Karachi on the same terms & conditions till 30-June-2025.**

ii. **Approved extension in contract manufacturing of products at Sr.No.39 to 47 from M/s NovaMed Pharmaceuticals (Pvt.) Ltd., Lahore on the same terms & conditions till 30-June-2025.**

iii. **Approved the request of firm for extension in contract manufacturing products at Sr.No.48 to 49 from M/s Opal Laboratories (Pvt.) Ltd., Karachi on the same terms & conditions till 30-June-2025.**

g. M/s ICI Pakistan Limited., S-33, Hawkes Bay Road, SITE, Karachi. *Dy.No.11679 (R&I) dt: 20-May-20*
Contract Manufacturer: M/s ICI Pakistan Limited, 32/2A, Phase-III, Industrial Estate, Hattar

50.	Wymox 250mg Capsules Each capsule contains: Amoxicillin (as Trihydrate)..250mg (USP Specification) Reg. No. 010015	Initial Reg. 13-Nov-88 Validity **30-Jun-20**	Transfer of registration from M/s Wyeth Labs.to M/s Cyanamid (Pakistan) Ltd., vide letter No.F.3-3/97-Reg.II dt:10-May-97. ***Products @ Sr.No.52–55:*** Transfer of registration from M/s Cyanamid Pakistan Ltd., to M/s Wyeth Pakistan Ltd., vide letter No.F.1-93/04-Reg.II(S) dated 7-May-07. ***Products @ Sr.No.50–51:*** Transfer of registration from M/s Cyanamid Pakistan Ltd., to M/s Wyeth Pakistan Ltd., vide letter No.F.1-93/04-Reg.II	• Fee Rs.50,000/-(**18-May-20)** for each product. • Copies of initial registration letters & extensions. • Copy of agreement b/w contract giver/acceptor. • Copies of DMLs of contract giver/acceptor. • Copies of Section approval. • Undertaking.
51.	Wymox 500mg Capsules Each capsule contains: Amoxicillin (as Trihydrate)…..500mg (USP Specification) Reg. No. 010016			
52.	Wymox Powder for Oral Suspension 125mg/5ml Each 5ml contains: Amoxicillin (as Trihydrate) … 125mg (USP Specification) Reg. No. 010017			
53.	Wymox 250mg Injection Each vial contains: Amoxicillin sodium equivalent to amoxicillin……250mg (BP Specification)	Initial Reg. 17-Nov-92 Validity		

	Reg. No. 013747	**30-Jun-20**	dated 17-Aug-10.	
54.	Wymox 500mg Injection Each vial contains: Amoxicillin sodium equivalent to amoxicillin…….500mg (BP Specification) Reg. No. 013748		Extension in contract manufacturing granted vide letter No.F.3-2/13-Reg.II (M-238) dated 4-Oct-13 till 30-Jun-15.	
55.	Wymox Powder for Oral Suspension 250mg/5ml Each 5ml contains: Amoxicillin (as Trihydrate) … 250mg (USP Specification) Reg. No. 012816	Initial Reg. 18-Aug-91 Validity **30-Jun-20**	Extension in contract manufacturing granted vide letter No.F.3-3/15-Reg.II (M-249) dated 10-Sep-15 till 30-Jun-20. Change of title of registration holder from M/s Wyeth Pakistan Ltd to M/s ICI Pakistan Ltd and change of manufacturer from M/s Macter Intl. to M/s Cirin Pharmaceutical vide letter No.F.3-4/18-Reg-II (M-281) (Misc.) dated 18-May-18. Change of title of contract manufacturer from M/s Cirin Pharmaceuticals (Pvt.) Ltd to M/s ICI Pakistan Ltd vide letter No.F.38-PRVC/20 (PR-I) dated 3-Mar-20.	
Decision:	**The Registration Board acceded to request of M/s ICI Pakistan Limited, Karachi for extension in contract manufacturing period of their above mentioned registered drugs from M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar on the same terms & conditions till 30th June, 2025.**			
h. M/s Amarant Pharma., 158-D, Tore Gadap Road, Super Highway, Karachi. *Dy.No.12130 (R&I) dt: 1-Jun-20* **Contract Manufacturer: M/s Medicaids Pakistan (Pvt.) Ltd, Karachi.**				
56.	Mutacef 1gm Dry Powder Injection Each vial Contains: Cefoperazone (as Sodium)…..500mg Sulbactam……500mg (Reg.No.070774)	Initial Reg. 18-Aug-11	Grant of permission for contract manufacturing from M/s Medicaids Pharmaceuticals vide letter No.F.3-2/11-Reg-II (M-231) dated 18-Aug-11 till 31-Aug-11. Extension of contract manufacturing granted vide letter No.F.3-2/13-Reg.II (M-238) dt:19-Sep-13 till 30-Jun-15. Last extension granted vide letter No.F.3-4/15-Reg.II (M-250) dated 16-	• Fee Rs.50,000/- **(1-Jun-20)** for each product. • Copies of initial registration letter & extensions. • Copy of agreement b/w contract giver/acceptor. • Copies of DMLs of contract giver/acceptor. • Copies of Section approvals.
57.	Mutacef 2gm Dry Powder Injection Each vial Contains: Cefoperazone (as Sodium)…..1000mg Sulbactam……1000mg (Reg.No.070775)	Validity **30-Jun-20**		
58.	Amtraxa 250mg Injection (IV) Each vial Contains: Ceftriaxone (as Sodium)……..250mg (Reg.No.070776)			
59.	Amtraxa 500mg Injection (IV) Each vial Contains: Ceftriaxone (as Sodium)……..500mg			

	(Reg.No.070777)		Oct-15 till 30-Jun-20.	
60.	Amtraxa 1g Injection (IV) Each vial Contains: Ceftriaxone (as Sodium)…….1g (Reg.No.070778)			
Decision:	**Registration Board acceded to request of M/s Amarant Pharma, Karachi for extension in contract manufacturing period of their above mentioned registered drugs from M/s Medicaids Pakistan (Pvt.) Ltd, Plot No.10, Sector 27, Korangi Industrial Area, Karachi on the same terms & conditions till 30th June, 2025.**			
i.	**M/s Abbott Laboratories (Pakistan) Ltd, Opp.Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.** *Dy.No.1333 (R&I) dt: 13-Feb-20* **Contract Manufacturer: M/s Highnoon Laboratories, Lahore.**			
61.	Thyronorm 50mcg Tablets Each tablet contains: Levothyroxin Sodium……50mcg (Thyroid Preparation) (Reg.No.076752)	Initial Reg. 24-Mar-15 Validity **31-05-2020**	Initially registered on contract manufacturing by M/s Highnoon Labs, Lahore vide letter No.F.3-1/15-Reg-II (M-247) dt: 24-Mar-15 till 30-Jun-15. Last extension granted vide letter No.F.3-2/15-Reg-II (M-248) dated 1-Jun-15 for five years (31-May-20).	• Fee Rs.10,000/- + Rs.40,000/- **(29-Jan-20)** for each product. • Copies of initial registration letter & extensions. • Copy of agreement b/w contract giver/acceptor. • Copies of DMLs of contract giver/acceptor. • Copy of Section approval.
62.	Thyronorm 125mcg Tablets Each tablet contains: Levothyroxin Sodium……125mcg (Thyroid Preparation) (Reg.No.076753)			
63.	Thyronorm 100mcg Tablets Each tablet contains: Levothyroxin Sodium……100mcg (Thyroid Preparation) (Reg.No.076754)			
64.	Thyronorm 75mcg Tablets Each tablet contains: Levothyroxin Sodium……75mcg (Thyroid Preparation) (Reg.No.076755)			
65.	Thyronorm 25mcg Tablets Each tablet contains: Levothyroxin Sodium……25mcg (Thyroid Preparation) (Reg.No.076756)			
Decision:	**The Registration Board acceded to request of M/s Abbott Laboratories (Pakistan) Ltd, Karachi for extension in contract manufacturing period of their above mentioned registered drugs from M/s Highnoon Laboratories Ltd, 17.5-Km Multan Road, Lahore on the same terms and conditions till 31st May, 2025.**			

Furthermore, Registration Board authorized its Chairman to grant extension in cases of contract manufacturing of already registered products if these are on same terms and conditions.

Case No.03: Change of Manufacturer of Bulk Import Source of Registered Drugs of M/s Martin Dow Limited, Karachi.

M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi has requested for the change of manufacturer of Bulk Import Source of their following registered drugs from M/s Cenexi SAS, France to M/s Siegfried Hameln GmbH, Germany. The details are as under;

Sr. No.	Name of Drug(s) with Composition & Reg.No.	Date of initial Reg. & Renewal Status	Existing Bulk Manufacturer	Proposed Bulk Manufacturer	Documents Submitted & Remarks (if any)
1.	Lidocaine 1% (2ml) Each ml solvent contains: Lidocaine Hydrochloride.....10mg (in form of lidocaine HCl monohydrate 10.66mg) (USP specification) (Reg.No.045355)	15-May-07 Renewal 22-Jun-16 & 15-Apr-19 (Fee Rs.20,000/-) for each product	Manufacturer: M/s Cenexi SAS, Fontenary, Sous Bois, France Marketing Authorization: M/s F.Hoffman La Roche, Basel, Switzerland.	M/s Siegfried Hameln GmbH, Langes Feld 13 31789 Hameln, Germany	➢ Fee Rs.100,000/-**(13-Dec-19)** for each product ➢ CTD dossiers for each product ➢ Copies of initial Reg.letters and last renewal status. ➢ Original/legalized of CoPP of M/s Siegfried Hameln GmbH, Germany. ➢ Original/legalized GMP of new manufacturing site. ➢ Original/legalized license of new manufacturing site ➢ Site Master File for new manufacturing site ➢ Agreement ➢ Termination letter from previous manufacturer. ➢ Undertaking.
2.	Lidocaine 1% (3.5ml) Each ml solvent contains: Lidocaine Hydrochloride…….10mg (in form of lidocaine HCl monohydrate 10.66mg) (USP specification) (Reg.No.045356)				
3.	Water for Injection (5ml) Each ampoule contains: Sterilized water for Injections…….5ml (USP specification) (Reg.No.045353)				
4.	Water for Injection (10ml) Each ampoule contains: Sterilized water for Injections …….10ml (USP specification) (Reg.No.045354)				

Remarks:

Firm not provided documents pertaining to Drug Substance part in Module 3 while documents pertaining to Drug Product part was complete. The Reason/Justification provided was *"being diluents (of Ceftriaxone injection) manufacturer performed all studies on FPP rather than Drug Substance. Hence DMF related part was not included"*

Further, the title/name of firm has also been changed from M/s Martin Dow Pharmaceuticals Limited to M/s Martin Dow Limited (DML No.000267-Formulation) vide Licensing Division's letter No.F.6-4/2014-Lic (M-235) dated 30th June, 2014 (Manufacturing site remains the same) and the firm has also requested for the change of title /name of firm for the above mentioned products.

Decision: Registration Board deferred for provision of information regarding quality control release of the products.

Case No. 04: Request for Extension of Permission of Bulk Import & Local Repacking of Drug (s) of M/s. Atco Laboratories, Karachi.

M/s. Atco Laboratories Ltd; Karachi has requested for extension of permission of bulk import and local repacking of their following already registered products:-

Sr. No.	Name of Drug(s) with existing formulation	Reg. No.	Registration history
1.	Hirudoid Cream 100gm Each 100gm contains:- Mucopolysacchride Polysulfuric acid ester … 0.3gm	014995	The firm was granted previous extension of permission for bulk import & local repacking on 13-12-2012 which was valid till 5 years. The approved manufacturer was Sankyo Pharma GmBH, Germany.
2.	Hirudoid Gel 100gm Each 100gm contains:- Mucopolysacchride Polysulfuric acid ester … 0.3gm	017481	-do-

They have further stated that have equipped their facility to manufacture the above product and the manufacturer did not allow them to manufacture these products locally in Pakistan. They have therefore, requested to extend the permission of bulk import and local repacking for further 5 years.

The management of the firm has provided following documents:-

i. Original challans of fee of Rs.100,000/- per product for this purpose.
ii. Copies of initial letters of registration and subsequent permission letters.

The Committee in its 3rd meeting deferred the case for provision of complete documents as per approved SOPs and placement before Registration Board. Now the firm has provided original & legalized CoPP and requested for extension of bulk import and local repacking permission as requested above.

As per CoPP provided by the firm for the above products following information has been retrieved:-

S.No.	Name of active ingredient	Name of Manufacturer	Product License Holder
1	100 g ointment contains:- 300mg Chondroitin polysulfate from Bovine tracheal cartilage 300 gm corresp. 25000 U* *Units determined by means of the activated partial thromboplastin time (APTT).	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany.	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany
2.	100 g Gel contains:- 300 mg Chondroitin polysulfate from Bovine tracheal cartilage 300 gm corresp. 25000 U* *Units determined by means of the activated partial thromboplastin time (APTT).	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany.	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany.

The manufacturer is Mobilat Productions GmbH, Germany.

Decision of M-281

Registration Board in its 281st meeting deferred the case and advised the firm to confirm whether the composition mentioned in the initial registration letter and composition mentioned in the CoPP is same.

The firm has now submitted original signed clarification issued by their principal manufacturer M/s Mobilat Produktions GmbH, Germany, clarifying that the composition mentioned in the

initial registration certificate is same as mentioned in certificate of pharmaceutical product with scientific rationale, stated as under:

The active substance mucopolysaccharide Polysulfate has different names, such as Mucopolysaccharide polysulphuric acid ester, Chondroitin polysulfate, Glycosaminoglycan Polysulfate, however the stand all for the same active ingredient that is manufactured based on bovine tracheal cartilage. Mucopolysaccharide Polysulfate is the proprietary name for the active substance. The systematic chemical name (IUPAC) is 2-acetamido-2-deoxy-D-galacto-D-glucurnoglycan-polysulfate sodium. Depending on the Health Authorities and Drug application, one of the above names are indicated in the drug registration and thus the CoPPs.

As per evaluation of the dossier/documents submitted by the firm, certain clarifications were sought from the firm. Detail of queries along with firm's response has been placed below:

Sr.#	Queries	Response/ Documents Provided By M/s Atco, Karachi
1.	Clarification is required regarding dosage form, as the registered product is "cream" whereas CoPP states "ointment".	Actually, the product name is "Hirudoid Cream", we have already been argued to our principal manufacturer to provide CoPP mentioning dosage form as cream but, they denied by giving reason that: "We cannot provide CPP indicating wording a cream instead of ointment. We hope you understand our situation and you may advice to compare the formulation. Sorry for inconvenient may cause you.
2.	Clarification is required regarding name of manufacturer	The firm has informed that they have already got approval for change of name of manufacturer from Daiichi Sankyo GmbH, Germany to Mobilat Produktions GmbH, Germany for Hirudoid Cream and Hirudoid Gel vide letter dated 16-11-2011

Decision of M-287:

Registration Board deferred the case due to following reasons:

- **i.** Submission of rational justification regarding dosage form of "Hirudoid Cream" mentioned on CoPP.
- **ii.** Clarification regarding Marketing Authorization/License Holder & manufacturer of above mentioned products.

Updated Status:

Now, the firm has submitted clarification letter from principal manufacturer of Hrudoid ointment/gel i.e Mobilat Produktions GmbH, Germany (original/legalized) clarifying that:

a) Hirudoid cream as approved in Pakistan is identical to Hirudoid ointment as approved in Germany and Hirudoid cream as approved in Switzerland
b) There is no change in Marketing Authorization Holder in Germany, STADA GmbH, Germany.
c) The provided CoPP of Hirudoid cream is issued from regulatory authority of Switzerland (original/legalized) which is DRAP defined reference authority. In Switzerland the marketing authorization holder and product owner is Medinova AG but in Germany it is STADA GmbH.

The MAH/Product license holder and manufacturer is clarified as under:

Sr. No.	Reg. No.	Product name and composition	Name of Manufacturer	Product License Holder
1	014995	Hrudoid cream Each 100g contains: Mucopolysaccharide polysulphuric acid ester…….0.3g	.M/s Mobilat Produktions GmbhH, Germany	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany
2.	017481	Hirudoid gel Each 100g contains: Mucopolysaccharide polysulphate …….300mg	M/s Mobilat Produktions GmbhH, Germany	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany.

It is submitted that approval of above mentioned manufacturer was granted on 16th November 2011 vide Letter No. F1-43/2010-Reg-I (Vol-I) while manufacturer mentioned on last approval letter for extension in permission (for bulk import and local repacking) was rendered as M/s Sankyo pharma GmbH, Germany. Firm did not apply for correction considering aforementioned approval as permission for extension in permission of bulk import and local repacking, merely. Since they got separate approval for name change of manufacturer.

Decision of 291st Meeting:
Registration Board deferred the request of firm for comparison of formulations of Hirudoid Ointment (approved in Germany) and Hirudoid Cream (approved in Switzerland)**.**

Updated Status:

The firm has submitted legalized original signed declaration letter from Product License Holder (STADA, Germany) confirming that it is a product with same formulation and same manufacturing process but different brand names as Hirudoid **Salbe/Ointment** (approved in Germany) and Hirudoid Cream (approved in Switzerland) and **Salbe** is a German word that can be inconsistently translated as cream or ointment.
Decision 293rd meeting: Registration Board deferred the request of firm for further deliberation.

Now the firm has submitted comparative table for comparison of formulations of Hirudoid Ointment (approved in Germany) and Hirudoid Cream (approved in Switzerland) as under:

Formulation Approved in Germany (Hirudoid Salbe 300 mg/100 g: Salbe Ointment)	**Formulation Approved in Switzerland (Hirudoid Cream)**	**Formulation Approved in Pakistan (Hirudoid Cream)**
100 g Hirudoid Salbe 300mg/100g contain:	Unit formula of 100 g	Unit formula of 100 g
Mucopolysaccharide polysulphate 300.0 mg	Mucopolysaccharide polysulphate 300mg	Mucopolysaccharide polysulphate 0.300 g (300mg)
Glycerol 85% 14.75 g/100g	Glycerol 85% 14.75 g/100g	Glycerol 85% 14.75 g/100g
Stearic acid 8.60 g/100g	Stearic acid 8.60 g/100 g	Stearic acid 8.60 g/100g
Wool wax alcohol ointment 7.50 g/100g	Wool wax alcohol ointment 7.50 g/100g	Wool wax alcohol ointment 7.50 g/100g
Emulsifying Cetostearyl alcohol 3.10 g/100g	Emulsifying Cetostearyl alcohol 3.10 g/100g	Emulsifying Cetostearyl alcohol 3.10 g/100g
Myristyl alcohol 3.10g/100g	Myristyl alcohol 3.10 g/100g	Myristyl alcohol 3.10 g/100g
Isopropyl alcohol 1.00 g/100g	Isopropyl alcohol 1.00 g/100g	Isopropyl alcohol 1.00 g/100g
Potassium hydroxide 0.70 g/100g	Potassium hydroxide 0.70 g/100 g	Potassium hydroxide 0.70 g/100g
Methyl parahydroxybenzoate 0.16 g/100g	Methyl parahydroxybenzoate 0.16g/100 g	Methyl parahydroxybenzoate 0.16 g/100g
Thymol 0.15 g/100g	Thymol 0.15 g/100g	Thymol 0.15 g/100g
Propyl parahydroxybenzoate 0.04 g /100g	Propyl parahydroxy benzoate 0.04 g/100g	Propyl parahydroxybenzoate 0.04 g/100g
Purified water 60.60 g/100g	Purified water 60.60 g/100g	Purified water 60.60 g/100g

Decision: Registration Board approved the request of firm for extension of permission for bulk import (manufactured by M/s Mobilat Produktions GmbhH, Germany) for period (13.12.2017 to 12.12.2022) (and local repacking for the period of five years, for above mentioned products.

Case No.05: Request for grant of contract manufacturing permission to M/s Helix Pharma (Pvt.) Ltd, Karachi

M/s Helix Pharma (Pvt.) Ltd, Karachi has requested for grant of permission for contract manufacturing of their following registered products from M/s Opal Laboratories (Pvt) Ltd, Karachi.

S.#	Reg. No.	Name of Product with Composition	Initial date of registration/ last date of renewal	Demanded FPP specifications	Remarks
1.	028931	Tycef Capsule Each capsule contains: Cefixime……..400mg	13th August 2002 02 August 2017	JP	Firm performed CDP in comparison to Cebosh capsule 400mg in lieu of innovator's product i.e Suprax capsule.
2.	028165	Tycef Paediatric Suspension Each 5ml contains: Cefixime Trihydrate eq. to cefixime …….100mg	10th August 2002 02 August 2017	USP	Comparative study was performed against Vencef 100mg suspension by Opal Lab in lieu of innovator's product Suprax 100mg oral suspension
3.	048552	Tycef DS Suspension Each 5ml contains: Cefixime Trihydrate eq. to cefixime…..200mg	20th March 2008 19th March 2018	USP	Comparative study was performed against Vencef DS suspension by Opal Lab in lieu of innovator's product Suprax 200mg oral suspension

The reason provided by firm for proposed change is business feasibility considering the low volumes and turnover with low margins of the said product and excess capacity/manufacturing facility at M/s Opal Laboratories, Karachi.

In this regard, the firm has submitted the following documents;

i. Application on Form-F along-with Fee of Rs.50,000/- each product (dated 15-Oct-19)
ii. Copies of Initial Registration and renewal status.
    Contract manufacturing agreement between M/s Helix Pharma (Pvt.) Ltd, Karachi and M/s Opal Laboratories (Pvt) Ltd, Karachi dated 24.07.2019
iii. Section approval letter by CLB dated 09th April, 2014 (M/s Opal Laboratories (Pvt.) Ltd, Karachi)
iv. Last GMP inspection report of M/s Opal Laboratories (Pvt.) Ltd, Karachi dated 19th September 2019.

Decision of 293rd meeting: Registration Board deferred the request of firm for status of cephalosporin section (capsule/dry suspension) of M/s Helix Pharma (Pvt.) Ltd, Karachi.

Updated Submission:

The firm has submitted clarification regarding Capsule/dry suspension cephalosporin section which was approved in 13th June 2002 vide letter No. F.2-20/84-Lic Vol-II (M-192). Firm has initiated a major renovation/up gradation project, revised lay out plan has been approved by Licensing division dated 22nd July, 2019 vide letter No. F.2-20/1984-Lic (Vol-IV). Considering that current renovation/up gradation project firm's business viability of cephalosporin area complemented with available excess capacity at manufacturing facility of M/s Opal Laboratories, Karachi for interim period of 03 years.

Decision: Registration Board deferred the request of M/s Helix Pharma (Pvt.) Ltd, Karachi for manufacturing of their above mentioned products on contract manufacturing basis from M/s Opal Laboratories (Pvt.) Ltd, Karachi for submission of renovation plan alongwith clear timelines and undertaking.

Case No.06: Request for change of manufacturing site of registered product of M/s ICI Pakistan Ltd, S-33, Hawkes Bay Road, S.I.T.E., Karachi.

M/s ICI Pakistan Ltd, Karachi has requested for change of manufacturing site of their following registered products from M/s Pfizer Pakistan Ltd, Karachi to their own site.

S.#	Reg.No.	Name of Product with Composition	Remarks
1	097003	Citralka Liquid Each 5ml contains: Disodium Hydrogen Citrate…1.315g (As per innovator's specifications)	Stability data (both accelerated and real time studies) submitted for 6 months. Being titrimetric analytical method, chromatograms are not applicable.

In this regard, the firm has submitted the following documents;

i. Application on Form-5F along-with Fee of Rs.20,000/- (Dated 20-Nov-19)
ii. Copies of Initial Registration letter dated 28th June, 2019.
iii. Evidence of Section approval by CLB dated 28th June, 2019.

Decision: Registration Board deferred for evaluation of registration application for completetion of documentsa s per Form5F.

Case No.07: Request for change of Contract Manufacturer of Registered Product of M/s Bayer Pakistan (Pvt.) Ltd, Karachi.

M/s. Bayer Pakistan (Pvt.) Ltd, Plot No.23, Sector 22, Korangi, Karachi has requested for permission of change in contract manufacturer from M/s Zafa Pharmaceuticals, Karachi to **M/s Nabiqasim Industries (Pvt.) Ltd, 17/24, Korangi Industrial Area, Karachi DML No.000105 (Formulation)**. The details are as under;

Sr.No.	Reg. No.	Name of drug (s) with composition	Date of i. Initial Reg. ii. Renewal Status	Previous Manufacturer
1.	023008	Baydal Syrup Each 5ml contains: Cetirizine Dihydrochloride…….5mg (BP Specification)	i. 29-Apr-99 ii.10-Jan-19 Change of Brand Name 10-Oct-07	M/s Zafa Pharmaceuticals, Karachi. **(Validity: 30-June-2020)**

In this regard, the firm has submitted the following documents;

i. Applications on Form-5F along-with Fee of Rs.50,000/- **(Date: 27-Jun-19)**
ii. Copies of initial registration letter & renewal status.
iii. Copy of valid DML **(dated 12-July-14)** of M/s Nabiqasim Industries, Karachi.
iv. Copy of agreement b/w M/s Bayer Pakistan (Pvt.) Ltd & M/s Nabiqasim Industries, Karachi **dated 24-April-2019.**
v. Evidence of Section approval of Liquid/Syrup of M/s Nabiqasim.
vi. Last inspection report of M/s Nabiqasim Industries **(Date: 23-July-19).**
vii. Undertakings.

Applied specification was BP while stability protocol submitted by M/s Nabiqasim Industries, Karachi was in accordance to manufacturer's specification.

Decision 292nd meeting: Registration Board deferred the request of firm for clarification regarding proposed specifications and stability protocol.

Updated Submission:

Firm has clarified proposed FPP specification i.e. BP and also submitted stability protocol in line with BP specification.

Decision: Registration Board deferred the request for submission of documents as per Form-5F.

Case No.08: Request for grant of contract manufacturing permission to M/s TG pharma Karachi.

M/s TG Pharma, Karachi has requested for grant of permission for contract manufacturing of their following registered products from M/s Seraph pharmaceutical Islamabad

S.#	Reg. No.	Name of Product with Composition	Date of registration/ last date of renewal	Remarks
1	036544	Rogofin 1g injection IM/IV Each vial contain Ceftriaxone sodium eq. to ceftriaxone……1000mg (USP specification)	14th May 2010 (transferred to the name of M/s TG pharma from M/s unicorn pharma Karachi) **Renewal status not confirmed**	Comparative study performed against Rocephin injection
2	036543	Rogofin 500mg injection IM/IV Each vial contain Ceftriaxone sodium eq. to ceftriaxone……500mg (USP specification)	14th May 2010 (transferred to the name of M/s TG pharma from M/s unicorn pharma Karachi) **Renewal status not confirmed**	Comparative study performed against Rocephin injection
3	044261	Rogofin 250mg injection IM/IV Each vial contain Ceftriaxone sodium eq. to ceftriaxone……250mg (USP specification)	14th May 2010 (transferred to the name of M/s TG pharma from M/s unicorn pharma Karachi) **Renewal status not confirmed**	Comparative study performed against Rocephin injection
4	036504	Entaris 400mg capsule Each capsule contain Cefixime as trihydrate eq to cefixime…….400mg (JP specification)	14th May 2010 (transferred to the name of M/s TG pharma from M/s unicorn pharma Karachi) **Renewal status not confirmed**	Comparative dissolution study performed against Cefspan capsule 400mg

The firm has submitted the following documents;

i. Application on Form-F along-with Fee of Rs.50,000/- each product (04-Dec-19)
ii. Copies of Registration letter and renewal status not confirmed
iii. Contract manufacturing agreement between M/s TG Pharma, Karachi and M/s Seraph pharmaceutical Islamabad dated 14.10.2019.
i. Section approval letter by CLB dated 12thJune, 2017 (M/s Seraph Pharma, Islamabad)
ii. Last GMP inspection report of M/s Seraph Pharma, Islamabad dated 11th July 2019.
iii. Approval of regularization of layout plan by CLB dated 21st December 2018
iv. Revocation of suspension order of M/s TG Pharma by CLB dated 20th December 2018

Decision 293rd meeting: Registration Board deferred the request of firm for renewal status of above mentioned products and reason for request of contract manufacturing.

Updated Submission:

Firm is working on renovation according to new layout plan as approved by licensing division. In order to prevent shortage of already registered products in market firm requested to grant contract manufacturing permission for stipulated time. Moreover, firm undertake take they will not seek extension of contract manufacturing permission.

Regarding delay in renewal fee submission it is submitted that father of MD T.G pharma was sick, he was unable to give time to the factory, he directed regulatory manager to submit the renewal applications of product but he did not submitted renewal fee without informing firm.
It is submitted that firm's manufacturing is stop due to renovation reason if the permission will not be granted to us their business and employees lives will be on stake.

The firm requested to grant registration of above mentioned products on contract manufacturing basis as fresh registration and neglect the previous renewal application.

CLB in 273rd meeting decided to cancel the DML of the firm under section 41 of Drug Act 1976, read with Rule 12 of the Drug (L,R&A) Rules,1976 due to non compliance of Rule 16 and 19 of the Drug (L,R&A) Rules,1976, vide letter No. F.8-5/2019-QA(M-273-CLB) dated 6th February 2020.

Decision: Registration Board rejected the request of firm for contract manufacturing permission due to invalid/ cancellation of DML by CLB of M/s TG Pharma, Karachi.

Case No.09: Standardization of formulation in accordance with Innovator's Product of Registered Drug of M/s Barrett Hodgson Pakistan (Pvt.) Ltd, Karachi.

(Dy.No.9410 (R&I) Dated: 24-Jun-19)

The request of M/s Barrett Hodgson Pakistan (Pvt.) Ltd, F/423, SITE, Karachi was discussed in 291st meeting of Registration Board regarding standardization of formulation of following registered drug in accordance with the innovator's specification. The details are as under;

Sr. No.	Reg. No.	Name of drug with Existing formulation & Specification	Name of drug with Proposed formulation & Specification
I	II	III	IV
1.	067693	Clotnil Plus Tablet 75mg+75mg Each tablet contains: Clopidogrel bisulphate equivalent to Clopidogrel……..75mg Aspirin…….75mg (Manufacturer's Specification)	Clotnil Plus Tablet 75mg+75mg Each film coated bilayer tablet contains: Clopidogrel bisulphate equivalent to Clopidogrel USP……..75mg Aspirin USP…….75mg (Innovator's Specification)

In this regard, the firm has submitted the following documents;

i. Application along-with Fee of Rs.5,000/- **(dated: 3-Jun-2019).**
ii. Copy of Reg. letter **(DoR: 15-Apr-11)** & Renewal Status **(dated: 31-Dec-15).**
iii. Evidence of TGA Australia approval.
iv. Undertaking.

Decision of 291st Meeting:

Registration Board deferred the request of firm for confirmation of innovator's formulation whether bi-layered (tablet within tablet) or single layered**.**

Updated status:

The firm has requested to approve their request as per innovator's formulation i.e. "film-coated bilayer tablet". In this regard, the firm has also submitted the following innovator's products;

"DuoCover" is presented as film coated bilayer tablet containing two active substances i.e. Clopidogrel bisulfate and Acetylsalicylic acid DuoCover (**EMA approved formulation**).

Decision 293rd Meeting:

Registration Board deferred the request of firm for confirmation of innovator's / RRA approved formulation.

Fresh Submission:

The firm has submitted the EMA EPAR (Public Assessment Report) of Duoplavin of Sanofi Aventis formerly applied as DuoCover showing that the product is film coated bilayer tablet. Furthermore from below mentioned link it can also be confirmed that the product "Duoplavin" has valid authorization throughout EU.

https://www.ema.europa.eu/en/medicines/human/EPAR/duoplavin-0#authorization-details-section

Decision: Registration Board approved request of firm for standardization of formulation of product Clotnil Plus Tablet 75mg+75mg (Reg.No.067693) as proposed vide column-IV above, in line with the innovator product Coplavix.

Case No.10: Change of Contract Manufacturer of Registered Drugs of M/s Bosch Pharmaceuticals (Pvt.) Ltd Karachi from own Plant-I to Plant-II.

Dy.No.4591 (R&I) dated: 16-Mar-20.

M/s Bosch Pharmaceuticals (Pvt.) Ltd, **(Plant-I)** 221, Sector 23, Korangi Industrial Area, Karachi has requested for manufacturing of their following registered products from **Plant-II** i.e. Plot No.209, Sector 23, Korangi Industrial Area, Karachi. The details are as under;

Sr. No.	Name of Drug(s) with Composition & Reg.No.	Date of initial Reg. & Renewal Status	Existing Address of Manufacturer	Proposed Address of Manufacturer	Documents Submitted & Remarks (if any)
1.	B Tig 50mg Injection Each vial contains: Tigecycline……..50mg As per Innovator's Specification (Reg.No.084761)	18-Sep-17	M/s Bosch Pharmaceuticals (Pvt.) Ltd, **(Plant-I)** Plot No.221, Sector 23, Korangi Industrial Area, Karachi	M/s Bosch Pharmaceuticals (Pvt.) Ltd. **Plant-II:** Plot No.209, Sector 23, Korangi Industrial Area, Karachi	➢ Fee of Rs.50,000/- for each product. ➢ CTD dossier for each product. ➢ Copies of initial registration letters & last renewal status for each product. ➢ Copies of Section approvals. ➢ Contract manufacturing agreement ➢ Undertaking.
2.	Zezot 500mg Injection Each vial contains: Azithromycin (as Dihydrate) ……..…..500mg Manufacturer's specification (Reg.No.055017)	16-Jan-09 28-Nov-16			
3.	Q-Pro 30mg Injection Each vial contains: Lansoprazole……30mg USP specification (Reg.No.055018)	16-Jan-09 28-May-18			
4.	Somezole20mg Injection Each lyophilized vial contains: Esomeprazole (as Sodium) ……..20mg Manufacturer's specification (Reg.No.047446)	19-Jan-08 12-Oct-17			
5.	Somezole40mg Injection Each lyophilized vial contains: Esomeprazole (as Sodium) …….40mg Manufacturer's specification Reg.No.045386)	13-Jun-07 21-Sep-16			
6.	Ticozid 200mg Injection Each vial contains: Teicoplanin……200mg Manufacturer's specification (Reg.No.050514)	27-Aug-08 5-Apr-18			
7.	Ticozid 400mg Injection Each vial contains: Teicoplanin……400mg Manufacturer's specification				

	(Reg.No.050515)				
8.	Vinjec 500mg Injection Each vial contains: Vancomycin HCl 525mg eq.to Vincomycin ….500mg (Reg.No.024114)	7-Oct-02 22-May-17			
9.	Vinjec 1000mg Injection Each vial contains: Vancomycin HCl 1050mg eq.to Vincomycin …….1000mg (Reg.No.024115)				
10.	Zentro 40mg Injection Each vial contains: Pantoprazole Sodium 44.39mg eq.to Pantoprazole …...40mg Manufacturer's specification (Reg.No.045388)	12-Jun-07 21-Sep-16			
11.	Omezole 40mg Injection Each vial contains: Omeprazole (as Sodium) …...40mg (Reg.No.024245)	7-May-02 21-Sep-16			

Remarks:

1. Validated analytical method of FPP was **not provided**.
2. Stability data (accelerated and real time) of only initial/0 month of FPP was submitted only; however, undertaking was submitted regarding submission of rest of data both accelerated and real time shall be submitted upon completion.
3. Impurity studies were **not performed** by FPP manufacturer (neither of Drug substance nor FPP)
4. Description regarding container closure system/suitability studies was **not provided.**

Decision: Registration Board deferred the request of firm for provision of above mentioned documents.

Case No. 11: Registration of Drug(s) of M/s Focus &Rulz Pharmaceuticals (Pvt) Ltd, Plot No.44-Industrial Triangle, Kahuta Road, Islamabad for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	**Submitted Documents**
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from renewal of DML dated 15th &17th January,2019
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificated based on evaluation inspection dated 17-01-2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	**Name of Drug(s) with composition**	**Generic/RRA Status**	**Diary No. date & Remarks.**
I	**II**	**III**	**IV**
1.	Barcadin Syrup Each 5ml contains: Codeine Phosphate ……11.95mg Diphenhydramine HCl….13.5mg Menthol……1.1mg Sodium Cirtrate ……54.4mg Excipients……. q.s In a flavored syrup base.	Me too/ RRA status not confirmed	Dy. No .1668 /-PE&R-(EFD) 13.05.2020. Rs.20000/- dated 17.02.2020 Rs.20000/- dated 05.05.2020 Rs.10000/- dated 07-05-2020
2.	Neuromine Forte Each film coated tablet contains: Thiamine Mononitrate ……..10mg Pyridoxine HCl…….3mg Cyanocobalamin……..15mcg Niacinamide……..45mg Calcium Pentothenate……5mg	Me too/ RRA status not confirmed	Dy. No.1669 /-PE&R-(EFD) 13.05.2020 Rs.20000/- dated 14.04.2020 Rs.30000/- dated 23.04.2020

The firm has submitted export order from Afghanistan.

Decision: Registration Board decided as follows:

i. **Approved the request of firm for registration of product mentioned at Sr. No. 2 for export purpose only**

ii. **Deferred product at Sr. No. 1 for confirmation of psychotropic section since formulation contain Codeine phosphate.**

Case No. 12: Registration of Drug(s) of M/s Swiss Pharmaceuticals (Pvt) Ltd, A-159, S.I.T.E Super Highway Karachi for export purpose.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from renewal of DML dated 30-12-2014 .
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection report dated 18-10-2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Tromodol 100mg Capsule Each capsule contains: Tramadol HCl……..100mg	Me too/ RRA status not confirmed	Dy. No 1670 /-PE&R-(EFD) 13.05.2020 Rs.50000/- dated 03.01.2020

The firm has submitted export order from Nigeria.

Decision: Registration Board approved above mentioned product of M/s Swiss Pharmaceuticals (Pvt) Ltd, A-159, S.I.T.E Super Highway Karachi for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No. 13: Registration of Drug(s) of M/s Mafins Pharmaceuticals, A-5,S.I.T.E Super highway Industrial Area, Karachi for export purpose.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified CLB letter No.2-10/2009-Lic dated 26.06.09
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from routine GMP inspection 05.10.17
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Tramol 100mg capsule Each capsule contains: Tramadol HCl….100mg	Me too/ RRA status not confirmed	Dy. No.1675/-PE&R-(EFD) 15.05.2020 Rs.30000/- dated 03.01.2020

The Firm has submitted the Purchase order from Kenya.

Decision: Registration Board approved above mentioned product of M/s Mafins Pharmaceuticals, A-5,S.I.T.E Super highway Industrial Area, Karachi for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th

meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No. 14: Registration of Drug(s) of M/s Danas Pharmaceuticals (Pvt.) Ltd, 312 Industrial Triangle, Kahuta Road, Islamabad for export purpose.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from 13-05-2005 DML dated 30-12-2014
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificated based on evaluation inspection dated 03-10-2017
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided.

Detail of the product is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Ferrate-FA tablet Each film coated table contains: Ferrous Fumarate …..200mg Folic Acid…….0.25mg	Me too/ RRA status not confirmed	Dy. No.1676/-PE&R-(EFD) 15.05.2020 Rs.20000/- dated 30.04.2020 Rs.30000/- dated 04.05 .2020

The firm has submitted export order from Senegal.

Decision: Registration Board approved above mentioned product of M/s Danas Pharmaceuticals (Pvt.) Ltd, 312 Industrial Triangle, Kahuta Road, Islamabad for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No. 15: Registration of Drug(s) of M/s Sigma Pharma (Pvt.) Ltd, Plot No.E-50, NWIZ Port Qasim Karachi for export purpose.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided. Approval of relevant section verified from Licensing Section letter F.No.6-6/2014-Lic dated 17.10.2014
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificated based on evaluation inspection dated 18-9-2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Tred Tablet Each film coated tablet contains: Tramadol HCl…..150mg	Me too/ RRA status not confirmed	Dy. No.1677 /-PE&R-(EFD) 13.05.2020 Rs.50000/- dated 13.03.2020

The firm has submitted purchase order from South Africa.

Decision: **Registration Board approved above mentioned product of M/s Sigma Pharma (Pvt.) Ltd, Plot No.E-50, NWIZ Port Qasim Karachi for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.**

Case No.16 : Registration of Drug(s) for Export Purpose Only of M/s. Don Valley Pharmaceuticals (Pvt.) Ltd, 31-Km, Main Ferozpur Road, Lahore

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	**DV-Clonaz 0.5mg Tablet** Each tablet contains: Clonazepam……..…..0.5mg	**Clonazil tablet** by M/s English Pharma. **(Reg. # 068006)**	Dy. No.347/19-EFD 25.02.2019. **Section approval not confirmed.**
2.	**DV-Clonaz 1mg Tablet** Each tablet contains: Clonazepam…….……..1mg	**Curo tablet** by M/s Wilshire Pharma. **(Reg. # 065700)**	Dy. No.348/19-EFD 25.02.2019. **Section approval not confirmed.**

Decision 26TH PRVC: The Committee deferred the products for clarification of manufacturing facility i.e., "Narcotic (Tablet) Section".

Now the concerned section i.e Tablet Narcotic/psychotropic has been approved by CLB vide letter no. F1-1/95-Lic (Vol-IV) dated 10th April 2020

Decision 40th PRVC: The Committee referred above mentioned products to Registration Board as Chairman Registration Board is not authorized for Narcotic and Psychotropic drugs approval.

Decision: **Registration Board approved above mentioned products of M/s. Don Valley Pharmaceuticals (Pvt.) Ltd, 31-Km, Main Ferozpur Road, Lahore for export registration. The firm shall comply with all rules and regulation specified for export of controlled substances.**

Case No.17: Registration of Drug(s) of M/s Biogen Pharma, 8-KM, Chakbeli Road, Rawat for Export Purpose Only (for veterinary use)

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML renewed dated 19.06.2013 (Approval of relevant sections verified from Licensing Division letters No. F.1-4/2007-Lic-(Vol-I) dated 09.07.2015 **Veterinary liquid injection vial**
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection dated 26.10.2018 rated as satisfactory
Undertakings that the applied product is exclusively for	Provided

export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	

Detail of the product is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Formicgen 60% Solution Each ml contains: Formic acid……600mg	Me too status /RRA approval status not available Purchase order from Afghanistan	Dy. No.666/2019-PE&R-(EFD) 02.07.2019. Rs.50000/- dated 25.06.2019
2.	Bekchlogen 5% Solution Each ml contains: Benzalkonium Chloride……..50mg	Me too status /RRA approval status not available Purchase order from Afghanistan	Dy. No.667/2019-PE&R-(EFD) 02.07.2019. Rs.50000/- dated 25.06.2019

Decision of 291st meeting of Registration Board:

Registration Board deferred above mentioned products of M/s Biogen Pharma, 8-KM, Chakbeli Road, Rawat for evidence of approval of applied formulations in importing country.

Now, the firm has clarified that applied formulations Formicgen 60% Solution and Bekchlogen 5% Solution intended to be used as an insecticide to kill bee mites. Either used as Fumigant or applied directly on bee hives/bee path.

Applied formulation is available in China for the same purpose.

Decision 293rd meeting:

Registration Board deferred the request for clarification from the firm about indications of above mentioned products.

Now the firm has submitted detail regarding indication of above mentioned formulation as under:

Benzalkonium Chloride is primarily used as a preservative and antimicrobial agent. It works by killing microorganisms and inhibiting their further growth.

Formic acid is commonly used as preservative and antibacterial agent in livestock feed. It is widely used to preserve winter feed for cattle.

Decision: Registration Board deferred above mentioned products for further deliberation.

Case No.18: Registration of Drug(s) of M/s Scilife Pharmaceuticals, (Pvt.) Ltd. Plot No. FD-57/58-A2, Kornagi Creek Industrial Park (KCIP) Karachi for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided. Approval of relevant section verified from Licensing Section letter F.No.2-4/2011-Lic dated 01.6.2016 (Page.691/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection dated 24.04.19
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks
I	II	III	IV
1.	Scifol 400 mcg tablet Each film coated tablet contains: L-Methyl Folate….400mcg	Me too status not confirmed	Dy.No.1426/19-EFD (PE&R) dated 20-01-2020 Rs. 20,000/- dated 31.03.2020 (pages 680-681/C)

Decision 39th PRVC: The Committee deferred the request of the firm for registration of above mentioned product of M/s Scilife Pharmaceuticals, (Pvt) Ltd. Plot No. FD-57/58-A2, Kornagi Creek Industrial Park (KCIP) Karachi for me too status of applied formulation

Now, the firm has submitted differential fee of Rs 30,000/- dated 20.05.2020 alongwith Form-5D and purchase order from Afghanistan.

Decision: Registration Board approved above mentioned product of M/s Scilife Pharmaceuticals, (Pvt.) Ltd. Plot No. FD-57/58-A2, Kornagi Creek Industrial Park (KCIP) Karachi for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No.19: Registration of Drug (s) of M/s Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Karachi For Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5D submitted
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided. Approval of relevant section verified from Licensing section letter No.F.2-20/85-Lic (Vol.III) (M-227) dated 20.06.2011.
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection report dated 05.08.2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Fosyject Injection 2g Each vial contains: Fosfomycin Disodium equivalent to Fosfomycin……2g	Me too status/ RRA status not available Purchase order from Philippines	Dy. No1726/ 2020-PE&R-(EFD) 03-06-2020. Rs.50000/- dated 26-11-2020

Decision: Registration Board deferred the request of firm for evidence of approval of applied formulation in importing country (Philippines).

Case No. 1 Request of M/s Linta Pharmaceuticals (Pvt.) Ltd., Islamabad for change of contract manufacturer of their already registered products.

M/s Linta Pharmaceuticals (Pvt.) Ltd., Islamabad has requested for change of contract manufacturer of their already registered products as detailed below.

Sr. No.	Applicant	Proposed contract manufacturer	Name of Drug(s) with composition	Reg. No.	Existing contract manufacturer	Initial date of Registration & Validity of contract manufacturing permission
1	M/s Linta Pharmaceuticals (Pvt.) Ltd., Islamabad	M/s Seraph Pharmaceuticals Industrial Triangle, Kahuta road, Islamabad	CT-X 250mg Injection IM Each vial contains: Ceftriaxone (as sodium)….250mg USP Specs	093275	M/s Wellborne Pharmachem & Biologicals, Hattar.	30-11-2018 29-11-2023
2			CT-X500mg Injection IM Each vial contains: Ceftriaxone (as sodium)….500mg USP Specs	093274		
3			CT-X 1gm Injection IV Each vial contains: Ceftriaxone (as sodium)….1gm USP Specs	093276		

Firm has submitted following documents:

i. Applications on Form-5F.
ii. Fee Rs.50,000/- per product dated 06-12-2019
iii. Registration letter and valid contract manufacturing permission
iv. Copy of agreement between M/s Linta Pharmaceuticals (Pvt.) Ltd., Islamabad and M/s Seraph Pharmaceuticals Industrial Triangle, Kahuta road, Islamabad, made on 04-12-2019
v. Evidence of approval of **Dry Vial (Cephalosporin)** section for M/s Seraph Pharma from Licensing Authority.
vi. GMP inspection reports of both the applicant and manufacturer.

Decision: Registration Board deferred the case for capacity assessment of M/s Seraph Pharmaceuticals Industrial Triangle, Kahuta road, Islamabad.

Case No. 2 Request for the permission of contract manufacturing of already registered drug of M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad from their own facility to M/s Vision Pharmaceuticals (Pvt.) Ltd. Islamabad

M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad has requested for the permission of contract manufacturing of their already registered drug from their own facility to M/s Vision Pharmaceuticals (Pvt.) Ltd. Islamabad as detailed below. The firm has stated that their facility is not ready at this moment to manufacture said product.

Sr. No.	Name of Drug(s) with composition	Reg. No.	Approved Packing	Date of initial registration & Renwal application
1	Linzy Infusion 600mg/300ml Each ml contains: Linezolid….2mg Global Specs	075071	100ml 200ml 300ml	26-12-2012 Renewal dated 24-11-2017

Previously the firm has three approved volumes but firm has now submitted stability of only one volume i.e, 300ml.

Firm has submitted following documents:

i. Applications on Form-5F with fee of Rs.50,000/-
ii. Registration letter and renewal application.
iii. Copy of agreement between M/s globalPharmaceuticals,Islamabad and M/s Vision Pharmaceuticals, Islamabad made on 03-06-2020
iv. Evidence of section approval Liquid Vial (General) LVP.
v. Already registered products on contract manufacturing are 06 and no of approved section are 08.
vi. GMP inspection reports of both the applicant and manufacturer.
vii. Long term stability (18 Months) and accelerated stability (06months) submitted for FPP at Zone-IV A conditions.
viii. Stability submitted for API at 25ºC ± 2ºC 60% rH ± 5% rH (Zone-II)
ix. Approval of manufacturing facility of API by regulatory body of country and validity, Vendor qualification / audit and its justification: **not submitted.**

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

a) Complete submission of all documents as per Form5F.
b) Justification of seeking permission for only linzy infusion on contract manufacturing as firm also has other infusion preparations

Case No. 3 M/s. Reko Pharmaceuticals (Pvt.) Ltd., Lahore

M/s. Reko Pharmaceuticals (Pvt.) Ltd., Lahore has requested to mention composition in registration letter of following product;

Sr. No.	Reg. No.	Existing Brand name	Proposed Brand name with composition	Initial date of Registration & Renewal	Remarks
1	001456	Glygol Elixir	Glygol **Expectorant** Each 15ml contains:- Glyceryl Guaiacolate ……90mg Theophylline BP/USP……150mg	30-09-1976 29-09-2016 09-05-2016 Renewal is ok	Fee Rs. 5000/- deposited dated 10-04-2019 **Consignment is cleared by AD (I &E) with consumption restricted till the mentioning of API on Registration Letter.**

Decision of 36th PRVC:-

Deferred the above product for documentary evidence of same formulation since grant of registration/BMR of, at least, each decade and justification of mentioning expectorant with brand name instead of elixir as expectorant is a pharmacological class and not a dosage form.

Remarks:-

The firm told that our product Glygol has no alcohol in its formulation since 05th September, 1988 therefore our product is not considered as *Elixir.*

Decision of 37th PRVC:-

The Chairman Registration Board referred above request to the Registration Board along with letters of DRAP and summary of batch records & RRA status.

Fresh submission:

Firm has submitted following documents:-

i. Price re-fixation letter No.11-1/2010-DDC (P) (10th DPC) dated 28.05.2010 which shows composition/ label claim of Glygol Elixir
ii. Batch manufacturing record of last decade.
iii. Evidence of approval of applied formulation could not be confirmed.

After exclusion of alcohol from the said product, firm is using the terms "expectorant and syrup", interchangeably in various requests.

Decision: Registration Board directed to issue corrigendum mentioning name and composition as follows:

Glygol Syrup
Each 15ml contains:
Glyceryl Guaiacolate ……90mg
Theophylline ……150mg

Case No. 4 M/s. Hoover Pharmaceuticals (Pvt.) Limited, Lahore.

The request for change of brand name of following products of M/s. Hoover Pharmaceuticals Pvt. Limited, Lahore was referred to Registration Board in 37th PRVC meeting. It is informed that M/s CCL, Lahore is interested in distribution/marketing rights with brand name ownership of products with M/s Hoover Pharmaceuticals Pvt. Ltd. on mutual understanding. Moreover, proposed brand name is already registered for M/s CCL products.

Sr. No	Reg. No.	Brand name with formulation of Drugs	Proposed brand name	Date of issue & renewal status	Fee & date of deposited	Remarks
1.	065912	ISO-Acne Gel Each tube contains:- Isotretenoin……0.05% Erythromycin……2%	**Isotret Plus Gel**	06-10-2010 05-10-2015 29-09-2015 Renewal is ok	Fee Rs. 20,000/- deposited dated 02-12-2019	**The firm has Withdrawn its request for both products.**
2.	077208	Mycostin 1% Cream Each gram contains:- Terbinafine (as HCl)…..10mg	**Terbi Cream**	05-06-2014 04-06-2019 09-05-2019 Renewal is ok	Fee Rs. 20,000/- deposited dated 02-12-2019	
3.	087566	Gatolin Powder for oral suspension Each sachet contains:- Omeprazole…….40mg Sodium Bicarbonate……..1680mg	**Faast + 40 sachet**	19-01-2018 18-01-2023 Renewal is not required	Fee Rs. 20,000/- for each product deposited dated 13-11-2019	
4.	087567	Gatolin Powder for oral suspension Each sachet contains:- Omeprazole…….20mg Sodium Bicarbonate……..1680mg	**Faast + 20 sachet**			
5.	086357	Essopel Insta 40mg Sachet Each sachet contains:- Enteric coated pellets of Esomeprazole Magnesium Trihydrate eq. to Esomeprazole ……40mg **Source: M/s Surge Laboratories, Lahore**	**Espra Sachet**	20-12-2017 19-12-2022 Renewal is not required	Fee Rs. 20,000/- For Each Product Deposited Dated 02-03-2020.	
6.	086358	Essopel Insta 20mg Enteric coated pellets Sachet				

		Each sachet contains: Esomeprazole Magnesium Trihydrate eq. to Esomeprazole ……20mg **Source: M/s Surge Laboratories, Lahore**				

Decision: **Registration Board was apprised that that presently same brand names are issued to a manufacturer/importer having same formulations. Now various applications have been received for issuance of same brand name under different scenario as follows:**

a) Issuance of same brand names to same formulations of different manufacturer/importer.
b) Issuance of diffeeferent brand names for different dosage forms of same formulation
c) Issuance of same brand names for different similar formulation
d) Issuance of different brand names for different dosage form/ strength and indications
e) Issuance of same brand name to same/similar formulation of product registered as drug and enlisted as HOTC product.

Registration Board decided to seek guidance from DRAP Authority on above points.

Case No. 5 Request to grant the same Brand name of the molecule of M/s Indus Pharma (Pvt.) Ltd. Karachi to the same molecule of M/s Dynatis Pakistan (Pvt.) Ltd. Lahore.

M/s Dynatis Pakistan (Pvt.) Ltd. Lahore has informed (Page 312-331/C) that M/s Indus Pharma (Pvt.) Ltd. Karachi bearing DML No. 000124 and M/s Dynatis Pakistan (Pvt.) Ltd. Lahore bearing DML No. 000891 are registered by the Security Exchange Commission of Pakistan (SECP), under the Companies Act 2017 as Private Limited Companies.

Moreover, the Directors/Management and share Holders of Both M/s Indus Pharma (Pvt.) Ltd and M/s Dynatis Pakistan (Pvt.) Ltd are the same. The same has been duly informed to and recorded by the Licensing Division.

In light of the above, M/s Dynatis Pakistan (Pvt.) Ltd. Lahore has requested to grant the same brand name of the molecule of M/s Indus Pharma (Pvt.) Ltd. Karachi to the same molecule of M/s Dynatis Pakistan (Pvt.) Ltd. Lahore, as detailed below:

Sr. No.	Name of Molecule	Dosage form/ Section approval	Brand name of M/s Indus Pharma (Pvt.) Ltd. Karachi	Existing Brand name of M/s Dynatis Pakistan (Pvt.) Ltd. Lahore and Registration Number	Requested Brand Name
1.	Esomeprazole	Enteric coated pellets/ sachets	Indazole	Natizol (Reg. No. 096599)	Indazole

The firm has submitted the following documents:
1. Application along with Rs**. 10,000/-** dated 16-12-2019
2. Copy of Registration letter dated 21-06-2019.
3. Justification for proposed change.
4. NOC regarding same brand names from M/s Indus Pharma (Pvt.) Ltd. Karachi.

Decision of 37th PRVC:

The Chairman Registration Board has considered the request of the firms for change of brand name and decided to refer the case to the Registration Board.

Moreover, The Registration Board in its 293rd meeting has approved following products M/s. Dynatis Pakistan Pvt. Limited with brand name Dyclo Emulgel 1% and Dyclo Emulgel 2%. Dyclo is also registered brand name of M/s. Indus Pharma and M/s. Dynatis has now requested to issue registration letter with same brand name.

Decision: **Registration Board was apprised that that presently same brand names are issued to a manufacturer/importer having same formulations. Now various applications have been received for issuance of same brand name under different scenario as follows:**

a) **Issuance of same brand names to same formulations of different manufacturer/importer.**
b) **Issuance of diffeeferent brand names for different dosage forms of same formulation**
c) **Issuance of same brand names for different similar formulation**
d) **Issuance of different brand names for different dosage form/ strength and indications**
e) **Issuance of same brand name to same/similar formulation of product registered as drug and enlisted as HOTC product.**

Registration Board decided to seek guidance from DRAP Authority on above points.

Case No. 6 M/s. Don Valley Pharmaceuticals (Pvt.) Ltd., Lahore

The request of M/s. Don Valley Pharmaceuticals (Pvt.) Ltd., Lahore for correction of strength and change of specifications of FPP in Registration letter for following already registered product was referred from 37th meeting of PRVC to the Registration Board as detailed below:

Sr. #	Reg. No.	Name of Product with existing composition & Registration Number	Name of Product with proposed Change composition/Registration	Initial Date of Registration Renewal Application	Submitted Documents / Remarks
I	II	III	IV	V	VI
1.	017394	Clamentin Suspension Each 5ml Contains:- Amoxicillin Trihydrate eq. to Amoxicillin (as trihydrate)……..125mg Clavulanic acid (as potassium salt)…..**32.8mg**	Clamentin Suspension Each 5ml Contains:- Amoxicillin Trihydrate eq. to Amoxicillin…..125mg Clavulanic acid (as potassium salt)……..**31.25mg** **(BP Specs.)**	27-06-1995 Transfer of registration at new site date 20-07-2016 w.e.f. **25-08-2011** Correction of formulation dated 22-03-2017 Renewal applied dated **06-05-2016** **(Rs. 10,000/)**	Dy. No. 28076 R&I dated **24-12-2019** Copy of Form-5 submitted at the time of initial application submission. The Proposed formulation is **USFDA and TGA approved** and the official monograph of the applied formulation **exists in BP**

Decision of 37th PRVC:

The Chairman Registration Board has considered the request of the firms for standardization/correction in composition and decided as under:

i. Referred the product to RRR section for confirmation of renewal, deferred for submission of fee and evidence of approval in RRAs, and then to Registration Board.

Fresh submission:-

Now the firm has deposited **fee Rs. 5000/-** dated 10-03-2020 and evidence of approval of proposed formulation from USFDA.

The firm has not submitted new application on form 5F, as per decision of Registration Board in its 283rd meeting.

Decision: **Registration Board decided to issue corrigendum for correct formulation as under:**

Each 5ml contains
Amoxicillin Trihydrate eq. to Amoxicillin....125mg
Clavulanic acid (as potassium salt)…..31.25mg

Case No. 7 M/s. Cunningham Pharmaceuticals Pvt. Ltd, Lahore

M/s Cunningham Pharmaceuticals Pvt. Ltd, Lahore has informed that they were granted registration of Acobmin 500mcg/ml Injection for IV route only. However, it can be administered through IM route as well. Now the firm has requested for correction of route of administration of the following registered product in registration letter as detailed below

Sr. #	Reg. No.	Name of Product with existing composition & Specifications	Name of Product with proposed Change, composition/specifications	Initial Date of Registration Renewal Application	Submitted Documents / Remarks
I	II	III	IV	V	VI
1.	094672	Acobmin 500mcg/ml Injection (IV) Each ampoule/ml contains: Mecobalamine……..500mcg (As per innovator's Specification)	Acobmin 500mcg/ml Injection **(IV/IM)** Each ampoule/ml contains: Mecobalamine….500mcg (As per innovator's Specification)	06-03-2019 05-03-2024 Renewal is not required	Rs. 5000/- deposited dated 20-02-2020 **Approved in PMDA for both IV and IM routes.**
Decision of 39th PRVC		The Chairman Registration Board referred the case to the Registration Board for its consideration.			

Decision: **Registration Board acceded to the request of the firm regarding correction in route of administration of Mecobalamine 500mcg/ml Injection.**

Case No. 8 M/s. Shaigan Pharmaceuticals, Rawalpindi

M/s. Shaigan Pharmaceuticals, Rawalpindi has requested for issuance of corrigendum with correct dosage form (Capsule) for following registered products as detailed below.

Sr.#	Reg. No.	Name of Product with existing composition & Registration Number	Name of Product with proposed Change composition/Registration	Initial Date of Registration Renewal Application	Submitted Documents / Remarks
I	II	III	IV	V	VI
1.	032960	Esso 20mg Tablet Each Tablet contains:- Esomeprazole magnesium trihydrate eq. to Esomeprazole……20mg	**Esso 20mg Capsule** **Each capsule contains:-** Esomeprazole magnesium trihydrate eq. to Esomeprazole…20mg	03-07-2004 02-07-2019	Fee not submitted due to **typo mistake while issuance of corrigendum**

2.	032961	Esso 40mg Tablet Each Tablet contains:- Esomeprazole magnesium trihydrate eq. to Esomeprazole……40mg	**Esso 40mg Capsule** **Each capsule contains:-** Esomeprazole magnesium trihydrate eq. to Esomeprazole…40mg		**date 13-10-2004 for correction of registration numbers.** Dy. No. 27308 R&I dated 17-12-2019

The firm was granted registration letter for capsule dosage form with incorrect registration number. Later on corrigendum was issued for correction in registration number but inadvertently dosage form tablet was mentioned instead of capsule.

Decision of 37th PRVC:-

"Deferred the products for submission of fee and all post-registration approvals and supporting documents".

Remarks:-

Now the firm has submitted following documents:-

i. Fee Rs. 5000/- deposited for each product dated 24-02-2020
ii. Application for renewal mentioned Esso 20mg and 40mg Capsule dated 22-04-2019.
iii. Approval for additional pack dated 22-01-2008 mentioned in Esso 20mg and 40mg Capsule dated 22-01-2008
iv. Undertaking on stamp paper,
"We undertake that, with the reference to registration letter no. F.3-5/2003-R-II (M-181) dated 18-10-2004 the products are registered in Capsule dosage since we are manufacturing in same dosage form. If at any stage any discrepancy/misinformation is detected/observed the firm/company will be held responsible as per law".

Decision of 38th PRVC:

The Chairman Registration Board referred the case to the Registration Board for its consideration.

Decision: Registration Board observed that correct composition was approved in initial registration letter No.F.3-5/2003-R.II (M-181) dated 3rd July, 2004 and by issuing corrigendum letter No.F.3-5/2003-R.II (M-181) dated 18th October, 2004 dosage form was inadvertngly mentioned as Tablet instead of Capsule. Accoreingly, Registration Board acceded to the request of the firm and advised to issue corrigendum as per following details:

Sr. No.	Reg. No.	Previous Name of Drug & composition	Newly Approved Name of Drug & composition
1.	**032960**	**Esso 20mg Tablet** **Each Tablet contains:-** **Esomeprazole magnesium trihydrate eq. to Esomeprazole……20mg**	**Esso 20mg Capsule** **Each capsule contains:-** **Esomeprazole magnesium trihydrate eq. to Esomeprazole…20mg**
2.	**032961**	**Esso 40mg Tablet** **Each Tablet contains:-** **Esomeprazole magnesium trihydrate eq. to Esomeprazole……40mg**	**Esso 40mg Capsule** **Each capsule contains:-** **Esomeprazole magnesium trihydrate eq. to Esomeprazole…40mg**

Case No. 9 Request for Fixation Source of Pellets by M/s Shaigan Pharmaceuticals (Pvt.) Limited, Rawalpindi.

M/s Shaigan Pharmaceuticals (Pvt.) Limited, Rawalpindi has requested for fixation of source of pellets for their registered drug (s). The details are as under;-

Sr.#	Registration number	Name of drug with composition& Reg. No.	Date of Initial Reg. &Renewal	Fixation Manufacturer of source of pellets
I	II	III	IV	V
1	032961	Esso-40mg Capsules Each capsule contains:- Esomeprazole magnesium trihydrate eq. to Esomeprazole……..……40mg	03-07-2004 02-07-2019 27-02-2019 Renewal is ok	Jiangsu Zhongbang Pharmaceutical Co., Ltd. 36 Shuanggao Road, Gaochum Development Zone, Nanjing, China

The firm has submitted the following documents;

Sr.#	Required documents as per approved SOPs	Submission
1.	Application with required fee as per relevant SRO.	Rs. 1,00,000/- deposited dated 28-10-2019
2.	Copy of registration letter and last renewal status.	Provided
3.	Both real time & accelerated stability studies of Half finished products (pellets / granules / ready to fill bulk) conducted by manufacturer of half finished product as per conditions of zone IV-A or zone IV-B on 3 commercial scale batches.	Provided
4.	Certificate of analysis of manufacturer.	Provided
5.	Documents confirming that the proposed source has valid permission for manufacturing of pellets / granules / ready to fill bulk by the regulatory authority of country of origin.	Provided
6.	Valid & legalized GMP certificate issued by regulatory authority of exporting country if not already submitted in DRAP during last 1 year.	The GMP certificate has been verified on-line from following web link as accessed on 23-12-2019 http://app1.sfda.gov.cn/datasearchcnda/face3/base.jsp?tableId=34&tableName=TABLE34&title=%D2%A9%C6%B7%C9%FA%B2%FA%C6%F3%D2%B5&bcId=152911762991938722993241728138
7.	An Undertaking that: i. Shelf life of finished product would be assigned after conducting product development studies, real time and accelerated stability studies on 3 batches of commercial scale, validation of manufacturing process and method of analysis before sale of drug. ii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. iii. That the provided information is true & correct.	Provided

Decision of 37th PRVC:-

The Chairman Registration Board decided to defer above request for clarification of dosage form (whether tablet or capsule as tablet is mentioned in corrigendum to letter No. F.3-5/2003-R-II (M-181) dated 18-10-2004).

Remarks:-

Now the firm has submitted following documents:-

a) Renewal letter mentioned Esso 40mg Capsule dated 22-04-2019.
b) Approval for additional pack dated 22-01-2008 mentioned in Esso 40mg Capsule dated 22-01-2008
c) Stability studies data as per zone-IV A Condition
d) Undertaking on stamp paper,
    a. *"We undertake that, with the reference to registration letter no. F.3-5/2003-R-II (M-181) dated 18-10-2004 the products are registered in Capsule dosage since we are manufacturing in same dosage form. If at any stage any discrepancy/misinformation is detected/observed the firm/company will be held responsible as per law".*

Decision of 38th PRVC:- The Chairman Registration Board referred the case to the Registration Board for its consideration.

Fresh submission:-

The firm has informed /clarified that they had applied for source fixation of pellets and now firm has revised their request to additional source of pellets form china. Moreover, the firm has also provided approval letter for source of pellets form M/s. Glenmarks, India.

Decision: Registration Board approved the above request of M/s Shaigan Pharmaceuticals (Pvt.) Limited, Rawalpindi for additional source of pellets from M/s. Jiangsu Zhongbang Pharmaceutical Co., Ltd. 36 Shuanggao Road, Gaochum Development Zone, Nanjing, China.

Case no. 10 M/s AAA Health Pharmaceutical Laboratories, Islamabad

M/s AAA Health Pharmaceutical Laboratories, Islamabad has requested for approval of new label/ unit carton design/ **20ml water in place of measuring cup/** colour scheme of their following registered products with details below.

S. No.	Reg. No.	Name of drug(s) with formulation	Date of initial registration & last renewal applied	Justification
1.	082648	Brodsef 100mg/5ml Dry Powder for suspension Each 5ml after reconstitution contains:- Cefixime as trihydrate……100mg (USP Specification)	19-02-2018 18-02-2023 Renewal is not required	Due to market demand
2.	082649	Brodsef 200mg/5ml Dry Powder for suspension Each 5ml after reconstitution contains:- Cefixime as trihydrate……...200mg (USP Specification)		

The firm has submitted following:

a) Fee Rs.5000/- deposited for each product dated 21-02-2020
b) Specimen of Old and New designs.
c) Difference b/w existing and proposed information in tabulated form

Sr. no.	Existing packing material and design	Proposed packing material and design
1	Unit carton with pink color strip on the top followed by thinner blue strip.	Removed
2	After blue color printed strip UC has consecutive white and pink color printed strips on front and back while sides do not have such strips.	Removed
3	Bottom of front and back has pink color	Bottom of sides have a strip of pink color and grey

	printed strip followed by blue printed strip, while sides do not have	color in a single row. Front and back of UC had yellow strip followed by wider strip of pink and grey strip.
4	Strawberry is printed in lower front and back portion of the unit carton.	Strawberry is printed in pink color portion of the UC while monogram of company is printed in grey portion
5	Printing color is black and blue	Printing color is black and blue.

d) Undertaking

Decision of 39th PRVC:

The Chairman Registration Board decided to refer the case to the Registration Board for its consideration after submission of details of type and whether already registered or not regarding 20ml water to be used as solvent.

Fresh Submission/Remarks:

Now the firm submit registration letter of sterile water 20ml of following source from M/s. Unisa Pharmaceuticals, Nowshera vide Registration No. 088558.

Decision: Registration Board noted the information for its record. Firm shall comply all provisions of Drugs (Labelling & Packing) Rules, 1986.

Case No. 11 M/s Wilshire Laboratories, (Pvt.) Ltd, Lahore

The request of M/s Wilshire Laboratories, (Pvt.) Ltd, Lahore for correction of composition and change of specifications of FPP in Registration letter for following already registered product(s) was referred from 29th meeting of PRVC to the Registration Board as detailed below:

Sr. No.	Reg. No.	Existing Name of Drug(s) and Composition	Desired correction
1	052509	Sizzle D 60mg Tablet Each tablet contains:- Fexofenadine HCl … 60mg Pseudoephedrine … 120mg (Wilshire's Specs)	Sizzle D 60mg Tablet Each **extended release** tablet contains:- Fexofenadine HCl … 60mg Pseudoephedrine **HCl**… 120mg **(USP Specs)**
2	090142	Sizzle D Tablet Each tablet contains:- Fexofenadine HCl … 180mg Pseudoephedrine … 240mg (USP Specs)	Sizzle D 180mg Tablet Each **extended release** tablet contains:- Fexofenadine HCl… 180mg Pseudoephedrine **HCl**… 240mg (USP Specs)

The firm has provided following documents in support of their request as per approved SOP:

1. Application with required fee Rs. 5000/- for each product
2. Copy of registration letters dated 18-09-2008 & 13-06-2018 and renewal status dated 15-01-2018
3. Undertaking as per approved SOPs.

Decision of 290th meeting: Registration Board deferred the above products for confirming manufacturing status of the product.

Firm has submitted that they have manufactured Sizzle D 60/120mg Tablet and sold the same in 2018, while Sizzle D 180/240mg was registered on 13-06-2018 and they could not manufacture this product due to non-availability of raw material.

For ready reference, following documents are being enclosed: -

1. Registration letter no. F.13-2/2008-Reg-II- (M-213) dated 18-09-2008 for Sizzle D 60/120mg Tablet and Registration letter no. F.15-6/2018-Reg-V- (M-281) dated 13-06-2018 for Sizzle D 180/240mg Tablet
2. Application for quota allocation of Pseudoephedrine HCl submitted on 07-01-2019

3. Manufacturing Record of Sizzle 60/120mg Tablet
4. Sales Record of Sizzle 60/120mg Tablet for the year 2017-2018
5. Standard Manufacturing Procedure (SMP) of our both above products
6. Standard Analytical Procedure (SA) of our both above products
7. Letter no. F.02-042/2019 DD(CD) dated 26-06-2019 from Controlled Drugs Division, DRAP for provision of corrigendum letter for both above products
8. Letter no. WLH/AA/162/2019 & letter no. WLH/AA/163/2019 both submitted on 27-03-2019 for issuance of corrigendum of our above products

Decision of 291st meeting: Registration Board deferred for confirmation of firm's request from registration application

Fresh submission:

Now, the firm has submitted copy of form-5 submitted at the time of initial application submission mentioning complete salt forms. Moreover, Sizzle D tablets180mg/mg240 was approved in 213th meeting of the Registration Board as extended release tablets.

Decision of 293rd meeting of RB:

Registration Board deferred the above products for confirming manufacturing status of the product.

Fresh Submission:

Firm has submitted their Master formulation and Standard manufacturing procedure with label claim indicating that said product is bilayer tablet with Fexofenadine HCl as immediate release layer while Pseudoephedrine HCl as sustained release layer which is in line with USFDA.

Decision: Registration Board acceded to the request of the firm and advised to issue corrigendum to initial registration letter No.F.13-2/2008-Reg-II (M-213) dated 18th September, 2008 for Sizzle D 60/120mg Tablet and registrarion letter No.F.15-6/2008-Reg.V (M-281) dated 13th June, 2018 for Sizzle D 180/240mg Tablet as per following details:

Sr. No.	Reg. No.	Previous Name of Drug, composition & specifications	Newly Approved Name of Drug, composition & specifications
1.	**052509**	Sizzle D 60mg Tablet Each tablet contains:- Fexofenadine HCl … 60mg Pseudoephedrine … 120mg (Wilshire's Specs)	**Sizzle D 60mg Tablet** **Each Bi-layered Tablet contains:** **Fexofenadine HCl..… 60mg** **Pseudoephedrine HCl…...120mg (as extended release layer)** **(USP Specs)**
2.	**090142**	Sizzle D Tablet Each tablet contains:- Fexofenadine HCl … 180mg Pseudoephedrine … 240mg (USP Specs)	**Sizzle D 180mg Tablet** **Each Bi-layered Tablet contains:** **Fexofenadine HCl..… 180mg** **Pseudoephedrine HCl …...240mg (as extended release layer)** **(USP Specs)**

Case No. 12 Change in Contract Manufacturer:-

M/s. Reliance Pharma, Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat have requested for change in contract manufacturer from M/s. EG Pharmaceuticals, 13-A Industrial Triangle Kahuta Road Islamabad to M/s. Global Pharmaceuticals, Plot No 204-205 Kahuta Triangle Industrial Area Islamabad and M/s. Nimrall Laboratories, Plot No. 24 St: No.SS-3 National Industrial Zone Rawat to M/s. Vision Pharmaceuticals, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad for the following registered products as per detailed below:-

S. No.	Existing Manufacturer	New Manufacturer	Reg. No.	Name of drug(s) & Composition	Initial registration date & contract permission validity	Fee & Date of submitted application
I	II	III	IV	V	VI	VII
1.	M/s. EG Pharmaceuticals, 13-A Industrial Triangle Kahuta Road Islamabad	M/s. Global Pharmaceuticals, Plot No 204-205 Kahuta Triangle Industrial Area Islamabad	092091	Relco 100mg Dry Suspension Each 5ml contain:- Cefixime (as trihydrate)……..100mg (USP Specs.)	13-10-2018 12-10-2023	Fee Rs. 50,000/- deposited dated 07-03-2019 Submission of application dated 07-03-2019 (photocopy)
2.			092092	Relco 400mg Capsule Each capsule contain:- Cefixime (as trihydrate)……..400mg (JP Specs.)		
3.			083666	Relcef 1gm Injection IM/IV Each vial contains:- Cefoperazone (as Sodium)….500mg Sulbactum (as Sodium)……500mg (JP Specification)	24-05-2017 23-05-2023	
4.			083667	Relcef 2gm Injection IM/IV Each vial contains:- Cefoperazone (as Sodium)….1000mg Sulbactum (as Sodium)……1000mg (JP Specification)		
5.	M/s. Nimrall Laboratories Plot No. 24 St: No.SS-3 National Industrial Zone Rawat.	M/s. Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad	083439	Reli-Chole Injection Each ml contains: Cholecalciferol ……... 5mg (BP Specifications)	26-04-2017 25-04-2023	Fee of Rs.50,000/- deposited dated 04-03-2019 for each product (Duplicate application with photocopy of fee challan). Submission of application dated 05-03-2019
6.			083440	Reli-cobal injection Each ml contains:- Mecobalamin…….500mcg		
7.			083441	Ketrometh injection Each ml contains:- Ketorolac tromethamine ……30mg		
8.			083442	Iro-sur injection Each ml contains: Iron Sucrose eq. to iron (Elemental)……20mg		

Firm has submitted following documents in this regard:

i. Application/Form 5
ii. Copy of contract manufacturing agreement between M/s. Reliance Pharma, Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat and M/s. M/s. Global Pharmaceuticals, Plot No 204-205 Kahuta Triangle Industrial Area Islamabad,
iii. Copy of contract manufacturing agreement between M/s. Reliance Pharma, Plot No. 8 Street No. S-8 RCCI Industrial Estate Rawat and M/s. Vision Pharmaceuticals, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad
iv. GMP certificate of M/s Vision Pharma Islamabad. (dated 26-01-2018)
v. GMP inspection report of M/s Reliance Pharma Rawalpindi (dated 27-12-2018)
vi. GMP inspection report of M/s Global Pharmaceuticals Pvt Ltd. (dated 11 & 24-10-2018)
vii. DML of both contract giver and acceptor.
viii. Copy of letter for section Approval of M/s. Global and M/s. Vision.
ix. Undertaking as per SOPs

Decision: **Registration Board decided as follows;**

a. **approved above request of firm for change in contract manufacturing of products at Sr. No. 1-4 from M/s. EG Pharmaceuticals, Islamabad to M/s. Global Pharmaceuticals, Islamabad valid till the period mentioned vide colum-VI above.**
b. **and products at Sr. No. 5-8 from M/s. Nimrall Laboratories, Rawat to M/s. Vision Pharmaceuticals (Pvt.) Ltd., Islamabad valid till the period mentioned vide colum-VI above.**

Further, this approval is post-registration variation and shall not be considered towards renewal of products. Fee shall ber verified as per procedure adopted by Registration Board in its 285th meeting.

Case No. 13: Extension in Contract Manufacturer:-

M/s. Vision Pharmaceuticals, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad have requested for extension in contract manufacturer from M/s. Global Pharmaceuticals, Plot No. 204-205 Kahuta Triangle Industrial Area Islamabad for the following registered products. Their previous approval was granted by Registration Board in its 261st valid for five years from the date of issuance as per detailed below:-

S. No.	Reg. No.	Name of drug(s) & Composition	Extension in contract manufacturing permission date and validity	Reg, Trail
1.	042654	Aczon Injection IM Each vial contains:- Ceftriaxone (as Ceftriaxone Sodium)…… 250mg	24-10-2016 Valid permission date 30-06-2020	Initial Reg. 25-02-2006 Contract Mfg. permission from M/s. Global Pharmaceuticals, Islamabad dated 07-07-2010 Extension in contract Mfg. permission dated 24-10-2016 valid til 30-06-2020
2.	042655	Aczon Injection IM Each vial contains:- Ceftriaxone (as Ceftriaxone Sodium)…… 500mg		
3.	042656	Aczon Injection IM Each vial contains:- Ceftriaxone (as Ceftriaxone Sodium)…… 1gm		
4.	030695	Aczon 1gm Injection IV Each vial contains: Ceftriaxone…….1 g		Initial Reg. date 24-07-2003 Change of brand name dated 31-01-2004

5.	030696	Aczon 250mg Injection IV Each vial contains:- Ceftriaxone……250mg		Date of Renewal: 31-01-2009 Contract Mfg. permission from M/s. Global Pharmaceuticals, Islamabad dated 30-06-2010 Last Extension in Contract Mfg. Permission vaild till 30-06-2020
6.	030697	Aczon 500mg Injection IV Each vial contains:- Ceftriaxone……500mg		
7.	030708	Flexeril 400mg Capsules Each capsule contains:- Cefixime….400mg		Contract Mfg. permission from M/s. Global Pharmaceuticals, Islamabad dated 24-07-2003 Last Extension in Contract Mfg. Permission vaild till 30-06-2020
8.	030709	Flexeril Dry Suspension Each 5ml contains:- Cefixime……100mg		
9.	053794	Flexeril Plus 200mg Dry Suspension Each 5ml contais:- Cefixime…….200g (USP Specs.)		Last Extension in Contract Mfg. Permission vaild till 30-06-2020
10.	030690	Nestox 250mg Injection Each vial contains:- Cefotaxime sodium eq. to Cefotaxime…… …250mg		Initial Reg. 24-07-2003 Change of brad name dated 27-08-2003 Date of Renewal: 27-08-2008
11.	030691	Nestox 500mg Injection Each vial contains:- Cefotaxime sodium eq. to Cefotaxime…….. 500mg		Contract Mfg. permission from M/s. Global Pharmaceuticals, Islamabad dated 10-08-2009 valid till 30-06-2010 Last Extension in Contract Mfg. Permission vaild till 30-06-2020
12.	030692	Nestox 1gm Injection Each vial contains:- Cefotaxime sodium eq. to Cefotaxime…… …..1gm		
13.	042650	Sufzon 1gm Injection IV Each vial (15cc) contains:- Cefoperazone (as Sodium)…… .500mg Sulbactum (as sodium)……500mg		Initial Reg. 25-02-2006 Contract Mfg. permission from M/s. Global Pharmaceuticals, Islamabad dated 10-08-2009 valid till 30-06-2010 Last Extension in Contract Mfg. Permission vaild till 30-06-2020
14.	042653	Sufzon 2gm Injection IV Each vial (15cc) contains:- Cefoperazone (as Sodium)……..…1000mg Sulbactum (as sodium)…1000mg		
15.	053209	Visoceph 250mg Capsules Each capsule contains:- Cephradine (as monohydrate)…….. 250mg (USP Specs.)		Last Extension in Contract Mfg. Permission vaild till 30-06-2020
16.	053210	Visoceph 500mg Capsules Each capsule contains:- Cephradine (as monohydrate)…….. 500mg (USP Specs.)		

Firm has submitted following documents in this regard:

i. Application along with fee of Rs.50,000/- for each product.
ii. Copy of registration letter and valid contract permission.
iii. Copy of drug manufacturing license

iv. Copy of last GMP Report
v. Copy of contract agreement.

Decision: Registration Board deferred the above request for provision of complete registration trail.

Case No. 14 Extension in Contract Manufacturer:-

M/s. Global Pharmaceuticals, Plot No 204-205 Kahuta Triangle Industrial Area Islamabadhave requested for extension in contract manufacturer from M/s. Vision Pharmaceuticals, Plot No. 22, Industrial Triangle, Kahuta Road, Islamabadfor the following registered products. Their previous approval was granted by the Registration Board in its 261st valid for five years from the date of issuance as per detailed below:-

S. No.	Reg. No.	Name of drug(s) & Composition	Extension in contract manufacturing permission date and validity	Registration Trail
1.	026985	Anarob Infusion Each 100 ml contains:- Metronidazole B.P……500 mg	28-08-2015 Valid permission date 30-06-2020	Initial Reg. Dated 16-06-2001 Permission of contract mfg: from M/s. Vision Pharmaceuticals, Islamabad 11-08-2003 Extension in contract mfg. from M/s. Vision Pharmaceuticals, Islamabad dated 20-10-2008 valid till 30-06-2010 Permission of contract mfg: from M/s. Mac & Ranis Pharmaceuticals, Lahore dated 27-09-2010 vaild till 31-12-2010 Approval for change of contract mfg.from M/s. Mac & Ranis Pharmaceuticals, Lahore to M/s. Vision Pharmaceuticals, Islamabad dated 16-01-2015 valid till 30-06-2015 Extension in contract mfg. permission dated 28-08-2015 valid til 30-06-2020
2.	026979	Nafcin Injection Each 100 ml contains: Ciprofloxacin (as Lactate)…….200 mg		
3.	026980	Ofloquin Infusion Each 100 ml contains: Ofloxacin(as HCl)…..…….... 200 mg		

Firm has submitted following documents in this regard:

i. Application and fee of Rs.50, 000/- dated 20-04-2020 for each product.
ii. Copy of registration letter and valid contract permission.
iii. Copy of drug manufacturing license
iv. Copy of last GMP Report
v. Copy of contract agreement.

Decision: Registration Board approved extension of the above products till 30.06.2025 in light of Rule 20A of (Drugs Licensing, Registering & Advertising) Rules, 1976.

Case No. 15. M/s. Trigon Pharmaceuticals Pvt. Limited, Lahore

M/s. Trigon Pharmaceuticals Pvt. Limited, Lahore has requested for change of brand name of their following registered product with details below.

Sr. No.	Reg. No.	Brand name with formulation	Brand name	Reg. date and renewal	Remarks
1	077194	T Drop-D Injection Each ml contains:- Cholecaleiferol (Vitamin D) 200,000IU/Ml	D-Lite	27-05-2014 Renewal dated 23-05-2019	Brand name resemblance with Indrop-D of M/s Neutro Pharmaceuticals, Lahore.

					Justification: Show cause notice for resembling of name, label & packing design with indrop-D

Decision of 36th PRVC:-

Deferred the request for status of production and renewal status of registered product.

Remarks:-

Now the firm has submitted last batch position manufactured in March,2019 and renewal application dated 23-05-2019.

Decision of 37th PRVC:-

The Chairman Registration Board decided to defer the above request for submission of more brand names.

M/s. Trigon Pharmaceuticals, Lahore informed that M/s. Kurative Green (Neutraceuticals) is our sister concerned firm (Vitamin D soft gel capsule enlisted under brand **D-Lite** soft gel capsule vide No. 09209 0002) and they have issued us NOC on July 10, 2019 that they have no objection if their sister concern M/s Trigon Pharmaceuticals Pvt. Ltd. Lahore uses same brand name for their allopathic product Vitamin D injection.

Decision of 38th PRVC:-

The Chairman Registration Board decided to refer case to Registration Board.

Decision: **Registration Board was apprised that that presently same brand names are issued to a manufacturer/importer having same formulations. Now various applications have been received for issuance of same brand name under different scenario as follows:**

a) Issuance of same brand names to same formulations of different manufacturer/importer.
b) Issuance of diffeeferent brand names for different dosage forms of same formulation
c) Issuance of same brand names for different similar formulation
d) Issuance of different brand names for different dosage form/ strength and indications
e) Issuance of same brand name to same/similar formulation of product registered as drug and enlisted as HOTC product.

Registration Board decided to seek guidance from DRAP Authority on above points.

Case No. 16 M/s. GT Pharma, Lahore

The request of M/s. GT Pharma, Lahore for clarification/correction in specifications of their following registered product was considered in 290th meeting of the Registration Board and deferred with details below:

S. No.	Reg. No.	Name of drug(s) with formulation	Desired specifications
I	II	III	IV
1	080881	ED-3 injection 1ml Each 1ml glass ampoule contains:- Cholecalciferol (Vitamin D3)…….5mg (BP Specifications)	ED-3 injection 1ml Each 1ml glass ampoule contains:- Cholecalciferol (Vitamin D3)…….5mg (As per Innovator's Specifications)

The firm had submitted that the BP recommends the quantity of Cholecalciferol (Vitamin D3) average 0.75% w/v in Ethyl Oleate per ampoule (i.e. 7.5mg/1ml ampoule), and lable claim is 5mg of Cholecalciferol/ampoule as per registration letter. There seems some controversy between specifications according to British Pharmacopeia and our registered product specifications in DRAP for our product ED-3 injection (Vitamin D3)……5mg/ml (BP

specifications).

Documents details as per SOPs approved 283rd Registration Board Meeting:-

Sr. No.	Requirement as per SOPs	Documents submitted
1	Application with Fee Rs. 5000/-	Provided
2	Copy of registration letter dated 07-06-2016	Provided
3	Documents in support of proposed correction	Provided
4	Analytical reports as per monograph of FPP	Provided
5	Undertaking that : The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. No case is pending at any forum / court of law regarding this product. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. The provided information/ documents are true/ correct.	Provided

Decision of 290th Meeting:-

Registration Board deferred for further deliberation.

Decision of 286th Meeting of RB:

Registration Board in its 286th meeting acceded to similar request of M/s Barrett Hodgson and M/s S. J. & G. FazulEllahie regarding correction in finished product specifications of Cholecalciferol 5mg/ml Injection from BP Specifications to "As per Innovator's Specifications" along with omission of "IM" (route of administration), mentioned alongside the brand name. **The Board further directed that finished product specifications of all other registered products of instant formulation shall be corrected accordingly.**

Decision of 292nd Meeting of RB:

Registration Board deferred the above product for status of applied formulation in pharmacopeia of RRA (ANSM).

Fresh submission

Firm has submitted that in various meetings of Registration Board Innovator Specification have been given to same product.

Decision: Registration Board acceded to the request of firm regarding correction in finished product specifications of Cholecalciferol 5mg/ml Injection from BP Specifications to "As per Innovator's Specifications".

Case No. 17: Request for change of route of administration of registered drug of M/s. Reliance pharma, Rawat

M/s. Reliance pharma, Rawathas requested for Change of route of administration for their registered drug (s). The details are as under;

Sr.#	Reg. No.	Existing Name of drug with composition& rout administration	ProposedName of drug with composition& rout administration	Date of Initial Reg. & Renewal	Remarks (if any)
I	II	III	IV	V	VI
1	099554	E-Rel 250mg Injection IV Each vial contains:- Ceftriaxone sodium eq. to Ceftriaxone …….250mg (USP Specs.)	E-Rel 250mg Injection **IM** Each vial contains:- Ceftriaxone sodium eq. to Ceftriaxone …….250mg (USP Specs.)	30-10-2019 29-10-2024 Renewal is not required	
2	099555	E-Rel 500mg Injection IV Each vial contains:- Ceftriaxone sodium eq. to Ceftriaxone …….500mg	E-Rel 500mg Injection **IM** Each vial contains:- Ceftriaxone sodium eq. to Ceftriaxone …….500mg		

		(USP Specs.)	(USP Specs.)		

The firm has submitted the following documents;

i. Fee Rs. 20,000/- deposited for each product dated 14-01-2020
ii. Copy of Registration Letter
iii. Justification of proposed changes (due to marketing purpose)
iv. Undertaking.

Decision: Registration Board acceded to the request of the firm regarding change in route of administration of above products from intravenous (IV) to "intramuscular (IM)".

Case No.18 Permission to use banned excipients in APIs manufacturing

A letter has been received from Assistant Director (I&E) Lahore regarding permission to use Methylene chloride in API manufacturing. It is informed that Registration Board in its 286th meeting has decided to prohibit the use of Methylene chloride and Sodium cyclamate in the formulation of pharmaceutical products on the basis of ban imposed by USFDA.

It is further informed that M/s. Pharmagen Ltd. use Methylene chloride as solvent in the manufacturing of APIs Amoxicillin, Ampicillin, Cephradine, Cephalexin, Cephadroxil, Cefaclor, Omeprazole, Betamethasone sodium phosphate, Betamethasone valerate and Betamethasone dipropionate.

Decision: Registration Board referred the case to Licensing Division, DRAP for consideration of firm's request as per prevailing rules.

Case No. 19: Change of Brand Name due to resemblance with products of M/s. Atco Laboratories, Karachi.

Chairman Registration Board in 28thmeeting of PRVC, considered the request of M/s. Atco Pakistan Limited, Karachi about resemblance of brand name with products of M/s. Searle IV Solution Pvt. Limited, Lahore. Since the brand name were granted to M/s. Atco Laboratories, Karachi prior, hence M/s. Searle IV Solution Pvt. Limited, Lahore where advised to change brand name due to resemblance. Since firm did not provided alternate brand name hence Remindersalso written (dated dated 12-06-2017, 25-08-2017 & 11-06-2019) but the firm has not responded yet.

S.#	Product name	Name of firm	Similar Brand
1.	Syngab ……..50mg (Reg. 048420) Syngab ……..100mg (Reg. 048421) Syngab ……..200mg (Reg. 048422) Syngab ……..75mg (Reg. 076691) Syngab ……..150mg (Reg. 076692) Syngab ……..300mg (Reg. 076693)	***M/s Searle IV Solution Pvt. Limited, Lahore***	Spingab 75mg (Reg. no. 079723) Spingab 100mg (Reg. no. 079724) Spingab 150mg (Reg. no. 079725) Spingab 300mg (Reg. no. 079726)

Decision of 292nd Meeting of Registration Board:

Registration Board decided to write a final letter with complete details to M/s Searle IV Solution Pvt. Limited, Lahore to change the brand name of their registered product i.e. spingab as Syngab of M/s. Atco Pakistan Limited, Karachi has been registered earlier to their product.

Fresh Submission:

The firm informed that recently this case appeared in 292nd meeting of the Registration Board bearing statement that the DRAP issued three letters on different dates to M/s. The Searle

Limited, Lahore herein we bring in your kind information that only a single letter dated 25-08-2017 received by our office and we had responded 04-09-2017. Here, one more clarity is needed that the registration of Spingab capsule belongs to M/s. The Searle Company Limited, 32 KM, Multan Road, Lahore; while in 292nd RB meeting shown the registration of Spingab capsule with M/s Searle IV Solution Pvt. Limited, Lahore.

Moreover, the brand name Spingab & Syngab is phonetically & morphologically quite different, further more they have informed that we also have Trade Mark (TM No. 440666), their artwork design also different from each other.

The firm has requested that they may be allowed to continued market spingab range with the same brand name.

Decision: Registration Board decided to issue show-cause notice to M/s Searl company limited, Lahore for the change of Brand Name of Spingab capsule range of products as mentioned above.

Item No. 01 Cases referred to Registration Board:

Registration Board in its 292nd meeting held on 01-02nd October, 2019 authorized Chairman Registration Board for grant of renewal of drugs registered for local manufacturing provided that these applications have been received within time as required under aforesaid rules. However, the renewal applications of imported products (Human & Veterinary), renewal applications wherein the fee is submitted after due date but within sixty days and application applied under SRO 1005(I)/ 2017 shall be placed before the Registration Board for decision. Accordingly application considered by renewal sub-committee and referred to Registration Board are tabulated below:

i. 1st Meeting of Renewal Committee

Sr. No.	Reg. No.	Brand Name, Composition& Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Decision
M/s. Ambrosia Pharmaceuticals , Plot No.18, St: No. 09, National Industrial Zone, Rawat					
1.	054927	Plekam 20mg Capsule Each capsule contains:- Piroxicam…….20mg	24-01-2009	Dy. No. 1181 dated 19-03-2019 20000/-	w.e.f. 24-01-2019 to 23-01-2024
2.	054928	Mocan Capsule Each capsule contains:- Artemether……20mg Lumefantrine….120mg	24-01-2009	Dy. No. 1181 dated 19-03-2019 20000/-	w.e.f. 24-01-2019 to 23-01-2024
3.	054929	Kozich 300mg Capsules Each capsule contains:- Gabapentin … 300mg	24-01-2009	Dy. No. 1181 dated 19-03-2019 20000/-	w.e.f. 24-01-2019 to 23-01-2024
M/s. Pharma Health Pakistan Limited, 17-Km Ferozepur Road Lahore					
4.	077099	Lyssa Depot Injection 250mg Each ml contains:- Testosterone Enantate… 250mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024
5.	077100	D-Gest Tablet 10mg Each film coated tablet contains:- Dydrogesterone...10mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024 The firm shall use API as per USP monograph.
6.	077101	Rol-M Tablet Each tablet contains:- Mesterolone … 25mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024
7.	077102	Star Gest Tablet Each sugar coated tablet contains:- Estradiol Valerate…. 2mg Norgestrel… 0.5mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024
8.	077103	Dot S Tablet Each tablet contains:- Ethinylestradiol … 0.002mg Gestodene … 0.075mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024
9.	077104	V-Dol Tablet Each sugar coated tablet contains:- Estradiol valerate… 2mg Cyproterone Acetate… 1mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024
10.	077105	Just N Tablet Each tablet contains:- Norethisterone …5mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024

11.	077106	Fam 21 Tablet Each tablet contains:- Ethinyl estradiol … 0.035mg Cyproterone Acetate… 2mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024
12.	077107	L-Metril Tablet 5mg Each tablet contains:- Lynestrenol… 5mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024
13.	077108	Z-Bron Injection Each ml contains:- Hydroxyprogesterone Caproate… 250mg Oestradiol Valerate… 5mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024
14.	077109	MS-2 Tablet Each tablet contains:- Methyloestrenolone … 5mg Methyloestrodiol…. 0.3mg	06-02-2014	Dy. No. 2401 dated 02-04-2019 20000/-	w.e.f. 06-02-2019 to 05-02-2024

ii. 2nd Meeting of Renewal Committee

Sr. No.	Reg. No.	Brand Name, Composition& Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Decision
M/s. Zephyr Pharmatec (Pvt) Ltd., A-39, S.I.T.E. II, Super Highway, Karachi					
15.	055013	Nyloz 20mgCapsule Each Capsules contain: Esomeprazole (as pellets)…20mg M.s Meenaxy Pharma Pvt limited, 5 Phase TLE Balanagar Hyderabad.	13-01-2009	Dy. No. 44593 Dated 31-12-2018 20000/-	w.e.f. 13-01-2019 to 12-01-2024
16.	055014	Nyloz 40mg Capsules Each Capsules contain: Esomeprazole (as pellets)…40mg M.s Meenaxy Pharma Pvt limited, 5 Phase TLE Balanagar Hyderabad.	13-01-2009	Dy. No. 44593 Dated 31-12-2018 20000/-	w.e.f. 13-01-2019 to 12-01-2024
Remarks: Firm has submitted the differential fee of imported pellets for renewal of year 2014.					
M/s. Shaigan Pharmaceutical, 14-Km Adyala Road Post Office Dahgal Rawalpindi					
17.	057503	Anso Capsule 30mg Each Capsule contains:- Lansoprazole……30mg M/s Lee Pharma Limited, Hyderabad India	20/05/2009	Dy. No. 4233 dated 22-04-2019 20000/-	w.e.f. 20-05-2019 to 19-05-2024
18.	057504	Anso Capsules 15mg Each Capsule contains:- Lansoprazole……15mg M/s Lee Pharma Limited, Hyderabad India	20/05/2009	Dy. No. 4233 dated 22-04-2019 20000/-	w.e.f. 20-05-2019 to 19-05-2024
19.	032960	Esso 20mg Capsules Each Capsule contains:- Esomeprazole magnesium	03/07/2004	Dy. No. 4233 dated 22-04-2019 20000/-	w.e.f. 03-07-2019 to 02-07-2024

		trihydrate eq. to Esomeprazole……20mg M/s. Alphamed Formulations Pvt. Ltd. Sy. No.225 Telangana India			
Remarks: Firm submitted the differential fee for imported pellets for regularization of renewal of year 2014 and 2019.					
M/s. Rotex Pharma (Pvt) Ltd, Plot No. 206-207 Industrial Triangle Kahuta Road Islamabad					
20.	056217	Volden Fort SR 100mg Tablet Each tablet contains:- Diclofenac Sodium…….100mg	17/03/2009	Dy. No. 3174 dated 10-04-2019 10000/-	w.e.f. 17-03-2019 to 18-03-2024
Remarks: Firm submitted the differential fee of Rs.10,000/- on 04-12-2019 for regularization of renewal, as the application was received but within 60days.					
M/s. Medisure Laboratories Pakistan (Pvt) Ltd, A-115, S.I.T.E. II, Super Highway, Karachi					
21.	03 1749	Sulvo Tablet 100mg Each Tablet Contain: Levosulpiride…..100mg	13-11-2003	Dy. No. 42662 13-12-2018 10000/-	w.e.f. 13-11-2018 to 12-11-2023
22.	03 1750	Faclo Tablet 135mg Each Tablet Contain: Mebeverine HCL…..135mg	13-11-2003	Dy. No. 42662 13-12-2018 10000/-	w.e.f. 13-11-2018 to 12-11-2023
23.	022547	Nidol Tablet 0.100g Each Tablet contain: Nimesulide ….0.100gm	28-11-1998	Dy. No. 42662 13-12-2018 10000/-	w.e.f. 28-11-2018 to 27-11-2023
24.	03 1747	Sulvo Tablet 25mg Each Tablet Contain: Levosulpiride….25mg	13-11-2003	Dy. No. 42662 13-12-2018 10000/-	w.e.f. 13-11-2018 to 12-11-2023
25.	03 1748	Sulvo Tablet 50mg Each Tablet Contain: Levosulpiride….50mg	13-11-2003	Dy. No. 42662 13-12-2018 10000/-	w.e.f. 13-11-2018 to 12-11-2023
26.	004184-EX	Rumapril Tablet 5mg Each Tablet Contains: Lisinopril Dihydrate eq. to Anhydrous Lisinopril…5mg	02-07-2013	Dy. No. 25024 dated 18-07-2018 10000/-	w.e.f. 02-07-2018 to 01-07-2023
27.	004185-EX	Rumapril Tablet 10mg Each Tablet Contains: Lisinopril Dihydrate eq. to Anhydrous Lisinopril…10mg	02-07-2013	Dy. No. 25024 dated 18-07-2018 10000/-	w.e.f. 02-07-2018 to 01-07-2023
Remarks: Firm submitted the differential fee 10000/- for each product above on 19-11-2019 as the renewal application has submitted late but within sixty days.					
M/s. Epla Laboratories (Pvt) Ltd., D-12, Estate Avenue, S.I.T.E., Karachi					
28.	050358	Esgerd 20mg Capsule Each capsules contains: Esomeprazole enteric coated pellets (as Magnesium Trihydrate)….20mg Source: M/s Inventia Healthcare Pvt Limited, F1-	04-08-2008	Dy. No. 25927 dated 27-07-2018 10000/- Differential fee for imported pellets on 06-08-2018	w.e.f. 04-08-2018 to 03-08-2023

		F1/1, additional Ambernath M.I.D.C Ambernath (East) 421 506, Distt Thane Maharashtra State India.			
Remarks: Firm submitted the differential fee for regularization of renewal of year 2013 on 25-10-2019.					
M/s. Standpharm Pakistan (Pvt) Ltd., 20-Km Ferozepur Road, Lahore					
29.	018659	Bludol Suspension Each 5ml contains Ibuprofen …. 100mg	**06-02-1996**	10,000 dated 15-01-2016 Dy. No. 9964 dated 16-03-2018 10,000/-	w.e.f. 06-02-2016 to 05-02-2021
Remarks: Firm was asked to clarify regarding the renewal application submitted in 2018, according to the initial registration date renewal is due on 05-02-2016 ,if there is any post registration variation evidence will required. Further evidence of renewal of year 2013 will also be submitted. In the reply firm stated that initial Registration date of Pack size (90ml) is 06-02-1996 and according renewal for pack size 90ml was applied on 2011 and 2016.While the approval for additional pack (120ml) has been given in 2008 and accordingly renewal applied in 2013 and 2018. It is deliberated that as the pack size of 120ml was also granted to the firm in continuation of the pack size of 90ml granted in Initial Registration Letter. Therefore, the renewal may be approved w.r.t. its initial date of registration.					
M/s. Bloom Pharmaceuticals (Pvt) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar					
30.	022577	Cyten 10mg Tablet Each tablet contains: Cetirizine Dihydrochloride...10mg	08-12-1998	Dy. No. 40460 dated 5-12-2018 10000/-	w.e.f. 08-12-2018 to 07-12-2023
31.	022576	Piroc-20mg Capsules Each capsule contains: Piroxicam…20mg	08-12-1998	Dy. No. 40460 dated 5-12-2018 10000/-	w.e.f. 08-12-2018 to 07-12-2023
32.	022578	Zonid 400mg Tablet Each tablet contains: Metronidazole…400mg	08-12-1998	Dy. No. 40460 dated 5-12-2018 10000/-	w.e.f. 08-12-2018 to 07-12-2023
33.	022579	Zonid Suspension 60ml Each 5ml contain: Metronidazole….200mg	08-12-1998	Dy. No. 40460 dated 5-12-2018 10000/-	w.e.f. 08-12-2018 to 07-12-2023
Remarks: Differential fee required as renewal of year 2013 was submitted after due date but within sixty days. Firm has now submitted the differential fee of Rs.10, 000/- each dated 08-11-2019.					
M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozepur Road Lahore					
34.	030859	Celicob Capsule 200mg Each capsule contains:- Celecoxib……..200mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 16-08-2018 to 15-08-2023
35.	030860	Seroless Tablet 20mg Each tablet contains:- Paroxetine (as HCl)…20mg	**16-08-2003** Change of brand name dated: 18-05-2011	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 16-08-2018 to 15-08-2023
36.	030870	Tretinex Cream Contains:- Tretinoin……..0.05%	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 16-08-2018 to 15-08-2023
37.	030875	Aerius Tablets 10mg Each tablet contains:- Ebastine…….10mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 16-08-2018 to 15-08-2023
38.	030876	Dinaphin Injection 500mg	16-08-2003	Dy. No. 33728	w.e.f. 16-08-2018 to

		Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone ……..500mg		dated 11-10-2018 20000/-	15-08-2023
39.	030880	Probase Tablets 5mg Each tablet contains:- Bisoprolol Fumarate……..5mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 16-08-2018 to 15-08-2023
40.	030881	Probase Tablets 10mg Each tablet contains:- Bisoprolol Fumarate…….10mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 16-08-2018 to 15-08-2023
41.	051159	Procon Tablets 10mg. Each enteric coated tablet contains:- Rabeprazole Sodium……..10mg.	01-09-2008	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 01-09-2018 to 31-08-2023
42.	051160	Procon Tablets 20mg. Each Enteric Coated Tablet Contains:- Rabeprazole Sodium……..20mg.	01-09-2008	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 01-09-2018 to 31-08-2023
43.	052469	Hyseke Solution Each Bottle Contains Ketoconazole..... 2% w/v	13-09-2008	Dy. No. 33728 dated 11-10-2018 20000/-	w.e.f. 13-09-2018 to 12-09-2023
M/s. Xenon Pharmaceuticals (Pvt) Ltd, 9.5-Km Sheikhupura Road Lahore.					
44.	057498	Somepra 20mg Capsule Each Capsule contains:- Esomeprazole magnesium trihydrate eq to Esomeprazole(Pellets) …20mg Source of Pellets: M/s Cornileus Pharmaceuticals (Pvt) ltd, Plot No. 43H..NO 7-1-414/43, Santosh Mansion srinivas colony (EAST) S.R, Hyderabad-500038 Andhra Pradesh, India.	19/05/2009	Dy. No.2217 dated 17/01/2019 Rs.10000 Differential fee Rs.10000/- for renewal of year 2019 submitted on 30-08-2019 Differential fee Rs.10000/- for renewal of year 2014 submitted on 10-10-2019	w.e.f. 19-05-2019 to 18-05-2024
45.	057499	Somepra 40mg Capsule Each Capsule contains:- Esomeprazole magnesium trihydrate eq to Esomeprazole(Pellets) …40mg Source of Pellets: M/s Cornileus Pharmaceuticals (Pvt) ltd, Plot No. 43H..NO 7-1-414/43, Santosh Mansion srinivas colony (EAST) S.R, Hyderabad-500038 Andhra Pradesh, India.	19/05/2009	Dy. No.2218 dated 17/01/2019 Rs.10000 Differential fee Rs.10000/- for renewal of year 2019 submitted on 30-08-2019 Differential fee Rs.10000/- for renewal of year 2014 submitted on 10-10-2019	w.e.f. 19-05-2019 to 18-05-2024
46.	057511	Omrazo 40mg Capsule Each Capsules contains:- Omeprazole (pellets) …40mg Source of Pellets: M/s Ravoos Laboratories Ltd H. No 5-35/234/4 Plot No.6	30/05/2009	Dy. No.2213 dated 17/01/2019 Rs.10000 Differential fee Rs.10000/- for	w.e.f. 30-05-2019 to 29-05-2024

		Mythri Nagar, IDA Kukatpally Hyderabad-500072, India.		renewal of year 2019 submitted on 30-08-2019 Differential fee Rs.10000/- for renewal of year 2014 submitted on 10-10-2019	
M/s. Atco Pharma International (Pvt) Ltd., B-18, S.I.T.E., Karachi					
47.	047676	Femizet Tablets 1mg Each Film Coated Tablets Contains: Anastrozole …1mg Manufactured by : M/s. Fresenius Kabi Oncology Limited, Village Kishanpura, P.O. Guru Majra,Tehsil Nalagarh,Distt. Solan ,India	05-08-2008	Dy. No. 25638 dated 24-07-2018 20000/-	Registration Board acceded to the request of the firm and confirms the receipt of renewal application of Femizet Tablets 1mg (047676) subject to prevailing Import Policy for Finished Drugs.
M/s. Medinet Pharmaceuticals Building No.601, Lane. No. 5, Main Peshawar Road, Rawalpindi					
48.	028490	Tamodex Tablets Each tablet contains: Tamoxifen Citrate equivalent to 20mg Tamoxifen base Manufactured by: M/s. Laboratorio Varifarma S.A. Argentina	01-09-2003	Dy. No. 28385 20-08-2018 Rs. 20,000/-	Registration Board acceded to the request of the firm and confirms the receipt of renewal application of Tamodex Tablets (028490) subject to prevailing Import Policy for Finished Drugs.
49.	028493	Progace Tablet Each tablet contains: Megestrol Acetate…160mg Manufactured by: M/s. Laboratorio Varifarma S.A. Argentina	01-09-2003	Dy. No. 28384 20-08-2018 Rs. 20,000/-	Registration Board acceded to the request of the firm and confirms the receipt of renewal application of Progace Tablet (028493) subject to prevailing Import Policy for Finished Drugs.
Remarks: Firm provide the Legalized CoPP as per WHO's Format or Legalized free sale certificate and GMP certificate:					
M/s. Himont Pharmaceutical (Pvt) Ltd, 17-Km Ferozpur Road Lahore.					
50.	057407	Clotless SS Injection 20mg/ ml Each 1ml contains: - Enoxaparin as Sodium … 20mg	23-04-2009	Dy.No.3688 Dated.28/01/2019 Rs.10000	Referred to Biological Evaluation & Research Division for verification of manufacturing facility and other requirements of the

					applied biological drug.
M/s. Zakfas Pharmaceutical (Pvt) Ltd, 12-Km Bosan Road Lutafabad Multan					
51.	057072	CD Raas Powder Each kg contains:- Tylosin Tartrate … 100gm Doxycycline Hyclate … 200gm Colistin Sulphate … 50gm Bromhexine HCl … 5gm	03-04-2009	Dy. No.2839 dated.22-01-2019 Rs.10000	w.e.f. 03-04-2019 to 02-04-2024
52.	057078	Broncofas Powder Each kg contains:- Tylosin Tartrate … 100gm Doxycycline Hyclate … 200gm Colistin Sulphate … 500MIU Phenylbutazone … 12gm Bromhexine HCl … 5gm	03-04-2009	Dy. No.2839 dated.22-01-2019 Rs.10000	Deferred for approval of Phenylbutazone containing formulations in RRA as approved by Registration Board.
53.	048156	Tylozak Plus Powder Each kg contains:- Tylosin Tartrate … 25gm Furaltadone … 75gm Colistin Sulphate ... 300MIU	02-07-2008	Dy. No.2839 dated.22-01-2019 Rs.10000	Show Cause Notice to the firm as per decision in 291st meeting of Registration Board. Application of tylozak plus was applied late in 2013. (applied on 12-02-2014) Registration is invalid
M/s. Glitz Pharma, Plot No 265, Industrial Triangle, Kahuta Road, Islamadad.					
54.	060187	Azogil Suspension Each 5ml contains:- Azithromycin (as Dihydrate)… 200mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
55.	060189	Esogip 20 Tablet Each Enteric Coated Tablet Contains: Esomeprazole as Magnesium Trihydrate …20mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
56.	060190	Esogip 40 Tablet Each Enteric Coated Tablet Contains: Esomeprazole as Magnesium Trihydrate …40mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
57.	060192	Adzole 20mg Tablet Each film coated tablet contains:- Omeprazole… 20mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
58.	060193	Azogil 250mg Tablet Each film coated tablet contains:-	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs.	w.e.f. 02-09-2019 to 01-09-2024

		Azithromycin (as Dihydrate) …250mg		20,000/-	
59.	060195	Garlex syrup Each 15ml contains:- Iron Protein Succinylate 800mg eq. to Elemental Iron … 40mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
60.	060196	Azogil Tablet 500mg Each film coated tablet contains:- Azithromycin (as Dihydrate)…. 500mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
61.	060197	Glitcure Syrup Each 5ml contains:- Polysaccharide-Iron Complex eq. to elemental Iron….. 100mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
62.	060198	Ebgit 10mg Tablet Each tablet contains:- Ebastine… 10mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
63.	60199	IPF Capsule Each capsule contains:- Iron III Hydroxide Polymaltose Complex…. 100mg Folic Acid… 0.35mg	02-09-2009	Dy. No. 17429 dated 13-09-2019 Rs. 20,000/-	w.e.f. 02-09-2019 to 01-09-2024
M/s. Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151 Sector 24 Korangi Industrial Area, Karachi.					
64.	53273	Mediprzole 40mg Capsule Each capsule contains Omeprazole (enteric coated pellets)……...40mg Source of Pellets: M/s SpansulexPharmatech Phase-I IDA (Pvt) Plot No. 153 gubhash Nagar Jeedimetla, Hderabad, India.	01-12-2008	Dy.No.38500 Dated.23-11-2018 Rs.10000	w.e.f. 01-12-2018 to 30-11-2023
Deferred for following: (M-291) Differential fee is required as according to registration letter, pellets are imported.					
Evaluation by RRR: Firm has submitted fee challan of Rs. 10,000/- (Challan#0532685) dated 05/09/2019 for imported pellets.					

Decision: Registration Board considered the above case and decision is mentioned against each in the last column.

Item No. 2: Deferred Cases of Vitamin Containing Formulation

i. **1st Meeting of RRR-Section**

Sr. No.	Reg. No.	Brand Name, Composition& Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Decision
M/s S.J&G FazulEllahie (Pvt) Ltd, E/46, S.I.T.E., Karachi.					
65.	050700	**Vivacol Injection** Each 1.5 ml contains:- Iron Sorbitol Citric Acid Complex Eq. To Elemental Iron ….. 75mg Folic Acid ...750mcg Vitamin B12 ..75mcg	23-09-2008	Dy. No. 29658 dated 04-09-2018 10,000	Deferred for evaluation under Vitamin Policy
M/s. Hilton Pharma (Pvt) Ltd., Plot No. 13 - 14, Sector 15, Korangi Industrial Area, Karachi					
66.	1196-Ex	Polzin Plus 15/500 tablet Each film coated tablet contains:- Glucosamine Sulphate…….500mg Chondroitin Sulphate…….200mg Calcium Carbonate…..75mg Vitamin C…..25mg	01-04-2009	Dy. No. 728 dated 14-03-2019 10000/-	Deferred for evaluation under Vitamin Policy
67.	2167-Ex	M-Vit Baby Syrup Each 5ml contains:- Vitamin A as Plminate……150IU Vitamin D3……100IU Vitamin C…….50mg Nicotinamide….10mg D-Penthenol…….5mg Folic Acid…….0.1mg Vitamin B1…..1.0mg Vitamin B2…….1.0mg Vitamin B12….1.0mg	26-06-2009	Dy. No. 728 dated 14-03-2019 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Abbott Laboratories Pakistan Ltd, Opposite Radio Pakistan Transmission Centre Hyderabad Road Landhi Karachi.					
68.	007278	Cofcol Elixir Each 15ml contains:- Paracetamol……..325mg Pseudoephedrine HCL..30mg Dextromethorphan HBr……10mg Chlorpheniramine Maleate……..1mg Vitamin C…….50.00mg	18-06-1984 Change of formulation dated 25-01-2002	Dy. No. 3750 dated 16-04-2019 10000/-	Deferred for evaluation under Vitamin Policy
M/s Zafa Pharmaceutical Laboratories Pvt Limited, L-4/1 , A&B , Block 21 Federal B Industrial Area Karachi					
69.	030625	Zecap Capsule 200mg Each Capsule contains:- Vitamin E (dl-Alpha Tocopherol acetate) …200mg	09-06-2004	Dy. No. 2790 dated 05-04-2019 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Wilson's Pharmaceuticals, 387-388 Sector I-9 Industrial Area Islamabad.					
70.	007584	Vitamin-E Tablets Each tablet contains:- Vitamin E…….100mg	11-10-1984	Dy. No. 3110 dated 09-04-2019 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Tabros Pharma, Plot No. L-20/B Karachi Industrial Area Sector-22 Federal B Area Karachi.					
71.	024972	**Zeest Tablet** Each tablet contains: Vitamin A …5000IU	09-08-1999	Dy. No. 7167 Dated 24-05-2019	Deferred for evaluation under Vitamin Policy

		Vitamin E …100mg Vitamin C …500mg L-Optizinc …20mg Selenium …0.02mg Chromium nicin bounded …0.20mg		Rs. 10000/-	

ii. **2nd Meeting of RRR-Section**

Sr. No.	Reg. No.	Brand Name, Composition& Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Decision
M/s. Martin Dow Marker Ltd., 7, Jail Road, Quetta ,Pakistan					
72.	033794	Osteocur-C-Effervescent Granules Each sachet of Effervescent Granules contains: Calcium Lactate Gluconate…….1000 mg, Calcium Carbonate.… 327 mg Ascorbic Acid..... 500 mg	06-09-2004 Transfer of registration dated: 03-03-2008 Transfer of registration dated: 07-06-2018	Dy. No. 6598 dated 21-02-2018 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi					
73.	009876	Vidaylin-T Tablet Each Tablet Contains: Vitamin A……...2500IU Vitamin D……..400IU Vitamin E……...15IU Vitamin B1…….1.05mg Vitamin B2……1.2mg Vitamin B12…..4.5mcg Niacinamid…...13.5mg Vitamin C…..60mg Folic Acid…….0.3mg Vitamin B6…..…1.05mg	19-09-1988 Change of brand name dated 07-02-2005	Dated 28-08-2018 10000/- Firm submitted evidence of renewal of year 2015 According to the date of change of brand name.	Deferred for evaluation under Vitamin Policy
Remarks: Firm is asked to provide the evidence of renewal submission of year 2013 according to the initial registration date. In their reply firm stated that they do not want to maintain the renewal of registration from initial registration dates and will continue the renewal of registration from the date of change of brand name (07-02-2005).Further firm provide the evidence of complete trail of renewal from the aforesaid date of change of brand name. (Reg. No. 009876)					
M/s. Genome Pharmaceuticals (Pvt) Ltd., Plot No.16/1 Phase No. IV Industrial Estate Hattar Distt Haripur.					
74.	060086	Alfagen Capsule Each capsule contains:- Alfacalcidol.....0.5mcg	02-09-2009	Dy. No. 16242 dated 29-08-2019 10000/-	Deferred for confirmation of manufacturing facility for soft gelatin capsule.
M/s. Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre Hyderabad Road, Landhi, Karachi					
75.	007734	Paramet-Fa GradumetFilmtab Each Tablet Contains:- Vitamin A…4000iu (1.2mg) Vitamin D …400iu (10mcg) Vitamin C 100mg Vitamin B1 3mg Vitamin B2 2mg	17-01-1985 Change of brand name dated 20-09-2013	Dy. No. 15683 dated 26-08-2019 10000/-	Deferred for evaluation under Vitamin Policy

		Vitamin B6 5mg Vitamin B12 3mg Nicotinamide 10mg Cal. Pentothenate 1mg Calcium 250mg (As Calcium Carbonate) 250mg Iodine (As Calcium Iodate) 100mg Copper (As Cupric Chloride) 0.15mg Iron (As Ferrous Sulfate) 60mg			
M/s. Neomedix, Plot No. 5, N/5 National Industrial Zone, Islamabad.					
76.	033698	Nytacon Liquid Each 5ml contains: Vitamin B12 ……..35mcg	31-08-2004	Dy. No. 14896 dated 19-08-2019 10000/-	Deferred for evaluation under Vitamin Policy
77.	033702	Calfit Syrup Each 5ml contains: Calcium Phosphate (Tribasic)…..210mg Vitamin D3……350 IU	31-08-2004	Dy. No. 14896 dated 19-08-2019 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Himont Pharmaceutical, 17-Km Ferozpur Road Lahore.					
78.	16046	Enervit Tablet Each tablet contains Vitamin B1… 15mg Vitamin B2… 15mg Vitamin B6… 10mg Vitamin B12… 10mcg Calcium Pantothenate… 25mg Vitamin C … 500mg Folic Acid … 1mg Niacinamde… 100mg	01-11-1994	Dy. No. 17362 dated 17-08-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy
79.	16047	Enervit Syrup Each 5ml contains:- Vitamin B1… 10mg Vitamin B2… 10mg Vitamin B6… 10mg Vitamin B12… 5mcg Calcium Pantothenate… 3mg Vitamin C … 300mg Folic Acid … 0.5mg Niacinamide… 50mg Lysine Monohydrate … 200mg	01-11-1994	Dy. No. 17362 dated 17-08-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy
80.	16048	Hikap M Tablet Each tablet contains: vitamin A… 5000 IU Vitamin D… 500IU Vitamin B1... 10mg Vitamin B2… 10mg Vitamin B6… 4mg Vitamin B12... 5mcg Vitamin E… 50IU Vitamin C.... 300mg Calcium Pantothenate… 20mg Folic Acid … 1mg Biotin … 300mcg Calcium… 100mg Iron … 50mg	01-11-1994	Dy. No. 17362 dated 17-08-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy

		Iodine… 100mg Magnesium … 10mg Copper .. 2mg Zinc…. 15mg Maganese… 5mg Chromium… 15mcg Selenium... 15mcg Molybdenum... 15mcg Potassium... 7.5mg Nicotinamide ... 50mg Phosphorus... 25mg			
81.	16049	Hikap M Syrup Each 5ml contains:- vitamin A… 1mg Vitamin D… 1mg Vitamin B1… 10mg Vitamin B2… 10mg Vitamin B6… 1mg Vitamin E… 25IU Vitamin C… 150mg Calcium Pantothenate… 5mg Folic Acid … 0.5mg Biotin … 100mcg Calcium… 50mg Iron … 25mg Iodine… 20mg Magnesium … 5mg Copper .. 1mg Zinc…. 1mg Maganese… 1mg Chromium… 5mcg Selenium... 5mcg Molybdenum... 5mcg Potassium... 2.5mg Nicotinamide ... 20mg Phosphorus... 50mg Choline ... 10mg Inositol... 10mg Lysine Monohydrate... 200mg	01-11-1994	Dy. No. 17362 dated 17-08-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy
M/s. Paramount Pharmaceuticals, 36 Industrial Triangle, Kahuta Road, Islamabad.					
82.	33992	Tricos Syrup Each 15ml contains:- Paracetamol… 325mg Pseudoephedrine HCl… 30mg Dextromethorphan… 10mg Vitamin C… 50mg Chlorpheniramine Maleate… 1mg	23-09-2004	Dy. No. 17604 dated 16-09-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy
M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi					
83.	25532	Avelac-C Chewablet Tablet Each chewabletcontains:- Calcium Ascorbate eq. to Vitamin C… 300mg	25/11/1999	Dy. No. 17258 dated 11-09-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy
84.	25531	Calix Chewablet Tablet Each Chewablet tablet contains:- Vitamin A …2500IU	**25-11-1999** Change of BN: 18-12-2003	Dy. No. 17258 dated 11-09-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy

		Ascorbic Acid …30mg Vitamin D …200IU Vitamin E …15IU Vitamin B1 …0.75mg Vitamin B2 …0.85mg Niacin …10mg Vitamin B6 …1mg Folate …0.2mg Vitamin B12 …0.003mg Biotin …0.02mg Pantothenic Acid …5mg Calcium …50mg Iron …9mg Phosphorus …50mg Iodine …0.075mg Magnesium …10mg Zinc …7.5mg Copper …1mg Sodium …5mg			
M/s. Glitz Pharma, Plot No 265 Industrial Triangle Kahuta Road Islamabad.					
85.	077698	Osilex-D Tablet Each film coated tablet contains Ossein Mineral complex……..830mg eq to calcium…..……177.60mg Phosphorous……82.20mg Residual mineral salts…..24.80mg collagen……..…224mg Other Proteins……88.4mg Trace elements F1,Mg,Fe,Nim Cu corresponding to Approx…….440mg Hydroxyapatitie Vitamin D.....400IU	10/12/2013	Dy.No.38206 Dated.28/11/2018 Rs.10000	Deferred for evaluation under Vitamin Policy
86.	077699	Osilex-D Suspension Each ml contains Vitamin D……..400IU Ossein mineral complex I,eHydroxyaoatite compound (Anhydrous)…….250mg Eq to calcium……..53.50mg Phosphorous……..24.80mg Residual Mineral salt…..7.50mg collagen……..…8750mg other protein…….20mg Trace element…..Fi, Mg, Zn, Fe, Ni, Cu corresponding to approx.....132.53mg hydroxyapatite	10/12/2013	Dy.No.38206 Dated.28/11/2018 Rs.10000	Deferred for evaluation under Vitamin Policy
87.	077700	Osilex-D Suspension Each 5ml contains Vitamin D……400IU	10/12/2013	Dy.No.38206 Dated.28/11/2018 Rs.10000	Deferred for evaluation under Vitamin Policy

		Ossein mineral complex I,eHydroxyaoatite compound (Anhydrous)…….400mg Eq to calcium……..85.59mg Phosphorous……..39.61mg Residual Mineral salt……...…12mg collagen……107.95mg other protein…….32mg Trace element…..Fi, Mg, Zn, Fe, Ni, Cu corresponding to approx.....212mg hydroxyapatite			
M/s. Bloom Pharmaceuticals (Pvt) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar					
88.	022580	Zyvit Syrup 120mg Each 5ml contain: Eiastase.....135mg Pepsin……..50mg Papine…….50mg Vitamin B1... 5mg Vitamin B2... 2mg Vitamin B6... 2mg Vitamin B12. 5mcg Nicotinamide… 20mg Cal. Pantothenate…..1mg	08-12-1998	Dy. No. 40460 dated 5-12-2018 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Polyfine Chempharma, 51 Industrial Estate Hayatabad Peshawar.					
89.	023585	Effeco Tonic Each 100ml contains:- Ferric Ammonium Citrate……900mg Folic Acid….10mg Thiamine HCl……20mg Pyridoxine……..40mg Nicotinamide….200mg	06-24-1999	Dy.No.3441 Dated.25/01/2019 Rs.10000	Deferred for evaluation under Vitamin Policy
90.	030919	Ferropro Tonic Each 10ml contains:- Vitamin A …..6000IU Vitamin D1 …. 1200IU Vitamin B1 …1.3mg Vitamin B2 …0.6mg Vitamin E … 3.0mg Nicotinamide … 13.5mg Ferric Ammonium. Citrate Green…..90mg	05-11-2004	Dy.No.3441 Dated.25/01/2019 Rs.10000	Deferred for evaluation under Vitamin Policy
M/s. Xenon Pharamaceuticals (Pvt) Ltd., 9.5-Km Sheikhupura Road Lahore					
91.	013873	Xevit Syrup 60ml/120ml Each 5ml Contains: Vitamin B1…1.5mg Vitamin B2…1.5mg Vitamin B6…1.25mg Vitamin B12…6.25mcg Vitamin C…125mg Nicotinamide…7.5mg Ferrous Sulphate…131mg	04-12-1994	Dy. No. 8717 dated 18-06-2019 10000/-	Deferred for evaluation under Vitamin Policy

M/s. Cirin Pharmaceuticals (Pvt) Ltd., Plot No. 32/2-A Phase III, Industrial Estate, Hattar					
92.	015989	Vitacal Extra Sachets Each sachet contains:- Calcium Glycerophosphate…373.3mg Calcium Carbonate…156.7mg Calcium Pantothenate…15mg Thiamine HCl (B1)…15mg Riboflavin-5-Phosphate Sodium (B2)…15mg Pyridoxine HCl (B6)…10mg Ascorbic Acid (Vit. C)…100mg Nicotinamide…50mg Sodium Bicarbonate…1000mg Citric Acid...1500mg Sodium Citrate...100mg Saccharin...6mg Dextrose (Anhydrous, Injectable Grade)...3000mg Orange Flavour...500mg	**20-09-1994** Transfer of reg to new title: 03-03-2020	Dy. No. 13985 dated 02-08-2019 10000/-	Deferred for evaluation under Vitamin Policy
93.	015990	Vitacal 1000+C Sachets Each sachet contains:- Calcium Gluconate…578mg Calcium Lactate…422mg Ascorbic Acid…500mg Calcium Carbonate…327mg Sodium Bicarbonate…500mg Citric Acid…1000mg Orange Flavour…70mg Saccharin Sodium…20mg Sodium Citrate…100mg Sucrose…6000mg	**20-09-1994** Transfer of reg to new title: 03-03-2020	Dy. No. 13985 dated 02-08-2019 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Jawa Pharmaceuticals (Pvt) Ltd., 112/10 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore					
94.	059911	Liveright Syrup Each 5ml contains:- L-Omithine L-Aspartate …… 300mg Nicotinamide…24mg Riboflavin Sodium Phosphate…0.76mg	02-09-2009	Dy. No. 15851 dated 27-08-2019 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad					
95.	025430	Super-7 Sachets Each sachet contains:- Calcium Carbonate.....550mg Calcium Lactate Gluconate……...250mg Vitamin C.....500mg Folic Acid.....1mg Vitamin B12....250mcg Vitamin B1.....2.5mg Vitamin B6.....2.5mg	23-11-1999	Dy. No. 15548 dated 23-08-2019 10000/-	Deferred for evaluation under Vitamin Policy
96.	025431	Geriaktive-M Capsules Each capsule contains:- Vitamin A (5000 iu).....5000iu Vitamin D.....500iu Vitamin B1.....10mg	23-11-1999	Dy. No. 15548 dated 23-08-2019 10000/-	Deferred for evaluation under Vitamin Policy

		Vitamin B2.....10mg Vitamin C.....300mg Vitamin B6.....4mg Calcium Pentothenate....20mg Vitamin B12.....5mcg Vitamin E.....50IU Folic Acid.....1mg Biotin.....300mcg Nicotinamide.....50mg Iron.....50mg Iodine.....100mcg Copper.....2mg Zinc.....15mg Magnesium.....10mg Manganese.....5mg Chromium.....15mcg Selenium.....15mcg Molebdenum.....15mcg Phosphorus.....25mg Potassium.....7.5mg Calcium.....100mg			

iii. **3rd Meeting of RRR-Section**

Sr. No.	Reg. No.	Brand Name, Composition& Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Decision
M/s Werrick Pharmaceuticals, 216-217,I-10/3, Industrial Area Islamabad					
97.	025040	High-C 1500 Sachets Each sachet contains:- CaCO3.....1000mg Vitamin C.....500mg Vitamin D.....500IU Vitamin B6.....10mg	05-08-1999	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
98.	025039	High-C 1500 Tablet Each tablet contains: CaCO3.....1000mg Vitamin C.....500mg Vitamin D.....500IU Vitamin B6.....10mg	05-08-1999	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
99.	016037	High- C Plus sachet Each sachet contains:- Thiamine HCl…….15mg Riboflavin-5-Phosphate Sodium….15mg Pyridoxine HCl……10mg Nicotinamide…….50mg Vitamin C……..100mg Total Calcium …….134.64mg (As Pantothenate, Carbonate/Glycerophosphate / Lactate/ Gluconate)	20-09-1994	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
100.	015666	Nutrition-6 Tablet Each tablet contains: Ferrous Gluconate…250mg Vitamin B1 (Thiamine	20-09-1994	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy

		BP)…100mg Vitamin B6 (Pyridoxine HCl)…100mg Calcium Glycerophosphate…350mg Folic Acid BP…1.0mg Vitamin B12 (Cyanocobalamine) BP…250mcg			
101.	016036	High-C 1000 Sachet Each sachet contains:- Calcium Lactate Gluconate…1000mg Calcium Carbonate….327mg Ascorbic Acid…….500mg	20-09-1994	Dy. No. 10683 dated 04-07-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
M/s Nabiqasim Industries (Pvt) Ltd., 17/24 Korangi Industrial Area Karachi					
102.	024971	Multical Plus Sachets Each sachet contains:- Calcium Pantothenate.....15mg Calcium glycerophosphate.373.3mg Calcium Carbonate...156.7mg Vitamin C.....100mg Vitamin B1.....15mg Vitamin B2.....15mg Vitamin B6.....10mg Nicotinamide.....50mg	20-07-1999	Dy. No. 10912 dated 08-07-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
103.	024970	Multical 1000 Sachets Each sachet contains:- Calcium Lactate Gluconate .....1000mg Calcium Carbonate...327mg Vitamin C.....500mg Folic Acid.....1mg Vitamin B12.....250mcg	20-07-1999	Dy. No. 10912 dated 08-07-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Jawa Pharmaceutical (Pvt) Ltd., 112/10, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.					
104.	060604	Calchew D Tablet Each chewable tablet contains:- Calcium Carbonate .. 1250mg (eq. to 500mg elemental Calcium) Vitamin D…125IU	21-10-2009	Dy. No. 20030 dated 08-10-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Neomedix, Plot No. 5/N-5 National Industrial Zone, Islamabad.					
105.	034090	Feplus B Liquid Each 5ml contains:- Ferrous Sulphate… 131mg Vitamin C… 125mg Vitamin B2… 1.5mg Vitamin B6… 1.25mg Vitamin B12… 6.25mg Nicotinamide… 7.5mg Dexpanthenol… 2.5mg	27-10-2004	Dy. No. 21666 dated 23-10-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Bloom Pharmaceutical (Pvt) Ltd, Plot No. 30 Phase I & II Industrial Estate Hattar.					
106.	016460	Blomic Syrup Each 5ml contains:- Ferrous Gluconate… 129.5mg Vitmain B1… 1mg Vitamin B2… 1mg Vitamin B6… 1.5mg	21-11-1994 Change of brand name from theron-F syrup on	Dy. No. 24563 dated 21-11-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy

		Biotin … 30mcg Nicotinamide… 15mg	19-11-1999		
107.	016478	Theron F Capsule Each capsule contains:- Ferrous fumarate… 300mg Vitamin B12…. 7.5mcg Vitamin C …100 mg Vitamin B1…. 10mg Vitamin B2…. 5mg Vitamin B6… 5mg Nicotinamide… 10mg Folic acid… 1mg Calcium Pantothenate… 10mg	21-11-1994	Dy. No. 24563 dated 21-11-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Irza Pharma (Pvt) Ltd, 10.2-Km Lahore Sheikhupura Road P.O Kot Abdul Malik District Sheikhupura.					
108.	007799	Ascorbic Acid 100mg Tablet Each tablet contains:- Ascorbic Acid… 100mg	01-01-1985	Dy. No. 22998 dated 07-11-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
109.	007806	K-Vit Tablet Each tablet contains:- Acetamenaphthone… 10mg	01-01-1985 Change of brand name from vitamin K tablet on 15-09-1997	Dy. No. 22998 dated 07-11-2019 Rs. 10000/-	Deferred for evaluation under Vitamin Policy
M/s. Olive Laboratories, 52 -S6, National Industrial Zone, Rawat, Rawalpindi					
110.	032615	Enemik Syrup Each 5ml Contains: Ferrous Gluconate…130mg Thiamine HCl(B1)…1.5mg Riboflavin (B2)…1mg Pyridoxine HCl (B6)…1.5mg Nicotinamide…15mg Calcium Pantothenate…1mg L.Lysine HCl…50mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy
111.	032616	Enemik Tablet Each Tablet Contains: Ferrous Fumarate…200mg Thiamine HCl (B1)…2.5mg Riboflavin (B2)…2.5mg Pyridoxine HCl (B6)…2.5mg Cyanocobalamine (B12)…25mcg Nicotinamide…25mg Folic Acid…1mg Calcium Pantothenate…10mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy
112.	032617	Olivit Tablet Each Tablet Contains: Thiamine HCl (B1)…15mg Riboflavin (B2)…15mg Pyridoxine HCl (B6)…10mg Cyanocobalamine (B12)…10mcg Nicotinamide…10mg Folic Acid…1mg Calcium Pantothenate…25mg Ascorbic Acid (Vit. C)…100mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy
113.	032618	Olivit Drop	07-11-2004	Dy. No.	Deferred for

		Each ml Contains: Thiamine HCl (B1)…3mg Riboflavin 5 Phosphate Sodium (B2)…3mg Pyridoxine HCl (B6)…2mg Cyanocobalamine (B12)…1mcg Ascorbic Acid (Vit. C)…50mg Nicotinamide…10mg Calcium Pantothenate (D-pantothenol)…25mg L.Lysine monohydrate (as HCl)…5mg		13187 dated 25-07-2019 Rs. 10,000/-	evaluation under Vitamin Policy
114.	032619	Olivit Syrup Each 5ml Contains: Thiamine HCl (B1)…10mg Riboflavin 5 Phosphate Sodium (B2)…10mg Pyridoxine HCl (B6)…10mg Cyanocobalamine (B12)…5mcg Ascorbic Acid (Vit. C)…150mg Nicotinamide…50mg Calcium Pantothenate (D-pantothenol)…3mg L.Lysine monohydrate (as HCl)…20mg	07-11-2004	Dy. No. 13187 dated 25-07-2019 Rs. 10,000/-	Deferred for evaluation under Vitamin Policy

Decision: Registration Board considered the above case and decision is mentioned against each in the last column.

Item No. 3 Harmonization of Formulation as per Reference Product:

Registration Board in its 293rd meeting decided that Renewal letter shall be issued as per format approved by Registration Board and following condition will also be included as well

"The manufacturer shall apply for post registration variation approval for correction in description of dosage form (for e.g. sugar coated tablet, film coated tablet, enteric coated tablet etc. addition and deletion of salt etc.) change in specification i.e. USP, BP, JP or Eur Ph. etc. and any other change in product that requires the said approval in accordance with approval of formulation in reference regulatory authorities as approved by Registration Board / innovator drug product"

It has now been proposed that correction in description of dosage form (for e.g. sugar coated tablet, film coated tablet, enteric coated tablet etc., may be reviewed by the RRR section and correction in accordance with approval of formulation in reference regulatory authorities as approved by Registration Board / innovator drug product may be approved by the renewal committee and renewal letter may be issued after the firm submit the prescribed fee for said correction.

Decision: Registration Board approved that correction in description of dosage form (for e.g. sugar coated tablet, film coated tablet, enteric coated tablet etc.), salt form, specifications and any other minor correction in the label / formulation shall be reviewed by the RRR section in accordance with approval of formulation in reference regulatory authorities as adopted by Registration Board / innovator drug product. The same shall be approved by the renewal committee and renewal letter shall be issued, after submission of prescribed fee for said correction by the firm.

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Item No. IV Division of Biological Evaluation & Research

Sr. No.	Detail of Products	No. of Cases
A	Imported Human Biologicals from Non-Reference Countries	01
B	Imported Veterinary Biologicals from Reference Countries	01
C	Imported Veterinary Biologicals from Non-Reference Countries	03
D	Miscellaneous/ Deferred cases	58
Additional Agenda		07
Total		70

Sr. No.	Assistant Director	Designated No.	No. of Cases
a.	Mr. Khurram Khalid	AD-I	09
b.	Mr. Saadat Ali Khan	AD-II	37
c.	Mr. M. Zubair Masood	AD-III	24

A: Imported Human Biologicals from Non-reference Countries

1.	**Name of Applicant**	**M/s Bristol Mayer Biotech Pakistan,** 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt.
	DSL details	DSL License No.05-352-0066-027191D valid upto 03-Jan-2020.
	Name of Manufacturer	VEM ÌLAÇ San. Ve Tic. A.S. Sogutozu Mahallesi 2177. Cad. No:10 B/49 Cankaya / ANKARA / TURKEY **Factory Address:** Cerkezkoy Organize Sanayi Bolgesi Karaagac Mahallesi Fatih Bulvari No:38 Kapakli/TEKIRDAG/TURKEY.
	Brand Name Dosage Form Strength	**Vasparin 25000 IU/5mL I.V.** Solution for Injection Vial Each vial contains 25000 IU Heparin sodium
	Composition	Each 5ml (1 vial) Contains: Heparin sodium…….25000IU
	Finished product specifications	European Pharmacopoeia (Ph. Eur.)
	Pharmacological Group	Antithrombotic agent/heparin group,
	Shelf life	36 Months [3 Years] (Store at room temperature below 25^{o}C)
	International availability	Heparin 5,000 I.U./ml, solution for injection by PANPHARMA Z.I. du Clairay 35133 Luitré France.
	Alternate Products already registered in Pakistan	Heparin-Belmed Injectionby M/s Genome Pharma, Rawalpindi.
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A Dy.No.14612(R&I)DRAP Dated 19-4-2018. Fee of 50,000/- dated 19-4-2018.
	Demanded Price Pack size	As per SRO 1 vial / box
	General documentation	i. Original Legalized Certificate of Pharmaceutical Product having Certificate No.2018/1615 issued by Turkish Medicines and Medical Devices Agency, Republic of Turkey, Ministry of Health valid until 26-04-2020. ii. Original Legalized GMP and Free Sales Certificate having Certificate No.2018/1553 issued by Turkish Medicines and Medical Devices Agency, Republic of Turkey, Ministry of Health valid until 25-04-2020.
	Evaluator Comments	Heparin is porcine sourced.
	Decision: Registration Board deferred the case till the decision of DRAP's Authority on products from porcine source.	

B: Imported Veterinary Biologicals From Reference Countries.

1.	**Name of Importer**	**M/s Saadat International,** 117-Habitat Appartments, Shadman-II, Jail Road, Lahore.
	DSL details	License No. 05-352-0063-034417D valid till 12-06-2020.
	Name of Manufacturer	**Product License Holder:** M/s Merial, 29 Avenue Tony Garnier, 69007 Lyon, France. **Manufacturer:** M/s Merial, Rue De L'Aviation, 69800 St Priest, France.
	Brand Name +Dosage Form + Strength	Avinew Neo Effervescent Tablet
	Composition	Each dose contains: Live Newcastle disease virus……..≥5.5$\log_{10}$$EID_{50}$(*) (*) EID_{50}: Egg Infectious dose 50%.
	Finished product specifications	Ph. Eur. Specifications.
	Pharmacological Group	Veterinary Vaccine

	Shelf life	19 months (2^0C -8^0C)
	International availability	France
	Products already registered in Pakistan	Avinew Neo 1 Blister of 10 Tablets of 1000 doses (Reg. No. 082024)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 1393, 26057, 2823 & 10608 Dated: 29-11-2016, 30-07-2018, 22-01-2019 & 03-07-2019 Rs. 100000/- Dated 29-11-2016
	Demanded Price /Pack size	1 Blister of 10 Tablets of 2000 doses / De-controlled
	General documentation	• Legalized GMP Certificate No. 18/213927 dated 06-09-2018 issued by French Agency for Veterinary Medicinal Products. • Legalized FSC No. 18-221829 dated 06-12-2018 issued by French Agency for Veterinary Medicinal Products.
	Remarks of Evaluator	• The firm already has registration of above product in pack size of 1 Blister of 10 Tablets of 1000 doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin and approval of France (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

C: Imported Veterinary Biologicals From Non-Reference Countries.

1.	**Name of Importer**	**M/s Mustafa Brothers P-186-D, People Colony No. 1, Faisalabad**
	DSL details	CDSL No: 06-331-0168-031770D Expiry Date: 21-06-2020 Place: Faisalabad
	Name of Manufacturer	Federal state enterprise "Stavropol biofactory" Stavropol city, 18 Biological street, 355019, Russia.
	Brand Name +Dosage Form + Strength	**Pulmovac** Inactivated emulsified vaccine against pasteurellosis of ruminant animal
	Composition	**Each dose of one ml contains:** • *Pasteurella multocida* (Strain no. 796/Serotype B) …At least $3x10^9$CFU • *Pasteurella multocida* (strain № 1231/serogroup A)..At least $3x10^9$CFU • *Pasteurella multocida* (strain № T-80/serogroup D)..At least $3x10^9$CFU • *Manncheimia* (*Pasteurella*) *haemolytica* (strain № H-42/serotype A: 1) ……At least $3x10^9$CFU
	Finished product specifications	BP Specification
	Pharmacological Group	Veterinary Vaccine
	Shelf life	18 months (2^0C -8^0C)
	Products already registered in Pakistan	
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 12801 (R&I) Dated 23-07-2019
	Demanded Price / Pack size	Decontrolled/ 100mL Vial
	General documentation	• Legalized copy of Free Sale Certificate dated 05-02-2019 issued by Russian Export Center Moscow • Legalized Certificate of compliance of GMP dated 16-02-2016 issued by

		Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) valid until 25-02-2019 • GMP certificate issued by German Regulatory body but legalization is not from Germany and it is mentioned clearly on the said certificate "This certificate is exclusively applicable to contract manufacturing & quality control of ringworm vaccines by the above named manufacturer for delivery to IDT Biologika GnbH." • Certificate of GMP compliance issued by Bulgarian Food Safety Agency but legalization is done in Russia.
	Remarks of Evaluator	GMP certificate provided by the firm has been issued by Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System). The regulatory status is not clear. The clarification was sorted from the firm and the firm has submitted that in the Russia the same authority is authorized to issue GMP for veterinary products and couple of our already registered & under registration vaccines which are from the Russia the GMP are issued by the same authority .Furthermore the following documents are submitted. i. The copy of Manufacturing License/Permit from Ministry of Agriculture "Federal Service for Veterinary and Phytosanitary Supervision" (ROSSEKHOZNADZOR). ii. German GMP attached along with clarification from the manufacturer "FSE Stavropol Biofactory" Russia. iii. Russian GMP is issued by their nominated competent authority "Rosstandart-Certification Body of Management System Moscow (Voluntary Certification System) All-Russian Scientist Research Institute for the Certification (JSC"VNIIS"). Links translation is enclosed.
	Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The panel of inspectors shall verify the authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by regulatory body of country of origin. The registration letter shall be issued after said verification.	
2.	Name of Importer	M/s Mustafa Brothers P-186-D, People Colony No. 1, Faisalabad
	DSL details	CDSL No: 06-331-0168-031770D Expiry Date: 21-06-2020 Place: Faisalabad
	Name of Manufacturer	Federal state enterprise "Stavropol biofactory" Stavropol city, 18 Biological street, 355019, Russia,
	Brand Name +Dosage Form + Strength	Antox 9 Inactivated vaccine against clostridiosis of agricultural animals
	Composition	*Active components in one immunizing dose of the drug:* • *Clostridium perfringens* type A…..2.0 International Unit • *Clostridium perfringens* type C…..10.0 International Unit • *Clostridium perfringens* type D….5.0 International Unit • *Clostridium novyi* (oedematiens) type B…3.5 International Unit • *Clostridium novyi* (oedematiens) type A…3.5 International Unit • *Clostridium tetani*……..2.5 International Unit • *Clostridium sordellii* ……3.5 International Unit • *Clostridium septicum*……$8x10^9$ Cells * • *Clostridium chauvoei*……..$8x10^9$ Cells * * – Allows to get a 90% level of protection of antibodies on test animals
	Finished product specifications	BP Specification

	Pharmacological Group	Veterinary Vaccine
	Shelf life	18 months (2^0C -8^0C)
	Products already registered in Pakistan	Toxipra Plus
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 12802 (R&I) Dated 23-07-2019
	Demanded Price / Pack size	Decontrolled/ 100mL Vial
	General documentation	• Legalized copy of Free Sale Certificate dated 05-02-2019 issued by Russian Export Center Moscow • Legalized Certificate of compliance of GMP dated 16-02-2016 issued by Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) valid until 25-02-2019 • GMP certificate issued by German Regulatory body but legalization is not from Germany and it is mentioned clearly on the said certificate "This certificate is exclusively applicable to contract manufacturing & quality control of ringworm vaccines by the above named manufacturer for delivery to IDT Biologika GnbH." • Certificate of GMP compliance issued by Bulgarian Food Safety Agency but legalization is done in Russia.
	Remarks of Evaluator	GMP certificate provided by the firm has been issued by Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System). The regulatory status is not clear. **(Response of the as described in above product)**
	Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The panel of inspectors shall verify the authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by regulatory body of country of origin. The registration letter shall be issued after said verification.	
3.	**Name of Importer**	**M/s Mustafa Brothers P-186-D, People Colony No. 1, Faisalabad**
	DSL details	CDSL No: 06-331-0168-031770D Expiry Date: 21-06-2020 Place: Faisalabad
	Name of Manufacturer	Federal state enterprise "Stavropol biofactory" Stavropol city, 18 Biological street, 355019, Russia,
	Brand Name +Dosage Form + Strength	**Leptogard** Inactivated lyophilized vaccine against leptospirosis of animals
	Composition	One immunizing dose of the vaccine (4cm^3) contains at least: VGNKI-1 (Grippotyphosa)…… 188 millions bacteria VGNKI-4 (Tarassovi)……188 millions bacteria VGNKI-6 (Pomona)…… ……..188 millions bacteria Hardjo (Sejroe)…… ……..188 millions bacteria
	Finished product specifications	BP Specification
	Pharmacological Group	Veterinary Vaccine
	Shelf life	18 months (2^0C -8^0C)
	Products already registered in Pakistan	
	Type of Form	Form-5A

	Dy No & Date of application,Fee submitted	Dy. No. 12800 (R&I) Dated 23-07-2019
	Demanded Price / Pack size	Decontrolled/ 100mL vial
	General documentation	• Legalized copy of Free Sale Certificate dated 05-02-2019 issued by Russian Export Center Moscow • Legalized Certificate of compliance of GMP dated 16-02-2016 issued by Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) valid until 25-02-2019 • GMP certificate issued by German Regulatory body but legalization is not from Germany and it is mentioned clearly on the said certificate "This certificate is exclusively applicable to contract manufacturing & quality control of ringworm vaccines by the above named manufacturer for delivery to IDT Biologika GnbH." • Certificate of GMP compliance issued by Bulgarian Food Safety Agency but legalization is done in Russia.
	Remarks of Evaluator	GMP certificate provided by the firm has been issued by Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System). The regulatory status is not clear. **(Response of the as described in above product)**
	Decision:	**Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The panel of inspectors shall verify the authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by regulatory body of country of origin. The registration letter shall be issued after said verification.**

D: Miscellaneous/ Deferred cases

1. Registration of human biologicals from M/s Seignior Pharma, Karachi to M/s The Searle Company Limited, Karachi applied by M/s The Searle Company Limited, Karachi deferred in 293rd meeting of Registration Board.

M/s The Searle Company Limited, Karachi applied for the registration of following human biologicals in their name from M/s Seignior Pharma, Karachi. The detail of the product is as follows:

Reg. No.	Name of Manufacturer	Brand Name & Composition	Document Details/ Pack Size	Dy. No. Date of Application Fee Status
031321	M/s Bio Sidus S.A., Av de los Quilmes 137, Bernal Qeste, Quilmes, Province of Buenos Aires, Argentina	Neutromax 300ug Injection Each vial contains: Figrastim……300ug Shelf Life: 24 months (2^0C-8^0C)	Valid legalized CoPP No. 20132020000142-18 dated 05-03-2018/ 1's Vial	Dy. No. 83(R&I) 24-04-2017 Rs. 100000/- 24-04-2017
031322		Neutromax 480ug Injection Each vial contains: Figrastim……480ug Shelf Life: 24 months (2^0C-8^0C)	Valid legalized CoPP No. 20132020000145-18 dated 05-03-2018/ 1's Vial	Dy. No. 81(R&I) 24-04-2017 Rs. 100000/- 24-04-2017

The firm has submitted the following documents:

a. Application on Form-5A
b. Fee Challan of Rs. 100000/-

c. Copy of Initial Registration letter dated 11-11-2003.
d. Last renewal submissions dated 24-10-2018
e. Termination letter (original) from manufacturer for previous importer
f. Authority letter/sole agent letter (original) from manufacturer
g. NOC from M/s Seignior Pharma, Karachi dated 18-09-2018
h. Biosimilarity data submitted by the firm is detailed below:

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill)manufactured from country of origin.	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	Primary Structure: a. Determination of Primary Structure (Full Amino Acid and Disulfide Bond Sequencing) b. Determination of the number of free sulfhydryl groups c. Verification of the correct formation of disulfide bonds d. N and C Terminal Sequence Analysis e. Peptide Mapping by RP-HPLC Secondary and Tertiary Structure: a. Circular Dichorism b. Fluorescence Molecular Mass and Quaternary Structure a. Molecular mass determination by LC ESI-TOF-MS b. SDS-PAGE Electrophoretic Profiles a. Characterization by Isoelectric Focusing b. SDS-PAGE c. Western Blot HPLC a. RP-HPLC b. SEC-HPLC
Biological Activity	Stimulating effect on the specific proliferation of a line cell derived from myeloid leukemia.
Immunochemical properties	To evaluate the immunogenicity of filgrastim in rats that received different preparations of recombinant human filgrastim
Impurities	Product Related Impurities 1. Forced Degradation a. Impurities with molecular masses that differ from that of Filgrastim b. Dimer and related substances with higher molecular mass c. Impurities with charges that differ from that of Filgrastim d. Related proteins: Oxidized and deamidated species 2. Natural degradation a. Impurities with molecular masses that differ from that of Filgrastim b. Dimer and related substances with higher molecular mass c. Impurities with charges that differ from that of Filgrastim d. Related proteins: Oxidized and deamidated species Process derived impurities a. Absence of Host Cell DNA b. Absence of Host Cell Protein
Non-clinical Studies	a. To evaluate the biological activity by means of an in vivo technique in Balb C mice. b. To observe the response at different doses, in pre-treated mice with cyclophosphamide c. Acute Toxicity studies in mice. d. Chronic toxicity studies in mice. e. To evaluate the toxicity of Neutromax and Neupogen in rats, by the administration of high doses (the dose equivalent to the maximum used in

	humans to a dose 10-fold the highest dose) for 28 days by subcutaneous route.
Clinical Studies	a. Bioequivalence study of generic Filgrastim Injection to an Innovator Neupogen in Healthy Thai Volunteers. b. Use of Filgrastim (Neutromax) in patients with leukemia during induction and consolidation treatment. c. Utilization study of Neutromax during autologus haematopoietic precursor transplantation for myeloma and lymphoma patients. d. Assessment of two Neutromax formulations containing Mannitol or Sorbitol in the hematologic recovery and Survival outcomes in the Autologus Bone Marrow Transplantation.
Decision of RB in 287th meeting	*Registration Board deferred the case for submission of following by the firm:* *a. List of countries where the above products are imported along with regulatory requirements of respective countries.* b. *Regulatory requirements for registration of Filgrastim containing products in country of origin.*

The firm then submitted that the said product is registered in following countries:

Argentina	Bolivia	Brazil
Chile	Colombia	Dominican Republic
Ecuador	El Salvador	Georgia
Guatemala	Honduras	Ivory Coast
Lebanon	Mexico	Nicaragua
Pakistan	Paraguay	Peru
Republic of Congo	Sri Lanka	Thailand
Tunisia	Ukraine	Uruguay
Vietnam		

The firm has submitted the regulatory guidelines of above countries out of which guidelines of only following countries were in English while the rest were in their own language:

Brazil, Georgia, Lebanon, Mexico, Vietnam

All the above guidelines indicate that the therapeutic equivalence is part of comparability exercise.

The firm then now submitted the following studies:

a. Use of filgrastim (Neutromax) in Non-Hodgkin lymphoma treated with R-CHOP scheme (Phase-IV)
b. Low dose Filgrastim enhances neutrophil recovery and decrease incidence of febrile neutropenia following CHOP regimen in Non Hodgkin lymphoma patient.
c. Periodic Benefit-Risk Evaluation Report from January, 2014-December, 2017.

The case was considered in 292nd meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case for submission, of safety and efficacy studies of the product in comparison with Innovator, by the firm."

The firm then submitted the following:

"The ANMAT Health granted registration of Neutromax in the year 1995 & at that time safety and efficacy studies of product in comparison with Innovator was not required for registration of these types of products. As per their guidelines, only bioavailability data of product was required. They submitted this data to ANMAT and got the registration approval on the basis of bioavailability data."

The firm has submitted the following documents:

1) Notarized copy of Rules for registration, elaboration, fractionation, prescription, sale, marketing, export and import of medicines.
2) Notarized Copy of translation of registration certificate of Neutromax issued by ANMAT.

The case was considered in 293rd meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case for further deliberation in next meeting."

Decision: **Registration Board deliberated that the said case is of registration of a product from one importer to another and the said product is registered in Pakistan since 2003. Moreover, the firm has submitted the bioequivalence study in comparison to Innovator product along with single arm efficacy study. The firm has also submitted the periodic safety evaluation report from January, 2014 to December, 2017 to indicate the safety of the product. Keeping in view the said discussion, valid legalized CoPP indicating product availability in country of origin & data submitted in light of decision of 278th meeting; Registration Board cancelled the registration of Neutromax 300µg Injection (Reg. No. 031321) & Neutromax 480µg Injection (Reg. No. 031322) from the name of M/s Seignior Pharma, Karachi and granted registration in name of M/s The Searle Company Limited, Karachi as per current Import Policy for Finished Drugs. The Registration letter shall be issued after confirmation of cold storage facility by the area FID and MRP verification from Pricing Division.**

2. Registration of imported human biological applied by M/s Pharm Evo (Private) Limited, Karachi approved in 282nd meeting of Registration Board.

Following product of M/s Pharm Evo (Private) Limited, Karachi was approved in 282nd meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Document Details	Decision of RB in 282nd meeting
Product License holder: M/s CJSC BIOCAD, Liter A, bld.34. Svyazi st., Strelna, Petrodvortsovy district, Saint Petersburg, 198515, Russia **Manufacturer:** M/s CJSC BIOCAD Petrovo-Dalnee Village Krasnogorsky district Moscow region, 143422, Russia	Traszeptin 440mg Powder for concentrate for solution for infusion Each dose contains: Trastuzumab…440mg Solvent (bacteriostatic water for injection) Benzyl Alcohol…11.0mg Water for injections…...q.s. to 1.0ml Shelf Life: 4 years (2^0C-8^0C)	Legalized CoPP No: 09/2016/0001823 dated 06-10-2016 valid till 16-06-2019 Pack Size: 1's Vials (440mg) + 1's Vial Solvent (20ml)	*Keeping in view the biosimilarity data and submitted CoPPs; Registration Board approved the above products subject to price fixation by Federal Government and compliance of current Import Policy for finished drugs.*

The panel inspection of manufacturer abroad was conducted on 09th-10th September, 2019 by following panel of Inspectors of DRAP:

i. Prof. Dr. Rafeeq Alam Khan
ii. Sayyad Hussain Khan

The panel recommended the facility and rated **"Good".**

The price of the product has already been notified by Federal Government vide SRO 252(I)/2018 dated 21-02-2018 as per following details:

Sr. No.	Brand Name & Composition	Pack Size	Approved MRP
158.	Trastuzumab 440mg Injection Each vial contains: Trastuzumab for Injection (r-DNA origin)……..440mg/vial	Single vial with water for injection Multiple use vial combipack	Rs. 89859/-

In this context, it is submitted that on the submitted CoPPs of above product, only address of manufacturer was mentioned while name was missing and same was recorded in

minutes of meeting. However, the registration letter was issued with the name of manufacturer applied on Form-5A as same was mentioned on panel inspection report of manufacturer abroad.

Decision: Registration Board acknowledged the above information.

3. Request of M/s RG Pharmaceutica (Pvt.) Ltd., Karachi for revised registration letters of Progeffik 100mg (Reg. No. 077513) and Progeffik 200mg (Reg. No. 077514) applied by M/s RG Pharmaceutica (Pvt.) Ltd., Karachi.

M/s RG Pharmaceutica (Pvt.) Ltd., Karachi requested to issue a revised registration letter at the earliest by rectification of following typo errors:

a. For Progeffik 200mg, Shelf life of 2 years being mentioned instead of 3 years. In this regard, a letter is already submitted in DRAP dated September 27th, 2013
b. Name of manufacturer is missing on the registration letter.

Manufacturer detail is as under:
Capsulgel Laboratory,
Z1 DE Camagnon, 56803 Ploermel- France

The details of the products are as follows:

Sr. No.	Reg. No. & Date of registration	Name of Manufacturer	Brand Name & Composition	Type of Form Dy No & Date of application Fee submitted Pack size/ Demanded Price	Document details (CoPP)
1.	077513 23-09-2013	M/s Effik Batiment le Newton, 9-11, rue Jeanne Braconnier-92366, Meudon la Foret, France	Progeffik 100mg (Soft capsules for oral or vaginal use) Each capsule contains: Progesterone…… …..100mg Shelf Life: 3 years	Form-5A Dy. No. 120(R&I) 10-09-2012 Rs. 15000/- 10-09-2012 Pack of 30's/ Rs. 1140/-	Legalized CoPP no. 12/06/0604 dated 22-06-2012
2.	077514 23-09-2013	M/s Effik Batiment le Newton, 9-11, rue Jeanne Braconnier-92366, Meudon la Foret, France	Progeffik 200mg (Soft capsules for oral or vaginal use) Each capsule contains: Progesterone…… ….200mg Shelf Life: 3 years	Form-5A Dy. No. 121(R&I) 10-09-2012 Rs. 15000/- 10-09-2012 Pack of 15's/ Rs. 1055/-	Legalized CoPP no. 12/06/0603 dated 22-06-2012

The case was evaluated in light of documents submitted at the time of application and registration letter issued to the firm and following deficiencies are observed:

i. Name of manufacturer applied on Form-5A is M/s Capsugel (Pfizer Group), Zl de Camagnon, 56803 PLOERMEL- France and Product license holder is Laboratories Effik, Batiment le Newton -9-11 rue Jeanne Braconnir-92366 Meudon la foret while as per CoPP product license holder and manufacturer is M/s Laboratories Effik, Batiment le Newton -9-11 rue Jeanne Braconnir-92366 Meudon la foret and is responsible for batch release.
ii. Name of manufacturer is not mentioned on Registration letter.
iii. Clinical trials were not submitted in the dossier
iv. The products were approved in 237th meeting of Registration Board but its reference along with signed minutes is not available.

v. Price fixation reference is not available.
vi. Shelf life applied on Form-5A of Progeffik 200mg is 3 years along with real time stability data of 3 batches for 36 months but shelf life mentioned on registration letter is 2 years which requires correction.
vii. Registration letter needs to be issued as per prescribed format.

The case was considered in 277th meeting of Registration Board wherein the Board decided as follows:

"Registration Board referred the case back to DBER for verification/ confirmation of the documents along with the details of the import (name of exporter & quantities) of above products since the date of registration."

The firm has already submitted the legalized GMP certificate of M/s Capsugel Ploermel, ZI de Camagnon, Ploermel, 56800, France issued by National Drug Safety Agency and Health Products. Now the firm has submitted the valid legalized Free Sale Certificates issued by Chamber of Commerce of above products indicating M/s Capsugel, France as manufacturer. Moreover, the firm has also submitted the import invoices of above products indicating M/s Effik on the invoices.

Regarding 237th meeting of Registration Board wherein the above products were approved but signed minutes are not available, a copy of letter of Dr. Obaid Ali, then Dy. Director Biological Drugs dated 21-05-2013 having subject **"Clarification regarding 237thMeeting"**is available in DBER which indicates the following:

"All three applications of M/s RG Pharmaceuticals, Karachi were completed and required just issuance of Registration letter. These products are registered in France and other European countries"

Moreover, the firm has provided a copy of letter of Dr. Obaid Ali, Dy. Director Biological Drugs dated 08-03-2013 indicating following products:

a. Progeffik 100 mg Soft Gel Capsule containing 100mg Progesterone
b. Progeffik 200 mg Soft Gel Capsule containing 200mg Progesterone
c. NewFlora Capsule containing 75 million Enterococcus faecium F68

The letter states the following:

"Your application(s) regarding the subject to Drug Regulatory Authority of Pakistan (DRAP) is considered in 237th meeting of Drugs Registration Board (DRB) under the Drugs Act, 1976 upon the recommendation of Expert Committee on Biological Drugs (ECBD) of Division of Biological Drugs. DRB approved waiver of your application for evaluation, assessment, under "iv" of Section 2 and "e" of Section 4 of newly promulgated Drug Regulatory Authority of Pakistan Act, 2012……."

The Pricing Division has verified the prices of above products.

The case was again considered in 293rd meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case and advised DBER to bring up the case in next Registration Board meeting with complete data along with already approved such other cases."

In this context, it is submitted that example of such other case is Ropegra of M/s Roche Pakistan Limited, Karachi which was approved in 237th meeting of Registration Board and registration letter was issued accordingly. Later, the firm applied for the change in manufacturing site of Ropegra and the case was finally approved in 256th meeting of Registration Board with following discussion:

"That the recorded minutes of 237th meeting of Registration Board pertaining to Biological Division are not available in routine format. The unsigned agenda and later communications including letter of the then DDC dated 29.05.2013 and F.1-11/2013-DDC 2nd ECBD dated 11.03.2013 reflect that the case of registration of Ropegra (Peg-interferon 180mcg 40 KD) 1ml vial was discussed in 237th meeting RB. Then registration letter of aforementioned product was issued by the then Director, Biological Drugs vide letter No. Human Biological Import-5 (HBI-5) dated 19th September, 2013 bearing Registration No. 077512. Accordingly, product is being

granted lot release certificate by National Control Laboratory of Biologicals, Islamabad and thus product is available in market. In the meanwhile a petition was filed in Honorable High Court of Sindh (W.P. No 1025/ 2015 and D-2190/ 2014 filed by M/s Getz Pharma Karachi Vs FOP & others) challenging status of registration of Ropegra vial, Registration No. 077512. In this case, DRAP has submitted para wise comments admitting that Ropegra vial, Registration No. 077512 was registered after due process of evaluation in accordance with Drug (L R & A), Rules 1976 and prayed that the Registration letter issued by the DRAP is based on European Medicine Agency Certificate of Pharmaceutical Product, declaring Ropegra for Pakistan is synonym of brand "Pegasys" as internationally available."

Dicussion: Registration Board deliberated the case in light of already regularized such case of Ropegra of M/s Roche Pakistan Limited, Karachi which was also approved in 237th meeting of Registration Board and for which a letter of the then DDC was available indicating the product's discussion in 237th meeting. The letter of the then DDC is also available in instant case indicating the completion of above application and only requirement of issuance of registration letters. Moreover, the firm has already submitted legalized Free Sale Certificates for above product indicating M/s Effik, Immeuble Le Newton -9-11 rue Jeanne Braconnier 92366 Meudon La Foret Cedex, France as product license holder & M/s Capsugel, Zone Industrielle de Camagnon 56803 Ploermel, France as manufacturer and same were applied on Form-5A in an initial application. The Free Sale Certificate indicates the shelf life as 03 years.

Decision: **Keeping in view the above discussion, legalized FSC indicating demanded product license holder & manufacturer and shelf life; Registration Board advised DBER to issue corrigendum of initial registration letter indicating following points:**

- **Product License Holder:** M/s Effik, Immeuble Le Newton -9-11 rue Jeanne Braconnier 92366 Meudon La Foret Cedex, France
- **Manufacturer:** M/s Capsugel, Zone Industrielle de Camagnon 56803 Ploermel, France
- **Shelf life of Progeffik 200mg:** 03 years

4. Registration of Dengue Vaccine applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

Following vaccines of M/s Sanofi Aventis Pakistan Limited, Karachi were approved by the Registration Board in its 260th meeting held on 28th-29th June, 2016 on recommendations of WHO Strategic Advisory Group of experts (SAGE) dated 12th-14th April, 2016, expert from PMRC and representative of WHO in Pakistan:

Sr. No.	Brand Name	Composition
1.	DENGVAXIA, powder and solvent for suspension for Injection Single dose.	One dose (0.5 ml) contains: CYD dengue virus serotype1,2,3,4…….each 4.5-6.0 log10 CCID50/dose
2.	DENGVAXIAMD, powder and solvent for suspension for Injection Multi dose.	One dose (0.5 ml) contains: CYD dengue virus serotype1,2,3,4…….each 4.5-6.0 log10 CCID50/dose

Registration letters of above products were issued to M/s Sanofi Aventis Pakistan Limited, Karachi in the light of decision of Registration Board in its 273rd meeting held on 28th-29th August, 2017 wherein it was decided to issue letters for govt. supplies only.

Meanwhile, it was noticed that Registration of Dengvaxia vaccine and Dengue Immunization programme was suspended by Philippines due to the new findings by M/s Sanofi Pasteur, France that severe cases of dengue can occur in the longer term among those vaccinated

without prior infection. Accordingly, WHO on 22nd December, 2017 published its interim position regarding the use of Dengvaxia vaccine which is reproduced as under:

"WHO acknowledges that in high seroprevalence settings, the vaccine can have significant population-level benefits. However, until a full review has been conducted, WHO recommends vaccination only in individuals with a documented past dengue infection, either by a diagnostic test or by a documented medical history of past dengue illness.

Any further guidance, including a review by SAGE and update of the WHO position paper on Dengvaxia®, will likely be available no earlier than April 2018 after a rigorous review of the new data and additional activities, such as population based modeling, are undertaken."

Keeping in view WHO interim position, Registration Board in its 277th meeting held on 27th-29th December, 2017 decided that the vaccine is not indicated for a mass vaccination program as Dengvaxiavaccineis indicated only in individuals with a documented past dengue infection (seropositive persons), confirmed either by a diagnostic test or by a documented medical history of past dengue illness. Moreover, in case of not using the vaccine, possibility of mortality can be high as observed in previous years. It was further decided that Registration Board will review case further as soon as the decision of WHO Strategic Advisory Group of Experts (SAGE) on immunization becomes available in April 2018.

On 19th April, 2018, WHO published "Revised SAGE recommendation on use of Dengue vaccine" which is at **Annex-I**. Keeping in view revised SAGE recommendations, Registration Board in its 283rd meeting held on 27th-29th June, 2018 decided to deliberate the said matter in next Registration Board meeting withconcerned departments.

Discussion in 286th meeting:

Dr. Asaaf Deputy Director, Federal EPI and Mr. Massab Umair Sr. Scientific Officer, NIH attended the meeting and submitted the following:

Dr. Asaaf Deputy Director, Federal EPI:

Exact disease burden of Dengue fever is yet unknown. In the absence of disease burden data the age bracketing is not possible which is essential for primary health care vaccines. Screening of seropositivity is very difficult as no assay will be 100% specific.Moreover, once vaccinated the efficacy of vaccine for 2-3 years is established. What will happen after that period is yet unknown. Further, dengue surveillance centers and proper storage facilities for dengue vaccines should be established first. Therefore, until the exact disease burden, seropositivity identification and safety data, the vaccine should not be registered.

Mr. Massab Umair, Sr. Scientific Officer, NIH:

Sensitivity and specificity of dengue diagnostic test is a major hurdle.Therefore, sampling time and type of diagnostic test should be assessed properly.Highly sensitive and specific dengue diagnostic kits are available in NIH. NIH can provide technical support regarding the development of diagnostic test facilities.

Registration Board after discussion decided as follows:

"Registration Board considered the matter in light of comments by EPI and NIHon disease burden data, cost and effectiveness of available Dengue Diagnostic tests. Registration Board deferred the case for further deliberation and advised DBER to come up with the current status of Dengvaxia vaccine in neighboring and tropical countries in next registration Board meeting."

In this context, it is submitted that in Philippines Dengue Immunization Programme is still suspended while in India and Sri Lanka, Dengvaxia is not yet registered. However, European Medicine Agency has granted the approval to Dengvaxia vaccine with following conditions:

*"**Conditions or restrictions regarding supply and use**:*

Medicinal product subject to medical prescription.

***Official batch release**:*

In accordance with Article 114 Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

***Other conditions and requirements of the marketing authorization**:*

Periodic Safety Update Reports

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal. The marketing authorisation holder shall submit the first periodic safety update report for this product within 6 months following authorisation.

***Conditions or restrictions with regard to the safe and effective use of the medicinal product**:*

Risk Management Plan (RMP)

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- *At the request of the European Medicines Agency*
- *Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.*

***Additional risk minimisation measures**:*

Prior to launch of Dengvaxia in each Member State the Marketing Authorisation Holder (MAH) must agree the content and format of the educational programme, including communication media, distribution modalities, and any other aspects of the programme, with the National Competent Authority.

The MAH shall ensure that in each Member State where Dengvaxia is marketed, all healthcare professionals who are expected to use Dengvaxia have access to/are provided with the following educational package:

- *Physician educational material*

The physician educational material should contain:

- *The Summary of Product Characteristics*
- *Guide for healthcare professionals*

The Guide for healthcare professionals shall contain the following key elements:

- *That there is an increased risk of severe and/or hospitalized dengue following vaccination in individuals not previously infected by dengue virus*
- *That healthcare professionals have to document before vaccination the previous dengue infection, which has to be assessed by laboratory confirmed history of dengue or through serotesting*
- *The healthcare professionals should be aware that the test they use should have adequate performance in terms of specificity and cross-reactivity based on the local disease epidemiology.*
- *That healthcare professionals should be aware of dengue early warning signs."*

Moreover, FDA has also granted the approval to Dengvaxia vaccine but with following limitations and warnings:

*"**Limitations of use:***

- *DENGVAXIA is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. Those not previously infected are at increased risk for severe dengue disease when vaccinated and subsequently infected with dengue virus. Previous dengue infection can be assessed through a medical record of a previous laboratory-confirmed dengue infection or through serological testing prior to vaccination.*

- *The safety and effectiveness of DENGVAXIA have not been established in individuals living in dengue non-endemic areas who travel to dengue endemic areas.*

WARNINGS AND PRECAUTIONS:

- *Increased Risk of Severe Dengue Disease Following DENGVAXIA in Persons not Previously Infected with Dengue Virus in unvaccinated individuals, first dengue infections rarely cause severe dengue, while second dengue infections with a different serotype are associated with an increased risk of severe dengue. DENGVAXIA administration to individuals not previously infected by dengue virus is associated with an increased risk of severe dengue disease when the vaccinated individual is subsequently infected with any dengue virus serotype. Therefore, healthcare professionals must evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus.*
- *Previous infection by dengue virus can be evaluated through a medical record of previous laboratory-confirmed dengue infection or through serotesting prior to vaccination.*

There is no FDA cleared test available to determine a previous dengue infection. Available non-FDA cleared tests may yield false positive results (e.g., due to cross-reactivity with other flaviviruses).*"*

The case was considered in 292nd meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case for submission of all the documents as advised by EMA and USFDA by the firm and advised DBER to process the case before finalization of the minutes."

The firm has submitted the following documents as advised by EMA:

Sr. No.	Documents Required by EMA	Documents Submitted by the firm
1.	In accordance with Article 114 Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.	Please note that the official batch release will be done by the ANSM Direction Des controls.
2.	The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal. The marketing authorisation holder shall submit the first periodic safety update report for this product within 6 months following authorisation.	Periodic safety update report of first six months from 07 Dec, 2018 to 07 June, 2019 is submitted to EMA. The firm has not submitted the report to DRAP.
3.	The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP. An updated RMP should be submitted: • At the request of the European Medicines Agency • Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.	The firm submitted that M/s Sanofi Pasteur has performed the required pharmacovigilance activities and interventions detailed in the agreed RMP and any agreed subsequent updates of the RMP.
4.	Prior to launch of Dengvaxia in each Member State the Marketing Authorisation Holder (MAH) must agree the content and format of the educational programme, including communication media, distribution modalities, and any other aspects of the programme, with the National Competent Authority.	The firm has submitted the physician educational material as suggested by EMA which contains the following: 1. Background information on dengue disease

	The MAH shall ensure that in each Member State where Dengvaxia is marketed, all healthcare professionals who are expected to use Dengvaxia have access to/are provided with the following educational package: • Physician educational material The physician educational material should contain: • The Summary of Product Characteristics • Guide for healthcare professionals **The Guide for healthcare professionals shall contain the following key elements:** o That there is an increased risk of severe and/or hospitalized dengue following vaccination in individuals not previously infected by dengue virus o That healthcare professionals have to document before vaccination the previous dengue infection, which has to be assessed by laboratory confirmed history of dengue or through serotesting o The healthcare professionals should be aware that the test they use should have adequate performance in terms of specificity and cross-reactivity based on the local disease epidemiology. o That healthcare professionals should be aware of dengue early warning signs."	2. Background information on Dengvaxia indication 3. Summary of official national recommendations (Optional section to be adopted at the country level if relevant) 4. Tools to make appropriate vaccination recommendation to patient. 5. Checklist prior to vaccination recommendation 6. FAQs about dengue vaccination with Dengvaxia

FDA has also granted the approval to Dengvaxia vaccine but with following limitations and warnings:

"**Limitations of use:**

- DENGVAXIA is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. Those not previously infected are at increased risk for severe dengue disease when vaccinated and subsequently infected with dengue virus. Previous dengue infection can be assessed through a medical record of a previous laboratory-confirmed dengue infection or through serological testing prior to vaccination.
- The safety and effectiveness of DENGVAXIA have not been established in individuals living in dengue non-endemic areas who travel to dengue endemic areas.

WARNINGS AND PRECAUTIONS:

- Increased Risk of Severe Dengue Disease Following DENGVAXIA in Persons not Previously Infected with Dengue Virus in unvaccinated individuals, first dengue infections rarely cause severe dengue, while second dengue infections with a different serotype are associated with an increased risk of severe dengue. DENGVAXIA administration to individuals not previously infected by dengue virus is associated with an increased risk of severe dengue disease when the vaccinated individual is subsequently infected with any dengue virus serotype. Therefore, healthcare professionals must evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus.
- Previous infection by dengue virus can be evaluated through a medical record of previous laboratory-confirmed dengue infection or through serotesting prior to vaccination.

There is no FDA cleared test available to determine a previous dengue infection. Available non-FDA cleared tests may yield false positive results (e.g., due to cross-reactivity with other flaviviruses)."

Decision: Registration Board deferred the case for submission of updated status of Dengvaxia vaccine in Reference Regulatory Authorities and Risk Management Plan by the firm.

5. Change in name of Product License Holder & Manufacturer of already registered human biological Shan 5 (Reg. No.090315) applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

M/s Sanofi Aventis Pakistan Limited, Karachi applied for the change in name of Product License Holder & Manufacturer of already registered human biological as per following details:

Reg. No. & Date of Reg.	Name of Product	Already Approved Product License Holder & Manufacturer	Newly Applied Product License Holder & Manufacturer
090315 10-10-2018	Shan 5 Suspension for Intramuscular Injection	M/s Shantha Biotechnics Private Limited, India	M/s Sanofi Healthcare India Private Limited, India.

The firm has submitted the following documents as per SOP approved in 283rd meeting Registration Board for the said change:

Sr. #.	Required Documents As per SOP	Documents submitted by the firm
1.	Application with required fee as per relevant SRO.	• Application on firms letter head is provided. • Fee Challan of Rs.5000/- is provided.
2.	Copy of registration letter and last renewal status.	• Copy of initial registration letter dated 10-10-2018 is provided.
3.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name Or Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin Or any legalized document of concerned regulatory authority confirming change of name of Manufacturer/ Marketing Authorization Holder without change in manufacturing site.	Original Legalized CoPP No.0303/STORES/2020 dated 28-01-2020 valid till 25-11-2021 indicating new name of product license holder & manufacturer is provided.
4.	Revised Sole Agency Agreement when there is change in MAH.	Provided.
5.	Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities.	Not applicable as both are same entities.
6.	g) Undertaking that the provided information/ documents are true/ correct.	Undertaking on the company letter head is provided.

The above product is WHO Prequalified and the status of change of name of product license holder and manufacturer is also verified from official website of WHO https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=162 accessed on 04-06-2020.

Decision: **Keeping in view the valid legalized CoPP & official website of WHO indicating new name of product license holder and manufacturer; Registration Board approved the change in name of product license holder & manufacturer of Shan 5 injection (Reg. No. 090315) from M/s Shantha Biotechnics Private Limited, India to M/s Sanofi Healthcare India Private Limited, India.**

6. Exemption of Urdu text, registration number & MRP and Import of products in standard export packs applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

M/s Sanofi Aventis Pakistan Limited has requested for the exemption of Urdu Text, Registration Number & MRP at the time of import on packs of below mentioned human biologicals:

S. No.	Name of Product	Pack Size
1.	Imojev Japanese Encephalitis Vaccine (Live, inactivated) Powder and Solvent for Suspension for Injection	1 dose of powder and 1 dose of solvent in separate vials with 1 sringe and 2 separate needles.
2.	Imojev Japanese Encephalitis Vaccine (Live, inactivated) Powder and Solvent for Suspension for Injection	10 vials of 4 doses of powder and 10 vials of 4 doses of solvent.
3.	Vaxigrip Tetra Suspension for injection in pre-filled syringe	1's PFS
4.	Cerezme 400U Powder for concentrate for solution for infusion	1's, 5's 25's Vials
5.	Adacel (Tetaus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed) Suspension for Injection	1's Vial 5's Vials

The firm has submitted the following documents:

1. Application with fee challan of Rs. 5000/- for each product
2. SOPs for control of repacking operations.
3. An undertaking that we will print the Registration Number and Maximum Retail Price (MRP) on each pack of above products at our Karachi site bearing DML No. 000007, before releasing the goods into the market.

The above mentioned products have already been approved by Registration Board in different meetings, however registration letters have not yet been issued as the Prices have not yet been fixed by the Federal Government. The firm submitted that they came to know through Pharma Bureau observer that it was discussed/ decided in 293rd meeting of Registration Board that such cases of exemption should be requested at the time of registration application/ before product registration.

The firm further submitted that vaccines b Saofi Pasteur are manufactured globally at a single source to fulfill the requirement of the whole world. Moreover, Cerezyme is indicated for a rare disease called Gaucher disease and required to be imported in limited quantit. Therefore, it is not possible for manufacturer to follow the packaging and labeling rules of every country at the time of export plus production, packaging, quality controls of these sterile and temperature sensitive products require specialized methods and techniques of handling under highly controlled environment.

Keeping in view the above, the firm has requested for the exemption of Urdu Text, Registration number & MRP on packs of above mentioned products and for permission to import above products in Standard Export Packs. However, in order to be compliant to the Pakistan Drugs Labeling and Packaging rules, they have given the undertaking that they will print Urdu text, Registration number and MRP on each pack under cold chain process before releasing the goods into the market.

Decision: **Registration Board acceded to the request of the firm for import of Imojev (1 dose), Imjev (4 dose), Vaxigrip Tetra (1's PFS), Cerezyme 400U (1's, 5's & 25's Vials) & Adacel (1's & 5's Vials) in Standard Export Packs. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text and other parameters as per Drugs (Labelling & Packing) Rules, 1978 before sale of drug at M/s Sanofi Aventis, Plot 23, sector 22, Korangi Industrial area, Karachi to comply the requirement as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for one (01) year only after issuance of registration letter. The firm shall submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1978 compliant packs.**

7. Change in manufacturing site of already registered human biologicals applied by M/s Roche Pakistan Limited, Karachi.

M/s Roche Pakistan Limited, Karachi applied for the change in manufacturing site of their already approved products as per following details:

Sr. No.	Reg. No.	Name of Product	Already Approved Manufacturing Site	Newly Applied Manufacturing Site
1.	059052	Mircera Injection 50mcg	M/s Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Manheim, Germany	M/s F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst, Switzerland
2.	059051	Mircera Injection 75mcg		
3.	059050	Mircera Injection 100mcg		

The firm has submitted the following documents as per SOPs formulated in 283rd meeting revised in 292nd meeting of Registration Board:

Sr. No.	SOPs formulated in 283rd Meeting revised in 292nd meeting	Documents submitted by the firm
1.	Application on Form-5F	Provided.
2.	Required fee as per relevant SRO.	Fee Challan of Rs. 150000/-
3.	Copy of registration letter and last renewal status.	Provided.
4.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	Legalized CoPPs indicating new manufacturing site are Provided.
5.	Site master file of new manufacturing site in case of change of manufacturing site/ source.	Provided.
6.	Revised Sole Agency Agreement when there is change in MAH.	Not Applicable as MAH is not changed.
7.	Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities.	Provided.
8.	Undertaking that provided information/ documents are true & correct.	Provided.

Decision: **Keeping in view the valid legalized CoPPs indicating new manufacturing site & approval of Swissmedic (Reference Regulatory Authority); Registration Board approved the change in manufacturing site of Mircera Injection 50mcg (Reg. No. 059052), Mircera Injection 75mcg (Reg. No. 059051) & Mircera Injection 100mcg (Reg. No. 059050) from M/s Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Manheim, Germany to M/s F. Hoffmann-La Roche Ltd., Wurmisweg CH-4303 Kaiseraugst, Switzerland as per current Import Policy for finished drugs.**

8. Change in manufacturing site of already registered human biological applied by M/s Pfizer Pakistan Limited, Karachi.

M/s Pfizer Pakistan Limited, Karachi applied for the change in manufacturing site of powder of their already registered product as per following details;

Reg. No.	Name of Product	Already Approved site	Newly Applied Site
091876	Nimenrix Powder and solvent for solution for injection	M/s GlaxoSmithKline Biologicals S.A., Parc de la Noire Epine, Rue Fleming 20, 1300 Wavre, Belgium.	M/s Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium.

The firm has submitted the following documents as per SOPs formulated in 283rd meeting revised in 292nd meeting of Registration Board:

Sr. No.	SOPs formulated in 283rd Meeting revised in 292nd meeting	Documents submitted by the firm
1.	Application on Form-5F	Provided.
2.	Required fee as per relevant SRO.	Fee Challan of Rs. 50000/-
3.	Copy of registration letter and last renewal status.	• Copy of initial registration letter • Copy of approval letter of change in manufacturing, secondary packaging & QA release sites • Copy of approval letter of change of product license holder.
4.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	Legalized CoPP No. 06/19/134097 & 01/19/134098 dated 02-08-2019 for 1's and 10's packs respectively indicating new manufacturing site issued by EMA.
5.	Site master file of new manufacturing site in case of change of manufacturing site/ source.	Provided.
6.	Revised Sole Agency Agreement when there is change in MAH.	Not Applicable as MAH is not changed.
7.	Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities.	Provided.
8.	Undertaking that provided information/ documents are true & correct.	Provided.

Decision: **Keeping in view the valid legalized CoPP indicating new manufacturing site & approval of EMA (Reference Regulatory Authority); Registration Board approved the change in manufacturing site of powder part of Nimenrix (Reg. No. 091876) from M/s GlaxoSmithKline Biologicals S.A., Parc de la Noire Epine, Rue Fleming 20, 1300 Wavre, Belgium to M/s Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium as per current Import Policy for finished drugs.**

9. Change in manufacturing site of already registered human biological applied by M/s Novo Nordisk Pharma (Private) Limited, Karachi.

M/s Novo Nordisk Pharma (Private) Limited, Karachi applied for the change in manufacturing site of their already registered product as per following details;

Reg. No.	Name of Product	Already Approved sites	Newly Applied Sites
010346	Mixtard 30 HM Penfill Pack Size: 1's x 3ml	**Manufacturer:** M/s Novo Nordisk A/s, Denmark. **Packaging Site:** M/s Novo Nordisk, Tianjin Plant, China.	**Manufacturing & Packaging Site:** M/s Novo Nordisk (China) Pharmaceuticals Co. Ltd., No. 99 Nanhai Road, TEDA, Tianjin, 300457-Peoples Republic of China.

The firm has submitted the following documents as per SOPs formulated in 283rd meeting revised in 292nd meeting of Registration Board:

Sr. No.	SOPs formulated in 283rd Meeting revised in 292nd meeting	Documents submitted by the firm
1.	Application on Form-5F	Provided.
2.	Required fee as per relevant SRO.	Fee Challan of Rs. 100000/-
3.	Copy of registration letter and last renewal status.	• Copy of initial registration letter dated 28-02-1990

		• Copy of approval letter of transfer of registration dated 24-04-1991 • Copy of approval letter of additional pack • Copy of approval letter of transfer of registration dated 11-11-2005 • Copy of approval letter of change in packaging site of 1's pack • Copy of last renewal submission dated 16-04-2015
4.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	Legalized CoPP No. 2019110066 dated 04-11-2019 indicating new manufacturing site issued by Danish Medicine Agency valid for two years
5.	Site master file of new manufacturing site in case of change of manufacturing site/ source.	Provided.
6.	Revised Sole Agency Agreement when there is change in MAH.	Not Applicable as MAH is not changed.
7.	Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities.	Not applicable as both are same entities i.e. M/s Novo Nordisk.
8.	Undertaking that provided information/ documents are true & correct.	Provided.

The firm has two (02) pack sizes registered against one number (010346) i.e. 1's x 3ml and 5's x 3ml while the firm has only applied for change of 1's x 3ml pack size. The firm further submitted that 5's pack has been discontinued and confirmed the suspension of registration of 5's pack.

Decision: **Keeping in view the valid legalized CoPP indicating new manufacturing & packaging sites & approval of Danish Medicine Agency (Reference Regulatory Authority); Registration Board approved the change in manufacturing and packaging sites of 1's pack of Mixtard 30 HM Penfill (Reg. No. 010346) from M/s Novo Nordisk A/s, Denmark & M/s Novo Nordisk, Tianjin Plant, China to M/s Novo Nordisk (China) Pharmaceuticals Co. Ltd., No. 99 Nanhai Road, TEDA, Tianjin, 300457- Peoples Republic of China as per current Import Policy for finished drugs. Registration Board further cancelled the registration of 5's pack of Mixtard 30 HM Penfill (Reg. No. 010346) as communicated by firm vide letter NoSC/REG/03/2020 dated 10.06.2020.**

10. Registration of Imported Human Biological applied by M/s Vikor Enterprises (Pvt.) Ltd., Karachi approved in 293rd meeting of Registration Board.

Following product of M/s Vikor Enterprises (Pvt.) Ltd., Karachi was approved in 293rd meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Document Details/ Pack Size	Decision of RB in 293rd meeting
M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet	Typbar TCV Typhoid Vi Conjugate Vaccine Each dose of 0.5mL contains:	Legalized CoPP No. 8735/STORES/2019 dated 11-01-2019 valid upto 15-04-2020.	*Keeping in view the above discussion, WHO Prequalification and valid legalized CoPP indicating product availability in country of origin; Registration Board cancelled the approval of Typbar TCV from the name of M/s Sind Medical Store, Karachi granted in*

Mandal, Medchal District-500 078, Telangana, India	Purified Vi Capsular Polysaccharide of *Salmonella typhi Ty2* conjugated to Tetanus Toxoid... ….25µg	1's Vial (0.5mL)/ Not Provided.	*284th meeting and granted approval in name of M/s Vikor Enterprises (Pvt.) Ltd., Karachi as per current Import Policy for Finished Drugs. The Registration letter shall be issued after confirmation of cold storage facility of by the area FID and price verification from Pricing Division.*

Initially, the product was approved in 284th meeting of Registration Board in name of M/s Sind Medical Store, Karachi wherein the Board decided as follows:
"Keeping in view the WHO Prequalification and valid legalized CoPP indicating the availability of product in country of origin; Registration Board approved the product subject to price fixation by the Federal government and compliance of current Import Policy for finished drugs. The firm will submit new brand name along with NOC from manufacturer abroad and Chairman Registration Board is authorized for issuance of Registration letter."

However, while the product was approved in name of M/s Vikor Enterprises (PVt.) Ltd., Karachi, the scenario of brand name was not discussed. The product has already been referred to Pricing Division for price fixation. In this context, it is submitted that M/s Vikor Enterprises (Pvt.) Ltd., Karachi has informed that the brand name change is not possible as M/s Bharat Biotech International Ltd., India is the originator of this product and Typbar TCV is their brand name which is internationally recognized, even it is WHO Preferred vaccine (with the same name) and till to date this product is not available with any other name globally, so that would not be possible for their principal to give new name for them.

Decision: Registration Board deferred the case for further deliberation in next meeting.

11. Basagine Injection approved in 256th meeting of Registration Board applied by M/s Getz Pharma (Pvt.) Limited, Karachi.

Following product of M/s Getz Pharma (Pvt.) Limited, Karachi were approved in 257th meeting of Registration Board as per following details:

Name of Manufacturer	**Brand Name & Composition as per CoPP**	**Brand Name & Composition as per minutes of RB**	**Decision of RB in 256th meeting**
M/s Gan & Lee Pharmaceuticals Ltd., No.8, Jingsheng North 3rd Street, Golden Bridge Science Industrial Base,Zhongguancun Science Park, Tongzhou District, Beijing,China.	Basagine (Recombinant Insulin glargine injection) Each ml contains; - Recombinant InsulinGlargine…..…..100U	BASAGINE Solution for Injection 100Units/ml Each ml contains: Recombinant Insulin Glargine.. …100Units / ml Shelf Life: 2years (2-8^{0}C)	*Approved as per valid Legalized CoPP subject to inspection of manufacturer abroad as per Import Policy for Finished Drugs, verification of storage facilities and fixation of MRP by Pricing Committee.*

Accordingly, the panel inspection of manufacturer abroad was conducted on 25th& 28thNovember 2016 wherein the panel "Recommended" the facility and rated "Very Good".

It is submitted that as per available record the product is already registered from same source in name of M/s East West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi with brand name Basalin

Insulin 100IU/3ml cartridge **(Reg. No. 053809)**. M/s Getz Pharma (Pvt.) Ltd., Karachi applied as new application and has provided the authorization letter in their name from M/s Gan & Lee Pharmaceuticals Ltd., China.

It is submitted that initial registration letter was issued dated 19-12-2008 in the name of M/s East West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi. However, it has been informed by renewal section that renewal application has not been received in 2018, neither available in previous years.

To confirm status of the product from M/s East West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi letter was forwarded on 19th June 2019. However, the letter forwarded was received backwith a note that no company with this title exist at the given address.

After searching for contacts, the firm was asked for address to which the specified letter could be forwarded. The firm informed that address of the firm is still the same and requested to resend the letter. The firm was advised to submit response and clarify its position on the matter within seven (7) days. However, no response was received. The case was taken in 291st meeting of Registration Board wherein the board decided as under;

"Registration Board advised DBER to issue a reminder to M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi and to ask DRAP office, Karachi to provide the data of import of Basalin by M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi. "

As per decision of Registration Board;

i. A reminder to M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi was issued dated 5th November 2019 but no response has been received yet.

ii. DRAP office, Karachi was asked to provide the data of import of Basalin by M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi. The reply has been received wherein the concerned office has informed that Basalin Insulin 100IU 3mL & 10mL Cartridge has not imported through this office since January 2018 to date, as per available record.

Decision: **Registration Board advised DBER to issue final letter to M/s East & West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi and advise them to appear before Registration Board in forth coming meeting for personal hearing to explain their position regarding the authorization of their product Basalin in name of M/s Getz Pharma (Pvt.) Limited, Karachi by their principal M/s Gan & Lee Pharmaceuticals Ltd., China. If M/s East & West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi failed to attend the meeting, Registration Board will make ex-party decision & shall grant the registration in name of M/s Getz Pharma (Pvt.) Limited, Karachi.**

12. Change in address of Importer of already registered human biologicals applied by M/s Genome Pharma, Rawalpindi.

M/s Genome Pharma, Rawalpindi applied for the change in address of importer for their already registered human biological as per following details:

Reg. No.	Name of Product	Previous Address	Newly Applied Address
062255	Folinis-150IU Injection	House No. 593-B, Street 10, Chaklala Scheme 3, Rawalpindi.	House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi. **Go-down:** C-19, Main Commercial, Access Road, RCCI Industrial Estate Rawat, Rawalpindi.

The firm has submitted the following documents:

a. Fee Challan of Rs. 5000/- for each product
b. Copy of initial registration letters and last renewal submissions

c. Copy of previous DSL.
d. Copy of new DSL indicating proprietor is same.
e. Original last renewal application of product is available in DBER.

It is pertinent to mention that Registration Board in its 293rd meeting has granted approval of above-mentioned change for five other biological products.

Decision: **Keeping in view the valid Drug Sale License, Registration Board approved the change in address of importer of above product from M/s Genome Pharma, House No. 593-B, Street 10, Chaklala Scheme 3, Rawalpindi to M/s Genome Pharma, House No. 166-A, Street No. 9, Chaklala Scheme III, Rawalpindi subject to storage facility verification of new godown situated at C-19, Main Commercial, Access Road, RCCI Industrial Estate Rawat, Rawalpindi.**

13. Registration of biological drug applied by M/s AGP Limited, Karachi, deferred in 292nd meeting of the Reg. Board:

Following biological product was applied by M/s AGP Limited, Karachiwhich was discussed in 292nd meeting of the Reg. Board held on 1st – 2nd October, 2019 and was deferred as per following details;

	Name of Applicant	**M/s. AGP Limited** B-23-C, S.I.T.E., Karachi.
	DSL details	Copy of DSL No. 0427 valid till 21-09-2019
	Name of Manufacturer	Manufacturer & Product License Holder **M/s Biocon Limited,** Special Economic Zone,Plot No.2, 3, 4 & 5 Phase IV, Bommasandra – Jigani Link Road,Bommasandra Post, Bengaluru – 560 099, India. Applicant for Certificate **M/s. Mylan Pharmaceuticals Pvt Ltd.,** Plot No.1-A/2, MIDC Industrial Estate, Taloja, Panvel, Dist-Raigad, Maharashtra – 410208.
	Brand Name Dosage Form Strength	**FULPHILA** PFS 6mg/0.6mL
	Composition	Each prefilled syringe contains: Pegfilgrastim……6mg/0.6ml
	Finished product specifications	As per Innovator
	Pharmacological Group	Immunostimulants
	Shelf life	36 Months (2^oC to 8^oC)
	International availability	Neulasta
	Alternate Products already registered in Pakistan	Peg- Filgen PFS by M/s BF Biosciences
	Type of Form Dy. No.&Date Fee submitted	Form 5-F. Dy.No.35617/(R&I)DRAP dated 26thOct, 2018. 100,000/-
	Demanded Price / Pack size	Rs. 59,668.47/ I's PFS
	General documentation	Legalized CoPP No. DCD/CR- 215/Spl.Cell – 1/2018-19 valid up to 10-01-2020

Biosimilarity data provided by the Firm is with NEULASTA	
WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison 1. Physicochemical Characterization	**IDENTITY (PEG-GCSF)** Intact Mass Analysis (Determination of Protein Molecular Mass) -MALDI-TOF-MS Reduced SDS-PAGE analysis **PRIMARY STRUCTURAL CHARACTERISTICS (PEG-GCSF)** i. Non-reduced Peptide Mapping - Endoproteinase Glu-C - primary structure identification (amino acid sequence identification) and Disulphide linkage identification - RP-HPLC with UV(@215 nm)-ESI-MS and MSMS detection ii. Non-reduced Peptide Mapping - Trypsin (2nd protease) - primary structure identification - RP-HPLC with UV(@215 nm)-ESI-MS detection iii. N-terminal PEGylation (PEG + Fragment 1) Mass analysis – MALDI-TOF-MS analysis of PEG + Fragment 1 derived after Glu-C and Trypsin digest. iv. Average Molecular Mass and Polydispersity of the PEG moiety **HIGHER ORDER STRUCTURAL CHARACTERISTICS -SECONDARY AND TERTIARY (PEG-GCSF)** a. Secondary structural analysis - Far UV - CD Spectroscopy b. Secondary structural analysis – FT-IR Spectroscopy c. Tertiary folding structural analysis - Intrinsic Fluorescence Assay d. Tertiary folding structural analysis – Extrinsic Fluorescence Assay e. Free cysteine analysis by UV spectroscopy **PRIMARYANDHIGHERORDERSTRUCTURALCHARACTERISTICS – IDENTIFICATION (Intermediate GCSFstage)** a. Intact Mass Analysis (Protein Molecular Mass) – RP-HPLC-ESI-MSdetection b. Non-Reduced Glu-C Peptide Mapping - RP-HPLC-ESI-MS/MSMSdetection - Primary structural (amino acid sequence) identification and **SIZE VARIANTS** a. SE-HPLC – identity, purity and Size variants analysis b. Non-reduced CE-SDS analysis c. SE-HPLC coupled with Static Light Scattering (SLS); SE-HPLCcoupled with Dynamic Light Scattering (DLS) **CHARGE VARIANTS** a. CIEX-HPLC – identity, purity and Charge/PEGylation variants analysis b. Determination of pI by Capillary Iso-Electric Focusing analysis **HYDROPHOBIC VARIANTS** a. RP-HPLC – identity, purity and Hydrophobic variants analysis
2. Biological Activity	Biological activity using M-NFS-60 proliferation assay
3. Immunochemical properties	GCSF-R Binding kinetic assay
Impurities	i. HMWP (PEG-GCSF): aggregates, Dimers of PEG-GCSF, Di-PEG-GCSF ii. LMWP (PEG-GCSF): Des PEG (GCSF), N-terminal truncation (LMWP-1, LMWP-2, LMWP-3) iii. Post translational modification (PEG-GCSF): Methionine oxidationM122, M127, and M138, Q108 deamidation iv. Post translational modification (GCSF): Methionine oxidation, Misfolded or partially reduced GCSF species, Acetylated form,Cysteinylated v. Co-translational modification (GCSF): Formyl-Met-GCSF variant, Norleucine substitution at methionine residue, Sequence variants, MGO

	adduct, Gluconoylated GCSF
Stability Studies	The firm has submitted the stability study
Non-clinical Comparison i. In-vitro Studies ii. In-vivo Studies a. Biological/ Pharmacodynamic activity b. Non- clinical toxicity as determined in one repeat dose toxicity study	• Comparative 28-day subcutaneous repeat-dose toxicity study in Sprague Dawley rats of MYL-1401H and EU- NEULASTA followed by a 2-week treatment-free recovery period. • Pharmacology Studies a. In vitro GCSF-R binding assay b. In vitro bioactivity assay c. In vivo pharmacodynamic study • Toxicology Studies a. 28 days repeat-dose toxicity study in Rats/Hsd:Sprague Dawley
Clinical Comparison	Phase-I single center, randomized, double-blind, 3-period, 3-treatments, 3-way crossover trial to evaluate the PK, PD, safety and tolerability of pegfilgrastim from a test product (MYL-1401H) compared to reference products EU- and US-Neulasta®. In 216 individuals. Phase single center, randomized, open-label, parallel trial to compare immunogenicity, safety, and tolerability of myl-1401h and us-licensed pegfilgrastim (neulasta®) after two subcutaneous (sc) injections at one dose level (6 mg) in healthy subjects. 50 Subjects. Phase III, Multicenter, Double-Blind, Randomized, Comparative Efficacy and Safety Study of MYL-1401Hand European Sourced Neulasta® in Stage II/III Breast Cancer Patients Receiving Neoadjuvant or Adjuvant Chemotherapy. 194 patients were randomized and received study treatment; 127 (MYL-1401H) and 67 (EU-Neulasta) **(Above mentioned studies are sponsored by: Mylan GmbH Thurgauerstrasse 408050 Zurich, Switzerland**
Remarks of Evaluator	1. All clinical data and some non-clinical data provided in biosimilarity reveals that it is sponsored by Mylan GmbH Thurgauerstrasse 40 8050 Zurich, Switzerland. The product with a brand name Fulphila is also approved in FDA. However, the product label shows following; **Manufactured by: Mylan GmbH, Turmstrasse 24, 6312 Steinhausen, Switzerland U.S. License No. 2062 Product of India. Code No.: KR/DRUGS/KTK/28D/7/2006 Distributed by: Mylan Institutional LLC, Rockford, IL 61103 U.S.A.** The firm claims that the product registered in FDA is manufactured by Biocon India and there is collaboration between Mylan GmbH & Biocon. 2. The firm has also submitted a copy of CoPP from USFDA which is not legalized and notarized and mentions following; <u>Manufacturer name and address</u> Biocon Limited PlotNo.2-5 Phase IV, Bommasandra – Jigani Link Road, Bengalore, Karnataka – 560099, India. <u>Applicant for Certificate</u> Mylan GmbH, Thurgauerstrasse 40, Zurich, Zurich CH-8050 Switzerland U.S. License No. 2062 3. The manufacturing address Special Economic Zone, Plot No.2, 3, 4 & 5 Phase IV, Bommasandra – Jigani Link Road, Bommasandra Post, Bengaluru –560 099, India, has been exempted for ABEVMY in 290th meeting of Registration Board.
Decision in 292nd RB meeting: *"Registration Board deferred the case for submission of clarification regarding the provision of clinical and non-clinical trials of product manufactured by Mylan GmbH, Turmstrasse 24, 6312 Steinhausen, Switzerland instead of the applied product manufactured by M/s Biocon Limited,*	

India."

In the above context, the firm has submitted legalized CoPP (Certificate No. 03/19/ 137598) from EMA with followng details;

"Biocon Limited Special Economic Zone,Plot No.2, 3, 4 & 5 Phase IV, Bommasandra – Jigani Link Road, Bommasandra Post, Bengaluru – 560 099, India" (Also responsible for quality control, primary, and secondary packaging) *Site responsible for batch release in EU: McDermott Laborateries t/a Mylan Dublin Biologics, Newenham Court, Northern Cross, Malahide Road, Dublin 17 Ireland. Site responsible for quality control: Charles River Laboratories Ireland Limited, Carrentrila, Ballina, County Mayo, Ireland (AND) Charles River Laboratories Edinburgh Limited, Elphistone Research Centre, Tranent, Edinburgh, EH33 2ne, United Kingdom. Site responsible for secondary packaging: DHL Supply Chain (Italy) S.p.A, Viale delle Industrie, 2, 20090, Settala, Milano, Italy."*

Moreover, the EMA assessment report available at www.ema.europa.eu/documents/assessment-report/fulphila-public-assessment-report_en.pdf reveals that the product has been registered as biosimilar having having biosimilarity studies done with Neulasta.

Furthermore, the Mylan website (www.Mylan.com) includes both countries India and Switzerland.

Decision: Keeping in view the valid legalized CoPP indicating product availability in country of origin & EMA Public Assessment Report; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

14. Change of address of importer for products under registration / approved Biological drugs of M/s CCL Pharmaceuticals Pvt. Limited, Lahore deferred in 292nd meeting of Reg. Board:

Following products of M/s CCL Pharmaceuticals Pvt. Limited, Lahore have been approved in 288th meeting of Registration Board held on 14th -15th February 2019. The details are as under;

Sr. No	Name of Manufacturer	Brand Name & Composition	Shelf life/ Pack size	Document Details	Decision of RB in 88th meeting
1.	M/s AryoGen Pharmed., address No: 140, corner of Tajbakhsh street, 24th Km Tehran- Karaj Makhsous road, Alborz, Iran	AryoTrust (Trastuzumab) 150mg White to pale yellow powder for concentrate for solution for IV infusion. Each vial contains: Trastuzumab…150mg	2 years at 2-8^{0}C 1's vial	CoPP, Certificate No. 665/37430 Dated 21/07/2018	Keeping in view the biosimilarity data and valid legalized CoPPs provided by the firm indicating the products are available in country of origin; Registration Board approved the products subject to compliance of current Import policy for finished drugs.
2.		AryoTrust (Trastuzumab) 440mg White to pale yellow powder and solvent for concentrate for solution for IV infusion. Each vial contains: Trastuzumab.…440mg + Bacteriostatic water for injection….20ml	2 years at 2-8^{0}C (1'sPowder vial + 1's 20ml BWFI vial) Combo pack	CoPP, Certificate No. 665/37442 Dated 21/07/2018	

The firm has been granted inspection exemption by the competent authority.

It is submitted that the firm has submitted two (2) DSLs which are in their name i.e.

DSL for which the product was registered	DSL for which cold storage facility has been verified
65-Industrial Estate, Kot Lakhpat, District Lahore	5-km, Sheikhupura Road, Tehsil Muridke

The case was taken in 292nd meeting of Reg. Board wherein the board decided as under;
"Registration Board refer the case to Legal Division of DRAP for confirming the legal provision as per Drug Act, 1976 and rules framed there under covering instant request of the firm."

The legal provision from Legal division was sought which is reproduced as under;
"As per Form 11 of the Punjab Drug Rules 2007 (Amended in 2014) the licensee can only stock/store registered products on the licensed premises or gowdown(s), if any, specified in the aforesaid license. Rule 17ibid stipulates that if a person desire to sell, store, exibit for sale or distribute drugsat more than one place, he shall apply for a separate license in respect of each place. However, this rule shall not apply in case the drugs are properly stored in gowdown, used only for storage of drugs and which meets the storage conditions and enlisted alongwith its complete address on the license."

However, meanwhile, the firm has applied for change of address for their above mentioned products. In this context, the firm has submitted following;

i. Fee of 5000/- for each product
ii. Revised Form 5A
iii. Previous DSL
iv. New DSL valid
v. Cold Storage facility report of the site is already available with the division.

The details of previous and new DSLs are as under;

DSL	Title of the firm	Proprietor / CNIC No.	Address
Previous	M/S CCL PHARMACEUTICALS (PVT.) LTD	Mr. Shoab Ahmed s/o Haji BAshir Ahmed 31303-2351640-5	65-Industrial Estate, Kot Lakhpat, District Lahore
New	M/S CCL PHARMACEUTICALS (PVT.) LTD	Mr. Shoab Ahmed s/o Haji BAshir Ahmed 31303-2351640-5	5-km, Sheikhupura Road, Tehsil Muridke, District Sheikhupura

Decision: **Keeping in view the valid Drug Sale License, Registration Board approved the change in address of importer of above products from M/s CCL Pharmaceuticals Pvt. Limited, 65-Industrial Estate, Kot Lakhpat, District Lahore to M/s CCL Pharmaceuticals Pvt. Limited, 5-km, Sheikhupura Road, Tehsil Muridke subject to storage facility verification of new address.**

15. Deferred case of Change of address for importer on registration letter of RhoGAM® Ultra-Filtered Injection. (Reg. No. 005571) applied by M/s Majeed Sons, Rawalpindi:

M/s Majeed Sons, Rawalpindi has applied for change of address on registration letter of RhoGAM® Ultra-Filtered Injection. **(Reg. No.** 005571**)**. The detail is as under;

Reg. No. & Date of Reg.	Brand Name of Product	Manufacturer	Address of importer on Reg. Letter	Applied / desired address of importer
005571 23-08-1995	RhoGAM® Ultra-Filtered Injection.	M/s Kedrion Biopharma USA 155, Duryea Road, Melville N.Y 11747, USA	M/s Majeed Sons, 55-A,Civil Lines, Mayo Road, P.O. Box 904, Rawalpindi Cantt.	M/s Majeed Sons, 115, Kahuta Industrial Triangle, Tehsil & District Islamabad

The firm has submitted;

i. Fee Rs. 5000/-
ii. Copy of registration letter and evidence of submission of renewal application
iii. Copy of DSL

It is pertinent to mention that in DSL, mentioned address is "115, Kahuta Industrial Triangle, Tehsil & District Islamabad*"* but cold storage facility report is not available with this division.
The case was deferred in 293rd meeting of Registration Board and the Board deferred the case for submission of NOC from previous proprietor**.**
Now the firm has submitted No Objection Certificate (NOC) given by the previous proprietor i.e. Mr. Shamim Ahmed Khan to the new proprietor.

Decision: Keeping in view the valid Drug Sale License and NOC given by previous proprietor, Registration Board approved the change in address of importer of above products from M/s Majeed Sons, 55-A,Civil Lines, Mayo Road, P.O. Box 904, Rawalpindi Cantt. to M/s Majeed Sons, 115, Kahuta Industrial Triangle, Tehsil & District Islamabad subject to storage facility verification of new address.

16. One Time Permission to Import RhoGAM® Ultra-Filtered Injection. (Reg. No. 005571) from previous filling and release site applied by M/s Majeed Sons, Rawalpindi:

The request of M/s Majeed Sons, Rawalpindi received through QA & LT division wherein they have applied for One Time Permission to Import RhoGAM® Ultra-Filtered Injection. (Reg. No. 005571) from previous filling and release site under the special SRO.
The request of the firm is reproduced as under for ready reference.

"With reference to our registered product RhoGAM® Ultra-Filtered Injection. (Reg. No. 005571) . Please note that we had applied for change of Filling and Release site received the letter of the same from the competent authority.

Now the new filling and release site (Kedrion) will take approximately 3 months to be functional while ready stock of previous filling and release site (Ortho) which is of short shelf life is available with the manufacturer.

This product is life saving and is used in RH Negative pregnant women to save the life of new born. Thus it is important that there must be availability of this product to handle such emergency cases because we already have in hand demands of this product. So it is requested to grant one time approval
to import consignment, under special SRO, on priority basis so that patient may not face shortage of the product which may be life threatening."

Decision: Registration Board decided to refer the case back to QA&LT Division as there is no rule that allows Registration Board to give such permission.

17. Imported Veterinary Vaccines applied by M/s Hilton Pharma (Pvt) Ltd, Karachi deferred in 292nd meeting of Registration Board.

Following product of M/s Hilton Pharma (Pvt.) Ltd., Karachi was deferred in 292nd meeting of Registration Board as per following details:

11.	**Name of Importer**	**M/s Hilton Pharma (Pvt) Ltd,Plot No.13 & 14, Sec 15, Korangi Industrial Area, Karachi**
	DSL details	CDSL No: 0751Expiry Date: 19-06-2020 Place: Karachi
	Name of Manufacturer	PT. MedionFarma Jaya Address Office: JI. BabarkanCiparay No.282, Bandung 40223, Indonesia Address Plant: JI. Raya Batujajar No.29, Bandung, Indonesia

	Brand Name +Dosage Form + Strength	**Medivac AE Pox** Freeze dried live vaccine for poultry
	Composition	Each dose contains:- Each dose of vaccine contains: Fowl pox virus of M-92 strain….at least $10^{3.0}EID_{50}$ Avian encephalomyelitis (AE) virus Calnek 1143strain……..at least $10^{2.5}$ EID_{50} **Composition of Diluent:** Each ml of Medivac AE Pox Diluent contains: Glycerol 20% Distilled water 80%
	Finished product specifications	Ph. Eur. Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	Products already registered in Pakistan	Gallivac AE+FP (Reg. No. 084603)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 8355 (R&I) Dated 13-06-2019 Rs. 50,000/- Dated 24-05-2019
	Demanded Price / Pack size	Decontrolled/ 5,00 Doses& 1000 doses with diluent
	General documentation	CoPP No.04135/PI.500/F/06/2018 dated 04-06-2018 issued by Ministry of Agriculture Directorate General of Livestock And Animal Health Services Indonesia CoPP No.08024/PI.500/F/10/2019 dated 18-10-2019 issued by Ministry of Agriculture Directorate General of Livestock And Animal Health Services Indonesia
	Decision of 292nd meeting of RB	*Registration Board deferred the case for submission of stability study data by the firm.*
	Remarks of Evaluator	Now the firm has submitted the stability study data along with the revised CoPP wherein the diluent is mentioned. The composition of the diluent is mentioned in the Form 5-A

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

18. Change in address of importer applied by M/s Hipra Pakistan (Pvt) Limited, Lahore.

M/s Hipra Pakistan (Pvt) Limited, Lahore has applied for the change in address of importer for their following veterinary vaccines as per following details:

S. No.	Reg. No.	Name of Product	Previous Address	Newly Applied Address
1.	094782	HIPRAGUMBORO-GM97	Office no.3&4,5th floor, 105-B-II, Ali Tower, M.M Alam Road, Gulberg, Lahore.	3rd floor, Plot no.8, Block CCA, Phas w 6-C,DHA, Lahore.
2.	094781	HIPRAVIAR-SHS		
3.	094777	BRONIPRA-1		
4.	094769	HIPRAVIAR-B1/H120		
5.	094766	HIPRAGUMBORO-CH80		
6.	094779	HIPRAVIAR-CLON		
7.	094773	TOXIPRA-S7		
8.	094781	CORIPRAVAC		
9.	094770	AVISAN MULTI		
10.	099081	HIPRABOVIS SOMNI/Lkt		

11.	094783	HIPRAVIAR-ILT		
12.	094784	HIPRAGUMBORO-BPL2		
13.	094774	AVISAN SECURE		
14.	094768	HIPRAVIAR-TRT		
15.	094775	HIPRAVIAR-TRT4		
16.	094776	HIPRAVIAR-BPL2		
17.	094780	HIPRABOVIS-4		
18.	094771	HIPRAVIAR-S		
19.	094778	BRONIPRA-ND		
20.	094767	BRONIPRA-ND/IBD		
21.	096848	EVALON		
22.	094465	SELECTAN		
23.	094466	EFFICUR		
24.	094467	GENTAMOX		
25.	094468	HIPRALONA ENRO-S		
26.	094469	HIPRALONA ENRO-I		
27.	Under Process. Approved in 286th meeting.	HIPRAPOX		
28.	Under Process. Approved in 286th meeting.	NASYM		
29.	Under Process. Approved in 286th meeting.	HIPRADOG-7		

The firm has submitted the following documents:

f. Fee Challan of Rs. 5000/- for each product
g. Copy of initial registration letter
h. Copy of previous DSL.
i. Copy of new DSL indicating proprietor is same.

All the products are recently transferred/fresh Registration (after 2018) in the name of the said importer therefore renewal is not yet.

It is to be noted that the proprietor of the company on the new DSL is also change and the NOC from the previous proprietor has not been submitted instead the firm has submitted notarized copy of the Resignation letter of the previous proprietor and notarized copy of the appointment letter of the new proprietor. And the firm has opinion that "**The NOC is not possible to have from his side as he himself has resigned so that for your reference we have submitted his resignation letter"**

Decision: Registration Board deferred the case for legal opinion by Legal Affairs Division of DRAP on above matter.

19. Deferred cases of M/s LDS pvt. Ltd., Rawalpindi, Pakistan.

Following product of M/s LDS Pvt. Ltd., Rawalpindi was deferred in 291st meeting as per follows:

Name of Importer	**M/s LDS pvt. Ltd. 111, Hali Road, Westridge 1, Rawalpindi, Pakistan**
DSL details	License No. 01-374-0176-041296D dated 07-03-2019 valid till 07-03-2021
Name of Manufacturer	**Manufacturer:** M/s Lyocontract GMBH Pulverwiese, Trift, Ilsenburg, D-38871, Germany **Marketing Authorization Holder:** Biofactor Gmbh Rudolf Huch Str 14, Bad Harzburg, D-38667, Germany
Brand Name +Dosage Form + Strength	**Biofactor** Streptokinase 15,00,000 Powder for infusion
Composition	Each vial contains: Streptokinase……15,00,000 IU
Finished product specifications	BP specifications
Pharmacological Group	Thrombolytic
Shelf life	12 months when stored at 30 ^{0}C 36 Months Store below 25^{0}C (Stability study not provided as per Zone IV-A)
International availability	Germany
Products already registered in Pakistan	DURAKINASE INJECTION of M/s Medisure Karachi
Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No 6845 Dated 22-02-2018 Rs. 100,000/- Dated 22-02-2018
Demanded Price / Pack size	Rs. 11,800/1's vial
General documentation	**CoPP No.PP10138834** dated 23 July 2015 issued by MHRA UK declaring the free sale of applied product but does not conduct inspection of the facility. However it is mentioned in CoPP that the certifying regulatory has been satisfied by the applicant on all aspect of manufacture of the product including GMP. **GMP Certificate No.DE-ST-01-GMP-2017-0008 dated 3rd February,2017** issued by Landesverwaltungsamt Saxony-Anhalt Department of Public Health ,Pharmacy Ernst-Kamieth-Strabe 2 06112 Halle/ Saale Germany.
Remarks of Evaluator	i. Submitted Letter of authorization to M/s LDS pvt. Ltd Pakistan from M/s Karma Pharmatech GmbH Germany, which is neither manufacturer nor Product license holder. The firm submitted a copy of letter indicating that the transfer of MAH is already fixed by contract and the transfer is scheduled in 4th quarter in name of M/s Karma Pharmatech GmbH. ii. Clinical data is not provided and M/s LDS Pvt. Ltd submitted that applied product is generic hence no need of clinical data.

Decision of 291st meeting of Registration Board: Registration Board deferred the case for submission of following by the firm:

a. Valid legalized CoPP issued by concerned regulatory authority
b. Clarification of difference of product license holder on CoPP and letter of authorization
c. Clinical trial data Or any legalized document from regulatory body of country of origin indicating that clinical trial is not necessary for Streptokinase.

The firm has submitted reply in response which are summarized below;

For Point no. a, the firm has submitted New CoPP issued by MHRA which is not legalized. &notarized copy of the same CoPP legalized from the Pakistan Embassy in Germany. The firm has once again stated that as the original CoPP is released from MHRA UK and bears the hologram, therefore it is not possible to get it legalized by the Embassy in UK (Legalization is not possible in UK). The firm has submitted that the said product is registered in MHRA UK & manufactured in Germany and application has been submitted for registration in Germany (on 22.05.2019), the process is ongoing.

For Point no. b, the firm has submitted New CoPP, in which the Market Authorization holder M/s Karma Medica GmBH Germany which the same agent who has issued Authorization letter to M/s LDS in Pakistan.

For Point no. c, the firm has submitted that the clinical documentation of submitted product Streptokinase is completely literature based as the current submitted application makes reference to the data generated in the clinical trials of the originator product. The firm has further submitted that Karma Pharmatech has taken over the MA of the originator (Braun Streptokinase) and the composition of the product, the efficacy as demonstrated in the clinical studies is based on this product. The clinical studies have been performed in the 70s, since then the product is constantly marketed and there are no hints with regard to an impaired risk-benefit balance. The firm also submit the literature references & summaries clinical research studies of the Streptokinase molecule in different indications on the basis of which they claim the said product is registered.

Decision: **Keeping in view the valid legalized CoPP indicating product availability in country of origin & approval of MHRA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**

20. Local human Biological applied for registration by M/s Macter International Limited, Karachi.

The following product for the local manufacturing biological drug was considered in 246th Meeting of Registration Board held on 10-11th December, 2014 but later on the Registration Board in its 270th meeting advise the division of Biological drugs to come up with working paper in the next meeting. The final guidelines regulatory requirements of Biological drugs using rDNA technology has been approved in 278th meeting of Registration Board. The Detail is as under;

1.	Name of Manufacturer	M/s Macter International Limited,F-216, Site, Karachi
	Brand Name +Dosage Form + Strength	Macgrastim ***300 mcg/1.2ml*** *(Filgrastim-Recombinant human granulocyte colon-stimulating factor*
	Composition	Each vial contains: Filgrastim…..300mcg/1.2ml
	Finished product specifications	BP Specification
	Pharmacological Group	Therapeutic Protein
	Shelf life	2 years when stored
	Products already registered in Pakistan	Grastim by CCL Pharma, Lahore.
	Type of Form Dy No & Date of application, Fee submitted	Form-5, Dy No.1118/2014(R&I) dated 10-10-2014 Rs. 20000 dated 16-09-2014
	Demanded Price / Pack size	Price: As per PRC Pack of 1's (Vial)

	Remarks of Evaluator	

The firm has submitted data as per the said guidelines. The submitted documents are evaluated as under;

Documents required as per 278th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)	**Documents submitted by firm**
1. The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Provided
2. The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Provided
3. The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity.	Provided & Evaluated below
4. The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	In China Filgrastim (rhG-CSF) is not included in products which require LOT Release Certificate.
5. The firm shall provide the 6 months accelerated and real time stability studies for drugsubstance.	Provided
6. The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform analytical studies(Physicochemical and biological) including protein content, appearance, pH, Osmolality, composition of key excipients including stabilizers (if formulation is same),visible/subvisible particles, identity testing to parent molecule, purity testing, in vitro biological activity, sterility, Pyrogen content, safety, potency and toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques). **The firm shall submit the results for processing of registration application.**	Provided
7. The manufacturer shall perform all tests locally as detailed on Certificate of analysis.	Provided
8. The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form in any country of the world (if available).	Provided
9. The firm shall provide the agreement with the source (of bulk concentrate/ready to fill)that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not Provided
10. Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will before forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Layout plane submitted.
11. The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Provided
12. If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Provided
13. All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Provided

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	i. Molecular Weight by Reducing SDS-PAGE ii. **Assay for chemical structure by following methods** a. Sequencing for recombinant DNA b. UV Spectrum c. Composition of Amino Acids d. Peptide Mapping e. N-terminal sequencing of rhG-CSF by Edman degradation
Biological Activity	**In-vivo activity** by Activity of rhG-CSF in vivo (Effects of rhG-CSF on CY-induced myelosuppression in rhesus Monkeys): In-vitro activity by a. 3H-TdR assay , b. MTT assay using NFS-60 cell line
Immunochemical properties	a. Identification (by Western Blot) b. ELISA (Enzyme-linked Immunosorbent Assay)
Impurities	**Purity assay by following methods** a. Non-Reducing SDS-PAGE & Reducing SDS-PAGE b. Isoelectric focusing c. Reverse Phase HPLC d. SEC-HPLC (Size Exclusion Chromatography HPLC) e. Capillary Electrophoresis
Stability Studies	Stability studies are provided.
Non-clinical Studies	**In Vitro Pharmacodynamic Study:** Effect of rhG-CSF on the proliferation of normal mouse and human bone marrow cells in vitro Effects of rhG-CSF on Acute Radiation-induced Hematopoietic Injury in Mice **Toxicity study is provided but not comparative.**
Clinical Studies	A Comparative Study between Jilifen (rhG-CSF) Hangzhou Jiuyuan Gene Engineering Co., Ltd China and Gran (rhG-CSF) manufactured by Kirin Brewery Company, Japan in Hematological Malignancy **(Conducted in 15 hospitals in Shanghai from Mar to Jun 1998)**

Decision of 291st meeting Registration Board: Registration Board deferred the case for submission of following by the firm:

a. Comparative toxicity studies data under biosimilarity studies.
b. Clarification regarding the import of finished product from same source with same name.

For the point no. (a) the firm has submitted that since comparative clinical studies in humans are provided and proving similarity in toxicity, importance of comparative toxicity data in animals is of secondary in importance and is not critical or confirmatory nature and ss per Chinese Biosimilar guidelines states that if Bio-similarity is proven by PK/PD and immunogenicity there is no need to do comparative toxicity in animals.

While the point (b), the firm has submitted that the finish product applied by them with the name brand name is from the different source and in the different dosage form i.e. PFS. And further it has been submitted by the firm that they will change the brand name of the finish product if required.

The original reply of the firm has been reproduced as under for ready reference and understanding.

a) "Our case of Macgrastim 300mcg, liquid solution for injection was deferred in 291st DRB meeting of DRAP on the basis of comparative toxicity data in bio

similarity studies, in this context we want to clarify that we have submitted comparative clinical trial in humans in which efficacy & safety (side effects & toxicity profile) are compared. (Refer to Vol.II annexure d.3 clinical study report page 1-7).

b) Since comparative clinical studies in humans are provided and proving similarity in toxicity, importance of comparative toxicity data in animals is of secondary in importance and is not critical or confirmatory nature.

c) As per Chinese Biosimilar guidelines states that if Bio-similarity is proven by PK/PD and immunogenicity there is no need to do comparative toxicity in animals.

d) Since robust comparative structural and quality data is given which suggests high similarity with innovator product (Refer to Macgrastim dossier as mentioned in annexure-d. biosimilarity study).

e) Since finished drug of same manufacturer is already registered in Pakistan and is marketed by AA pharma with brand name JILIFEN injection registration No.045618.

f) Accepting Dr. Sarfraz Niazi petition US FDA has accepted that if robust analytical data suggests similarity then comparative clinical trial data is unnecessary to prove similarity. (see attached recent US FDA draft guidelines on Insulin page 3, lines 95-107. Insulin and GCSF are similar size peptides of same class cytokines.

g) US FDA updated thinking reflects that requirement of even comparative clinical data can be waived while in our case comparative clinical trial data in humans is given and toxicity data in animals is provided but it is not comparative. As per current thinking of US FDA comparative toxicity in animals is of no importance. In Macgrastim case we have submitted robust comparative analytical, structural and human clinical studies and single arm extensive toxicity data in animals is also submitted which stands sufficient to prove bio-similarity. We request that our product Macgrastim solution for injection (300ug Filgrastim) may kindly be approved for registration.

h) Same product with same formulation is registered & marketed in china i.e. country of origin

Second query was clarification regarding the import of finished product from same source with same name.

a) We also want to clarify that Macgrastim prefilled syringes (PFS) & Macgrastim 300mcg, liquid solution for injection are two different dosage form and both of them are from two different sources. The source of Macgrastim prefilled syringes is BEIJING SL PHARMACEUTICAL.CO LTD while the source of Macgrastim vials containing liquid solution for injection is HANGZHOU JIUYUAN GENE ENGINEERING CO., LTD. As Macgrastim prefilled syringe was also applied by us for registration. We are waiting for some data from our source BEIJING SL PHARMACEUTICAL.CO LTD and we may change brand name if required.

Decision: **Registration Board deferred the case for further deliberation in next meeting regarding point number 6 of guidelines and advised DBER to bring up the details of all similar cases which have already been approved on the basis of guidelines approved in 278th meeting of Registration Board.**

Item No. V Division of Quality Assurance & Laboratory Testing

S No.	Subject	Status
	AGENDA ITEM NO.1 – OLD CASES RELATED TO DRAP OFFICE, QUETTA REFERRED BY HONOURABLE DRUG COURT QUETTA.	
01.	CASES DECIDED BY BOARD FOR WHICH IMPLEMENTATION PART IS NOT TRACEABLE/PENDING.	

AGENDA ITEM NO. 02: NEW / ONGOING QC CASES		
S No.	**Subject**	**Status**
1	MANUFACTURE & SALE OF IMITATION PRODUCT POVIDONE-I SOLUTION, BATCH NO. D299, REG. NO. 025552 MANUFACTURED BY M/S N.B.S PHARMA, LAHORE.	
2	MANUFACTURE & SALE OF SUB-STANDARD COLISTIN S WATER SOLUBLE POWDER (FOR VETERINARY USE ONLY), BATCH NO. U08J17 BY M/SALINA COMBINE PHARMACEUTICALS (PVT.) LTD., KARACHI.	
3	MANUFACTURE & SALE OF SUB-STANDARD ATROFATE SULPHATE INJECTION, BATCH NO. AT.10118 MANUFACTURED BY M/S BAJWA PHARMACEUTICALS (PVT.) LTD., LAHORE.	
4	MANUFACTURE & SALE OF SUBSTANDARD DICMAF 50MG TABLETS, BATCH NO.T-043 MANUFACTURED BY M/S MAFINS PHARMA, KARACHI.	
5	CASE REFERRED BY PQCB, PUNJAB REGARDING DIFFERENT MANUFACTURERS FOR NOT PROVIDING THE METHOD OF ANALYSIS.	
6	CASE REFERRED BY PQCB, PUNJAB REGARDING KAYMAX 75MG SUGAR COATED TABLETS, B# GX1733, MANUFACTURED BY M/S QUAPER (PVT.) LT., 26-A S.I.E LAHORE ROAD, SARGODHA.	
7	CASE REFERRED BY PQCB, PUNJAB REGARDING NON PROVISION OF METHOD OF ANALYSIS.	
8	CASE REFERRED BY PQCB, PUNJAB REGARDING NON PROVISION OF METHOD OF ANALYSIS BY M/S UNISON CHEMICAL WORKS.	
9	CASE REFERRED BY PQCB, PUNJAB REGARDING NON PROVISION OF METHOD OF ANALYSIS BY M/S CREST PHARMACEUTICALS (PVT.) LTD.	
10	CASE REFERRED BY PQCB, PUNJAB REGARDING INJECTION SULFAPRIME, BATCH NO. I-109, MANUFACTURED BY M/S ATTABAK PHARMA ISLAMANBAD.	
11	CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOGIN TABLETS, B# 346, MANUFACTURED BY M/S OPAL LABORATORIES (PVT.) LTD., LC-41, L.I.T.E., LANDHI, KARACHI.	
12	CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOGIN TABLETS, B# 348, MANUFACTURED BY M/S OPAL	

	LABORATORIES (PVT.) LTD., LC-41, L.I.T.E., LANDHI, KARACHI.	
13	CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOPRIN TABLETS 75MG, B# 006502L, MANUFACTURED BY M/S PACIFIC PHARMACEUTICALS (PVT.) LTD., 30TH km MULTAN ROAD, LAHORE.	
14	CASE REFERRED BY PQCB, PUNJAB REGARDING INJECTION DANADAX, BATCH NO. 104, MANUFACTURED BY M/S DANAS PHARMACEUTICALS, ISLAMABAD.	
15	MANUFACTURE AND SALE OF SPURIOUS DRUG (QUINOZEF 250MG TABLETS, BATCH NO. AP0014) – M/S AMBRO PHARMA (PVT.) LTD., ISLAMABAD.	
16	CASE REFERRED BY PQCB, PUNJAB REGARDING CAPSULE CAPSOL ZOL 40, BATCH NO. 0198, MANUFACTURED BY M/S FESTAL LABORATORIES, JINNAH INDUSTRIAL ESTATE, LINK KATTARBAND RAOD, LAHORE.	
17	CASE REFERRED BY PQCB, PUNJAB REGARDING SUBSTANDARD MEDIDOL TABLET, MANUFACTURED BY M/S MIDICON PHARMA (PVT.) LTD., PESHAWAR.	
18	MANUFACTURE & SALE OF COUNTERFEIT ZOTANIL 3MG TABLETS, BATCH NO.055 MANUFACTURED BY M/S ZANCTOK PHARMACEUTICAL LABS, HYDERABAD.	

ITEM NO. 01– OLD CASES RELATED TO DRAP OFFICE, QUETTA REFERRED BY HONOURABLE DRUG COURT QUETTA.

It is submitted that the FID,Q@K vide letter vide letter 3-1/2009-FID(Q)K dated 28.01.2019 stated that the Honorable Drug Court, Quetta has passed the orders during proceedings on 3rd December, 2018 in the case titled "Surat Khan Medical Store and others" to provide the list of pending cases of DRAP, Quetta. Moreover, the FID Quetta requested vide letter No.3-1/2019-FID(Q) K dated 05th August 2019 "the old pending cases may kindly be discussed in the Boards concerned on priority basis and necessary decisions may kindly be passed in order to submit the status/copies of decisions in the Honorable Drug Court, Quetta".

As per information provided regarding the cases referred by the Honorable Drug Courts, Quetta and FID, Quetta @ Karachi, as per records shared by DRAP Office Quetta, following are the details of cases. The FID Quetta claimed that the cases were submitted to the Chairman CLB&RB, Government of Pakistan, de-funct Ministry of Health, Islamabad in the said years. As per available record of the section it seems that the referred cases by the FID Quetta were not processed and found pending to date due to reasons not revealed yet.

In light of request of FID Quetta, the agenda of said pending cases have been prepared according to records available in the section and the records shared by DRAP Office Quetta, for the consideration of Board please. The details of the cases are as under:-

Case No. 01: CASES DECIDED BY BOARD FOR WHICH IMPLEMENTATION PART IS NOT TRACEABLE/PENDING.

Name of drug	Manufact-ured by	Declared by CDL as	Current Status of case	Decision of 291st Meeting of RB held on 02-04th September, 2019	Communication of Decision of 291st RB	Proceeding & Decision of 292ndmeeting of RB held on 01-02 Oct, 2019
1. Tabs. Paracetamol **Batch No.** 1595	M/s Pakistan Pharmaceutical and chemical Hyderabad	Substand-ard	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of registration of Paracetamol 500mg Tablet (Reg. No. 004251) for 2 months, • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of chairman, Registration Board. • Sampling of drug after resumption of production. The decision of the Board was communicated vide letter no. 03-33/2009-DDC(QC-I) dated 10th August, 2012	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

			and 29th August, 2012 to the quarter concerned for its implementation.	implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		

Response of FID vide letter no.F.SAA-001/2019-FID-V(K)(INV) dated 30th September, 2019:

"In compliance to decision of the Drug Registration Board undersigned along with Dr. Kirshan, Assistant Director, DRAP, Karachi visited the premises of M/s Pakistan Pharmaceuticals and chemicals, A-34, SITE, Hyderabad on dated 30th September, 2019 to ensure the implementation of the decision of the 234th Meeting of Drug Registration Board. During the course of the visit Mr. Sultan-ul-Haq Qureshi and Miss Maqsooda Begam (QC Incharge) were present at the premises, the manufacturing section of the firm was closed and it was observed that there was no any manufacturing activity being carried out for some time period, in addition there was no any record of said batch of paracetamol available at the premises of the firm and no any fresh stock of tablet paracetamol was available for re-sampling. The owner of the firm informed that they had never produced the said batch number (B.No. 10) of product paracetamol tablet and never received any letter pertaining to the said batch number from the DRAP, Islamabad / any concerned quarter."

Additional Director, DRAP, Karachi has been telephonically once again requested to send the implementation status before the meeting.

Proceedings and Decision of Board in its 293rd Meeting

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- That area FID be directed to again visit the firm and communicate the implementation of Board's decision of the case.
- The Board once again directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report:
    1. The area Additional Director, field office DRAP
    2. The area FID
    3. The area Assistant Director (I&E)

That the area FID shall submit a complete report including implantation status along with supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.

In light of the above said decision of the Registration Board in its 293rd meeting, the area FID, DRAP, Karachi was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 21st April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter is also issued on 02-06-2020.

Till now, no report has been submitted by the area FID, DRAP, Karachi in the instant case.

Proceedings and Decision of Board in its 295th Meeting

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter and submit complete report including implementation status along with supporting documents/evidences/ annexures/inspection reports within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation**

officers for compliance of decision of Registration Board within stipulated time.						
2. AB -Clor **Batch No.** D-173	M/s Alience Pharmaceuticals Peshawar	Sub-Standard and Adulterated	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of registration of AB-Clor 250mg/5ml Suspension till the submission of stability data by the firm, • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of chairman, Registration Board. • Sampling of drug after resumption of production. The decision was communicated vide no.F.3-28/2009-QC-I dated 10th August, 2012 and 29th August, 2012 to the quarter concerned for its implementation.	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status along with supporting documents/evidences/ annexures/inspect	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

				ion reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		

Response of FID-II, DRAP, Peshawar vide No.F.11-54/19-Alliance-DRAP(P)-FID-II-6092:
"[…]The firm has submitted in reply that they appeared for personal hearing before the 234th DRB Meeting held on 23rd July, 2012.
3. The panel constituted vide letter no. F.3-28/2009-QC-I dated 29th August, 2012 conducted inspection on 05th and 26th December, 2013 wherein panel recommended restoring the production of the product.
Recommendation.
Therefore the panel recommends restoring the production of AB-Clor dry powder suspension as the firm has done sufficient improvements on the advice of the panel. (Copy of inspection report attached).
4. However there is no approval of Chairman, Registration Board available as per available office record.
5. Sampling of drug has also not been done as the firm has not manufactured the said product batches as per their letter no. 104-All/QC-19-20 dated 25th Sep, 2019. (Copy attached).
[…]"
6. As per company statement dated 25-09-2019 in the light of decision by DRB, despite recommendation by the panel regarding restoring the said product until now we have not manufactured the said product. However, no stability data is attached with the report.

Proceedings and decision of 293rd meeting of the Board

In the light of report submitted by FID, Peshawar, the board decided to verify the claims of the firm by corroborating it with import data of raw material required for manufacturing of product AB-Clor and place the case in forthcoming meeting of Registration Board. Aforementioned data shall be verified by DRAP, Peshawar.

In light of the above said decision of the Registration Board in its 293rd meeting, the area FID, DRAP, Peshawar was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 22nd April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter is also issued on 02-06-2020.
Till now, no report has been submitted by the area FID, DRAP, Peshawar in the instant case.

Proceedings and Decision of Board in its 295th Meeting.

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter, to verify the claims of the firm by corroborating it with import data of raw material required for manufacturing of product AB-Clor and submit complete report within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.**

3. Narobe Infusion **Batch No.** 104092	M/s. Razee Therapeutis (pvt) Ltd	Substandard	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the

			registration of Narobe Infusion (Metronidazole) (Reg. No. 046772) for 2 months, • Re-sampling from manufacturer's premises and from market. • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of Chairman, Registration Board. • Sampling of drug after resumption of production. The decision was communicated vide **No. F. 3-50/2010-DDC (QC-I) dated 10th August 2012.** **That the-then DDC(QC) mentioned that the firm forwarded order on order of Islamabad High Court dated 07-08-2012 and 10-08-2012 received on 17-08-2012**	directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status along with supporting documents/evidences/ annexures/inspection reports **<u>within 15 days positively</u>**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.	the decision of Board.	said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

			wherein the Honorable Court has restrained the respondents from suspending registration of the petitioner i.e. Razee Therapeutics Lahore the copy of the write petition was not 2587/2012 is being obtained from the Court, which will be processed accordingly. **That the parawise comments in the afore said writ petition was submitted on 26.09.2012 in the Honorable Islamabad High Court. That in response to U.O. Note No. F.3-50/2012-DDC/QC-I (Pt) dated 06.09.2012 the Law & Justice Division vide No. F.2(1424)/2012 -Sol-III dated 20.09.2012 nominated the DAG in the case.**			

FID, DRAP, Lahore vide No. 13146 /2019-DRAP (L-IV) dated 18.10.2019 forwarded the inspection report, which was conducted on 03rd October, 2019 by a Panel of inspectors from DRAP Lahore and conclusion of report is reproduced as under:

> *"Samples of the available batches of the product under investigation were drawn and sent to CDL for test analysis. The panel of inspectors was of the view that the firm was not operating at a satisfactory level of compliance with GMP with respect to liquid injectable section. The firm was advised to upgrade the section immediately and to meet GMP requirements."*

It is submitted that the aforesaid inspection report has already been forwarded to QA-Section for taking legal

action with reference to the report of FID.

Proceedings and Decision of 293rd Meeting of the Board:

The Board after detailed discussion and deliberations after considering the facts of the case decided as under:

"the matter shall be placed again before the Board to decide the fate of registration of product in question, after having decision of Central Licensing Board on GMP non-compliance in Liquid Injectable Section by M/s Raazee Therapeutics, Lahore"

It is submitted that the Central Licensing Bord in its 273rd meeting held on 15-01-2020 decided as follows:-

1. Constitute following panel of Export for detailed GMP Inspection of the firm:-
   i. Dr. Munawar Hayat, CDI, Punjab.
   ii. Mr. Ajmal Sohail Asif, FID, Lahore
   iii. Area FID Lahore.
2. Direct the panel to submit detailed report with clear and candid recommendation:
3. Production in the Liquid injectable Section shall remain suspended till verification by panel of exports and subsequent approval by the Central Licensing Board
4. Refer the case to Drug Registration Board for necessary action at their end regarding manufacturing and sale of substandard Narobe Infusion B.No.104092.

Proceedings and Decision of Board in its 295th Meeting.

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

"To issue show cause notice & personal hearing letter to the firm for suspension/cancellation of the said product."

4. Nutrival Powder **Batch No.** 05855	M/s Sogeval Labs; France	Misbranded & Spurious	As per available record of 219th Meeting of RB held on 20th August, 2009 wherein the case was presented before the Board and the Board after scrutiny of the record has decided to • Conduct CGMP inspection • Investigate the matter through a panel • To draw the fresh samples. Furthermore, according the available record with Section the CDL test report of the said sample is time barred and received after 392 days.	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

				Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status along with supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		

Area FID, DRAP, Karachi vide No.F. 01-03/2019-FID-(K-iii&iv) dated 30th September, 2019 submitted as under:

"I have the honor to refer DRAP, Islamabad letter no. 03-41/2019-QC (291-RB) dated 19th September, 2019 on the subject cited above. In this regard it is submitted that at the time of visit there is "No'' shop/ distributor in the name of R.Y. International in Zeenat Medicines Market. Denso Hall Karachi. **As per directions the cGMP inspection could not be conducted as the subject product manufactured and imported from France as per the above subject."**

It is pertinent to mention that DRB decided in its meeting No. 219th held on 20th August, 2009 as under:

- **Conduct CGMP inspection**
- **Investigate the matter through a panel**
- **To draw the fresh samples.**

Furthermore, according the available record with Section the CDL test report of the said sample is time barred and received after 392 days.

As the shop of M/s R.Y. International in Zeenat Medicines Market Denso Hall Karachi could not be identified by the area FID and AD, DRAP, Karachi, so decision of the above said meeting could not be implemented.

Additional Director, DRAP, Karachi has been telephonically once again requested to send the implementation status before the meeting.

Registered Office: A62/15 chaudry khaliq-uz-zaman road, gizri road Karachi, Pakistan.
Liaison Office: 2nd floor Zeenat medicine market, north napeir road , Karachi 74000

Proceedings and Decision of 293rd Meeting of the Board:

That the Board was also apprised regarding following report submitted by FID-V, Karachi vide letter no. SAA.001/2020-FID-V(K)(INV) dated 02nd January, 2020 :

> "I have the honor to refer to the DRAP's letter no. F. 03-41/2019-QC(291-RB) (copy enclosed herewith) and the subsequent directions by the Addl. Director DRAP, Karachi, for investigation of subject matter in compliance of the decision of the Drugs Registration Board, the undersigned along with Mr. Abdul Rasool Shaikh, FID and Mr. Waqar Ahmed, Asst. Director, DRAP, Karachi visited to search the registered office of M/s R.Y. International, A62/15, Chaudhary Khaliq-uz-Zaman Road, Gizri, Karachi on 02 January, 2020, but the said office was not found at above mentioned address and the team moved to their Liaison Office located at 2nd Floor, Zeenat Medicine Market, Street No. 01,

Napier Road, Karachi where the area FID, Mr. Hakim Masood also joined the team for joint investigation on the matter. Mr. Muhammad Umar, the person present at said office, during investigation, informed that they have not imported the product NUTRIVAL POWDER since last fifteen (15) years and the registration rights of the said product have been transferred to any other company of Lahore. They also informed that all the imported stock was utilized/ sold out and currently there is no any stock on-hand for re-sampling. The firm also informed that currently they do not possess the old record in their office; however they will submit the import and registration record along with copies of relevant correspondence to the office of area FID within a week."

Board after detailed discussion and deliberations after considering the facts of the case decided as under:

"directed FID resubmit complete case with clear candid recommendations along with verify the claims of firm that it has not imported the product since last fifteen (15) years from concerned DRAP fields offices."

In light of the above said decision of the Registration Board in its 293rd meeting, the area FID, DRAP, Karachi was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 22nd April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter has also been issued on 02-06-2020.

Till now, no report has been submitted by the area FID, DRAP, Karachi in the instant case.

Proceedings and Decision of Board in its 295th Meeting

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter and submit complete case with clear candid recommendations along with verification of firm's claim that it has not imported the product since last fifteen (15) years from concerned DRAP fields offices within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.**

5. Caps. Epoclox 500mg **Batch no:** 5A001	M/s Epoch Pharmaceuticals, Karachi	Substandard & Misbranded	As per available record of 219th Meeting of RB held on 20th August, 2009 wherein the case was presented before the Board and the Board after scrutiny of the record has decided to • Conduct CGMP inspection • Investigate the matter through a panel • To draw the fresh samples. The decision vide letter No. F. 03-59/2006-QC dated 30-09-2009	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

			communicated to the-then Deputy Director (QA) for its implementation.	comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		

Area FID, DRAP, Karachi vide no. F. 4-10/2019-FID-II-(K)1180 dated 04.10.2019 submitted as under:

"I have the honor to refer to your letter No.F.03-41/2019-QC (291-RB) dated 19th September, 2019 regarding subject cited above and to state that M/s Epoch Pharmaceuticals Karachi was contacted to clarify the subject matter.

2. The firm vide letter no. Nil dated 25th September 2019, submitted that the required inspection in that connection had been conducted by the then FID and Director CDL Karachi on 27th January 2010, but the sample of under referenced product was not taken for test & analysis.

3. It is further stated that as the necessary inspection has already been conducted thereby only samples were taken and sent to Federal Government Analyst, CDL Karachi for test & analysis in compliance to the direction.

4. All necessary documents in this matter are hereby attached for your information & further necessary action/direction."

Proceedings and decision of 293rd Meeting

Registration Board after detailed discussion and deliberations after considering the facts of the case decided as under:

> **"Directed area FID, Karachi to carryout Product (Caps. Epoclox 500mg) Specific Inspection for verification of root cause analysis, Corrective and preventive action (CAPA) by the firm and panel comprising of Dr. Rafeeq Alam Khan, Member Registration Board, Area FID and Ms. Hira Bhutto, AD-CDL.**
> **Submit test/analysis report of already taken samples."**

In light of the above said decision of the Registration Board in its 293rd meeting, the area FID, DRAP, Karachi was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 21st April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter is also issued on 02-06-2020.

Till now, no report has been submitted by the area FID, DRAP, Karachi in the instant case.

Proceedings and Decision of Board in its 295th Meeting

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter and conduct Product (Caps. Epoclox 500mg) Specific Inspection for verification of root cause analysis, Corrective and preventive action (CAPA) by the firm and submit complete report with clear & candid recommendations within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.**

6. Inj. Neutim 250mg **Batch No.** 0265P061	M/s Neutro Pharma (Pvt) Ltd; Lahore.	Substandard	As per available record the case was presented in 228th Meeting of RB held on 12 & 13th October, 2010 wherein the Board decided as under: • strict warning to the firm. • Panel GMP inspection • Sampling of the raw material.	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

				implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		

The Additional Director, DRAP, Lahore vide no. 16078/2019-DRAP(L-VI) dated 04.12.2019 informed that the inspection of M/s Neutro Pharmaceuticals, 9.5-Km Sheikhupura road, Lahore was conducted by the panel of inspectors on 02.10.2019. The conclusion of said report is reproduced as under:

"**Conclusion**:
In the light of above the panel has given some advises regarding GMP compliance and also observed that the firm is not manufacturing drug namely Neutim 250mg injection since last 7-8 years. No manufacturing record was available of the above said drug even no any raw material was available for sampling of the said product at the time of visit, so it is suggested that the registration of the said product Neutim 250mg Injection Registration No. 038852 may be suspended/ cancelled as the management also discontinued this drug since 7-8 years due to its unavailability of demand in local market (copy of firm's Reply attached) on the other hand, the firm GMP practices was found satisfactory and few shortcomings were noticed and communicated to the firm representative for immediate compliance and also asked for their compliance report as stated above"
It is proposed that as identified in the report, the firm is not manufacturing drug namely Neutim 250mg injection since last 7-8 years, so the registration of the said product may be withdrawn/cancelled as per prevailing law.

Proceedings and Decision of 293rd Meeting
Board after detailed discussion and deliberations after considering the facts of the case decided to issue show cause notice to the firm/responsible persons for cancellation/suspension of Registration of Neutim 250mg injection as recommended by the panel in inspection report dated 02-10-2019. The board Further decided to verify the claims of the firm by corroborating claim of not producing it with import data of raw material from DRAP Lahore required for manufacturing of product Neutim Injection and place the case in forthcoming meeting of Registration Board.

- The FID, DRAP, Lahore was requested vide letter No.F.03-65/2019-QC (293rd RB) dated 22nd April, 2020 to comply with the decision of the Registration Board in its true letter and spirit. Reminder of the above said letter is also issued on 02-06-2020.

Till now, no report has been submitted by the area FID, DRAP, Lahore in the instant case.

Proceedings and Decision of Board in its 295th Meeting.
The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

- **Last/final chance shall be given to the FID/Investigation officer for compliance of the already communicated decision in the instant matter and to verify the claims of the firm by corroborating claim of not producing it with import data of raw material from DRAP Lahore required for manufacturing of product Neutim Injection & submit report with clear and candid recommendations within 15 days positively.**
- **QA&LT Division, DRAP, Islamabad is advised to direct Federal Inspector of Drugs/Investigation officers for compliance of decision of Registration Board within stipulated time.**

ITEM NO. II: NEW QC CASES

Case No. 01: Manufacture & Sale of Imitation product Povidone-I Solution, Batch No. D299, Reg. No. 025552 Manufactured by M/s N.B.S Pharma, Lahore.

The FID-VI, DRAP Karachi visited the premises of M/s Madina Medical Store, Gulshan-e-Maymar, Karachi in light of the national task force on 09-01-2019 and taken the following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name:	Povidone-I Solution
Registration No:	025552
Batch No:	D299
Manufacturing Date:	Oct-2018
Expiry Date:	Oct-2020
Manufactured By:	M/s N.B.S Pharma, 8th KM, Thokar Raiwind Road, Lahore.

The FID-VI, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.ARS-05/2019-FID-VI (K) dated 10-01-2019 as required under Section 19(3)(i) of the Drugs Act, 1976.

The Government Analyst, CDL, Karachi declared the sample as **Imitation product** vide test/analysis report **No.R.KQ.26/2019** dated 06th February, 2019 which is violation of Section 23 (1) (a) (ii) of the Drugs Act, 1976 and rules framed there under. Results of the test are reproduced as under;

Description:	*Brown colored solution in plastic bottle.*
Identification:	*Povidone Iodine identified.*
pH Determined:	*3.01*
Limits:	*1.5 to 6.5*
Assay for available Iodine:	
Determined amount/100ml:	*0.7159g*
Stated amount/100ml:	*0.75g*
Percentage:	*95.5%*
Limits:	*85.0% to 120.0% Complies.*

Remarks:

1) *The sample was suspected as counterfeit/imitation product with brand leader i.e. "Pyodine Solution" manufactured by M/s Brooks Pharma (private) Limited, Karachi. Therefore, the sample was tested for iodine and its label and outer packing compared with pyodine solution.*

2) *The label claim, color scheme, name of sample, text and presentation of outer packing of sample povidone-I solution nearly resemble as to be calculated to deceive the label and outer packing of the brand leader product "Pyodine solution" Registration number 009528, manufactured by M/s Brooks Pharma (private) Limited, Karachi. Hence sample is declared intimation product under section 3 (f) of the Drugs Act, 1976.*

The area FID-VI, Karachi vide letter No.ARS-05/2019-FID-VI (K) dated 12-02-2019 has asked the firm M/s N.B.S Pharma, 8th KM, Thokar Raiwind Road, Lahore to explain their position in the matter of manufacturing and selling of substandard drug with direction to recall the above said batch from the market.

M/s N.B.S Pharma, 8th KM, Thokar Raiwind Road, Lahore submitted their reply vide letter Nil dated 18-02-2019 wherein the firm intents to change the presentation of their product and design of its label and discarding & withdrawing 9000 bottles of drug in question for better regulatory compliance.

The FID DRAP Karachi recommended keeping in view the commitment of firm for better regulatory compliance the firm may be heard in person in the upcoming meeting of DRB to fix the charges deemed fit by the board. The FID has also provided names of the technical persons provided by the firm and are mentioned below;

i. Sheikh Shahzad Nabi (CEO)
ii. Dr. Abdullah (Production Incharge)
iii. Waseem Ahmed Chughtai (Quality Control Incharge)

The Drugs Licensing Division was requested for verification of the names provided by the FID DRAP Karachi for the period of October 2018 for further processing of the case. The Licensing Division provided the required details which are mentioned below;

i. Mr. Sh. Shahzad Nabi (Proprietor)
ii. Mr. Muhammad Abdullah (Production Incharge)
iii. Mr. Waseem Ahmed (Quality Control Incharge)

Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-12/2019-(QC) dated 13-05-2019 and the reply of the firm is yet not received.

Proceeding of the 290th Meeting of Registration Board.

Mr. M. Abdullah (Production Incharge), Mr. Shahzad Nabi (Proprietor) and Mr. Waseem Ahmad (Q.C. Incharge) of M/s N.B.S Pharma, 8th KM, Thokar Raiwind Road, Lahore appeared on behalf of M/s N.B.S Pharma, 8th KM, Thokar Raiwind Road, Lahore to plead the instant case of manufacture & sale of Imitation product Povidone-I Solution, Batch No. D299, Reg. No.025552, before the Board in its 290th meeting on 04th July, 2019.

Representatives of the firm informed that they have already applied for change of color scheme of their product to the concerned section of DRAP for better regulatory compliance.

Decision of the 290th Meeting of Registration Board.

The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided as under:

i. The firm will process case for change in color scheme of the product in question and inform the Board.
ii. Registration shall remain suspended till the approval of color scheme by Chairman, Registration Board.
iii. A general advisory shall be issued to all manufacturers/ importers for refraining from imitating of the color scheme of the brand leaders to mislead the peoples. All the Chief Drug Inspectors and Additional Directors of field offices should enforce these directions in true letter and spirit. A comprehensive report may be submitted before the Registration Board.

The above said decision was communicated to the firm with direction to comply with the decision of the Registration Board in its true letter and spirit and submit compliance report before the resumption of production of the product in question vide letter No.F.03-37/2019-QC (290th RB) dated 26th September, 2019.

Current Status of the Case.

M/s N.B.S Pharma vide reference No. nil dated 22-01-2020 submitted that they have changed the design & color scheme of their product and also got approval of packing design and color scheme from DRAP vide letter No.F-35-PVRC/2019 (PR-II) dated 24-12-2019.They further requested to resume the production of their product.

Proceedings and Decision of Board in its 295th Meeting

Registration Board considered the facts/available record of the case, and after thorough deliberation decided to resume the production of Povidone-I Solution, Registration No. 025552, Manufactured by M/s N.B.S Pharma, 8th KM, Thokar Raiwind Road, Lahore. The Board further directed to comply Drugs (Labelling & Packing) Rules, 1986 and conditions of registration.

Case No. 02: **Manufacture & Sale of Sub-Standard Colistin S Water Soluble Powder (For Veterinary Use Only), Batch No. U08J17 by M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi.**

The FID-VI, DRAP Karachi visited the premises of M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi on 27-08-2018 to check the GMP compliance level of the firm and taken the following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name:	Colistin S water Soluble powder
Composition:	Each gram contain colistin Sulphate 4800000 I.U
Registration No:	058872
Batch No:	U08J17
Manufacturing Date:	10-17
Expiry Date:	09-20
Manufactured By:	M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi

The FID-VI, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.ARS-123-125/2018-FID-VI (K) dated 03-9-2018 as required under Section 19(3)(i) of the Drugs Act, 1976.

The sealed portion of samples were also sent to Chairman, Registration Board, DRAP, Islamabad vide letter No.ARS-123-125/2018-FID-VI (K) dated 03-09-2018 as required under the provision of clause (b) (3) Schedule V (Procedure for Inspector) of DRAP Act, 2012.
The Government Analyst, CDL, Karachi declared the sample as of **Sub-standard** quality **on the basis of assay content** vide test/analysis report **No.KQ.627/2018** dated 01st November, 2018 which is violation of Section 23 (1) (a) (v) of the Drugs Act, 1976 and rules framed there under. Results of the test are reproduced as under;

Description:	*White powder in plastic container.*
Identification:	*Colistin and Sulphate identified.*
Assay for Colistin Sulphate:	
Determined amount/gm:	*6913183.38 I.U*
Stated amount/gm:	*4800000 I.U*
Percentage:	*144%*
Limits:	*90.0% to 110.0%* ***Does not comply.***

Remarks:- *The sample is of* ***" substandard"*** *quality under the Drugs Act. 1976.*

The area FID-VI, Karachi vide letter No.ARS-123-125/2018-FID-VI (K) dated 12th November & 12th December, 2018 has asked the firm M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi to explain their position in the matter of manufacturing and selling of substandard drug with direction to recall the above said batch from the market.

In response, M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi submitted their reply vide letters dated 07-12-18 & 21-12-18 wherein they have informed that total quantity of the batch manufactured was 50kg which is lying in their warehouse however they didn't accept the test report based on their finding and commercial viability.
That the firm did not request to retest the sample from Appellate laboratory, NIH, Islamabad rather they requested FID to kindly withdraw the show cause notice.
That the firm in another letter dated 07-01-2019 requested to send the sample to NIH, for retesting of the sample but their request was not acceded as the request was not made within stipulated time of 30 days under the Drugs Act, 1976.
Name of the technical persons provided by the FID are as under:

- Imran Rehman Memon, Director (CNIC No. 42201-2142624-1)
- Muhammad Abdul Aziz Moosa, Production Manager (CNIC No.42101-9964252-1)
- Mrs. Rizwan Nighat, QC Manager (CINC No. 42201-0657326-6)

The Drugs Licensing Division was requested to verify the names provided by the FID-VI, DRAP, Karachi for further processing of the case and they provided the following names being responsible persons;

M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi.	Imran RehmanMemon**(Director)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi
Abdul RehmanMemon**(Director)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi	Farida RehmanMemon**(Director)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi
Ali RehmanMemon**(Director)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi	RizwanaNighat**(Q.C Incharge)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi
Ajmal Ali Huda **(Production Incharge)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi	

Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-87/2018-(QC) dated 28-08-2019.
M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi submitted their reply to show cause notice vide letter No. nil dated 06-09-19 which is reproduced as under:
This is in reference to your letter No.F.03-87/2018-QC dated 28th August, 2019 concerning our veterinary product Colistin S water soluble powder (B# V08K17) which was drawn from our premises by the respected Area FID during routine GMP inspection of our plant and was sent to CDL for test/analysis.

The Government Analyst of the CDL, Karachi declared our sample substandard on the basis of an assay percentage of 144%. The same was informed to us by the area FID.

We are enclosing herewith a copy of the area FID's letter No. ARS-123-125/2018-FID-VI (K) dated 12-12-2018 which was received by us on 21-12-18. Vide this letter the area FID in point No. 7 inquired from us if we would like to challenge the CDL test report. To its reply, through our letter dated 07-01-2019 we categorically stated that we are challenging the CDL test report. A copy of our reply dated 07-01-2019 is enclosed which also shows the receiving signature of the area FID's office. Hence we did not contravene any provisions of the Drugs Act, 1976 as we replied to the area FID within the stipulated time period of 30 days of receipt of this letter dated 12-12-18 requesting him to send our sample to NIH for retesting. Unfortunately, despite our request our sample has not been sent to NIH for retesting which is in contravention of our rights under the Drugs Act, 1976. Hence we are again requesting you to please heed to our request to send our product for retesting in NIH before the product is expired. We further reiterate that the entire stock manufactured of the subject batch is still lying in our warehouse and has not been sold in the local o export market.

Proceeding of the 292nd Meeting of Registration Board.

Mr.RehmatUllahBaig, Regulatory Representative (42201-0462916-1) appeared on behalf of M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi to plead instant case of manufacture & Sale of Sub-standard Colistin S Water Soluble Powder (For Veterinary Use Only), Batch No. U08J17, manufactured by M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi.

Representatives of the firm re-iterated points already mentioned in their letter as recorded herein above and requested to retest their product from Appellate laboratory, NIH, Islamabad as they have applied for retesting within one month of the letter of FID wherein they were asked for retesting.

Decision:

The Board after hearing the representative of the firm deliberated the matter in depth in the light of available record/ investigation report of FID and letters issued by the FID to the manufacturer decided as under:

i. That the Board's portion of the sample (Colistin S Water Soluble Powder (For Veterinary Use Only), Batch No. U08J17, manufactured by M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi) shall be sent for testing by Appellate Laboratory, NIH, Islamabad.
ii. QA&LT Division shall prepare an SOP for processing of cases pertaining to test / analysis of samples and their further processing by Federal Inspector of Drugs.

The Said sample was received in NIH, Islamabad for retesting as per above decision dated 19-11-2019.

Current Status of the Case.

The Appellate Laboratory, NIH, Islamabad declared the sample of Colistin S Water Soluble Powder (For Veterinary Use Only), Batch No. U08J17, manufactured by M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi as of "Standard" quality vide their test report No. 023-M/2019 dated 09th January, 2020. Test report of NIH is reproduced as under:

Description:	*White powder contained in white labeled plastic bottle*			
Identification:	*Colistin Sulphate identified.*			
Assay:	*Stated*	*Found*	*Limit*	*Percentage*
Colistin Sulphate	*8400000 IU/gram*	*4648080 IU/gram*	*90-110%*	*96.835%*

Complies with manufacturer's specifications.

In the opinion of the undersigned the sample is of standard quality as defined in the Drugs Act, 1976 for the reasons given below:

Nomenclature:	*Colistin S water Soluble powder (for veterinary use only).*
Batch No.	*U08J17*
Date of Mfg.	*10-2017*
Date of Exp.	*09-2020*
Manufacturer:	*M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, S.I.T.E. Super Highway, Karachi.*

Description:	*White powder contained in white labeled plastic bottle*			
Identification:	*Colistin Sulphate identified.*			
Assay:	*Stated*	*Found*	*Limit*	*Percentage*
Colistin Sulphate	*8400000 IU/gram*	*4648080 IU/gram*	*90-110%*	*96.835%*

Complies with manufacturer's specifications.

Conclusion: The sample is of **standard** quality on the basis of tests performed.

Proceedings and Decision of Board in its 295th Meeting

As report of NIH, Islamabad (Appellate Laboratory) for Colistin S water Soluble powder (for veterinary use only), Batch No.U08J17, Manufactured by M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, S.I.T.E. Super Highway, Karachi is of standard quality thus no further action is required.

Case No. 03: Manufacture & Sale of Sub-Standard Atrofate Sulphate Injection, Batch No. AT.10118 Manufactured By M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore.

FID-II, DRAP, Lahore visited the premises of M/s Bajwa Pharmaceuticals Industries, 36-km GT Road, Gujranwala Road, District Sheikhupura on 21-02-2018 and taken following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3:

Name:	Atrofate Sulphate Injection
Composition	Each ml contain 1mg of Atropine Sulphate
Registration No:	085776
Batch No:	AT.10118
Manufacturing Date:	Jan.2018
Expiry Date:	Dec.2019
Manufactured By:	M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore

FID-II, DRAP, Lahore has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.2999/2018-DRAP (L-II) dated 01-03-2018 as required under Section 19(3) (i) of the Drugs Act, 1976.

FID-II, DRAP, Lahore has also forwarded one sealed portion of sample as Board's Portion vide letter No.3000/2018-DRAP (L-II), dated 01-03-2018 as required under Section 19(3)(ii) of the Drugs Act, 1976.

The Federal Government Analyst, CDL, Karachi declared the sample as of **sub-standard** quality vide test/analysis **report No.LHR.26/2018**, on the basis of pH (**pH determined= 5.72, Limits= 2.8-4.5**) dated 20th April, 2018.

FID-II, DRAP, Lahore vide letter No.5464/2018-DRAP (L-II) dated 24-04-2018 directed M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore to recall the said drug on war foot basis.

M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore submitted their reply vide letter No.BPL/MOH/18/101dated 14-05-2018 wherein they challenged the results of the CDL, Karachi and requested for retesting of sample by appellate laboratory – NIH, Islamabad U/S 22 (4) of the Drugs Act, 1976.

On the request of the firm, sample was sent for the appellate testing from Appellate laboratory, NIH, Islamabad dated 13-08-2018 under section 22(5) of the Drugs Act, 1976 after seeking due approval from the Chairman, Registration Board (in exercise of delegated power of Registration Board in it 283rd Meeting held on 27 to 29th June, 2018) as required U/S 22(5) of the Drugs Act, 1976.

The Appellate Laboratory – NIH, Islamabad vide their test report No.018-M/2018 dated 04-10-2018, has also declared the sample as of **Sub-standard** quality on the basis of pH **(pH determined=6.08, Limits= 2.8-4.5)**.

Stance of The Firm:

M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore vide reference No.BPL/MOH/18/138 dated 03 November, 2018 have stated that upon testing of samples in quality control lab, pH of Atrofate sulphate (Atropine sulphate 1mg/ml) injection was found within limits as per BP 2017 specifications.

They stated that all other tests complied BP specs such as assay, physical Appearance, BET and sterility but pH showed compliance with USP 39 specifications instead of BP specifications. However pH results did not interfered physical appearance and no complaint was received from health section regarding pH doing harm for human.

They further requested that production of the said product is stopped on the orders of FID and if they are given a chance to resume production of the said injection, it would be very helpful to overcome the shortage of emergency product in major hospitals. They further requested to review their product as they are under immense pressure from major institutional hospitals.

Remarks of the Deputy Director (Quality Control):

The sample of Atropine Sulphate was declared on the basis of Ph limits. The company stopped production of the said product and conducted investigation. They also conducted the stability studies. Furthermore the said product is reportedly short item. The case is yet to be considered by the Registration Board. To save the time it is proposed that a panel may be constituted for verification of the stability data and product specific inspection, so that if the company fulfills the criteria, they may start production to avoid market shortage and to ensure free availability.

Proceeding and Decision of the 287th Meeting of Registration Board.

The facts of the case were presented before the Registration Board in its 287th meeting on 04th January, 2019. The Board deliberated the matter in depth in the light of available record/ remarks of the Deputy Director (Quality Control), decided as under:

I. Verification of the stability data provided by the firm as soon possible by the following panel of inspectors:
   - Additional Director, DRAP, Lahore.
   - Dr. Shafiq Ur Rehman, Director, DTL, Lahore.

The above said decision was communicated to the firm and panel members vide letter No.F.03-92/2018-QC (287-RB) dated 28th February, 2019.

M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore vide reference No.BPL/MOH/19/159 dated 29th April, 2019 stated that since the issuance of above said letter, the firm has still not been inspected by constituted panel of inspectors. They further requested to reconstitute the panel to resolve the matter and oblige.

Proceeding and decision of the Board.

The case was presented before the Registration Board in its 289th meeting on 16th May, 2019 for reconstitution of the panel which was constituted by the Board in its 287th meeting and the Board reconstituted the panel as follows;

a) Director, Drug testing Laboratory, Lahore.
b) Area Federal Inspector of Drugs.

The above said decision was communicated to the panel and the firm vide letter No.F.03-31/2019-QC (289th RB) dated 03rd July, 2019.

Current Status of the Case.

The FID-II, DRAP, Lahore vide reference No.1223/2020-DRAP (L-II) dated 20-01-2020 wherein she has forwarded the inspection report of M/s Bajwa Pharmaceuticals (Pvt.) Ltd, 36-k.m. GT Road, Gujranwala Road, District Sheikhupura. The Panel inspection was carried out on 19-12-2019 in response to No.3-92/2018-QC (287-RB), dated 28-02-2019 and F. No. 03- 31/2019-QC (289-RB) dated 03-07-2019 for the verification of stability data. Observations noted by the Panel are reproduced as under:

During the inspection of M/s. Bajwa Pharmaceuticals (Pvt.) Ltd., on 19/12/19, the panel checked the SOPs BMR, testing reports, water treatment plant validation and HVAC validation and noted the following observations:-

i) *Firm informed the panel that they have recalled and destroyed the Atrofate Sulfate Injection B. No. AT 10118. Firm was advised not to destroy recalled material in future without intimation and approval from area FID.*

ii) *Firm did not have vendor validation SOP for processing packing material. Ampoules for filling Atrofate Sulfate were procured from local vendor without CoA. Moreover, firm had also not conducted test for leachable substances on the empty ampoules.*

iii) *Firm had not done process validation for Atrofate Sulfate Injection.*

iv) *Firm had not conducted cleaning validation of equipment used in manufacturing and filling of Atrofate Injection.*

v) *Firm had not conducted since sampling of previous product (Noloxo-X) manufactured before Atrofate Injection on the same line.*

vi) *Firm had sterilized the batch in two autoclaves in parts as the batch size was 126,000 ampoules whereas autoclaves were smaller.*

vii) *BMR had several inconsistencies.*

viii) *Primary and secondary reference standards for Atropine Sulfate were not present.*

ix) *Master batch formula for Atrofate Injection was not developed.*

x) *Firm had imported Atropine Sulfate R/M complying with BP specifications but had generated in house CoA on USP specifications.*

xi) *Autoclave validation protocol was not proper. Validation had been done using biological indicators only.*

xii) *Firm had done incomplete testing of Atropine Sulfate RM and had not conducted tests for*

impurities.

xiii) *Finished product testing was done on UV whereas pharmacopoeial method stated testing on HPLC. Firm was advised to increase the number of HPLCs.*

xiv) *Atropine Sulfate is "to be protected from light" but product was packed in clear glass ampoules.*

xv) *Firm had not conducted validation of water treatment plant.*

In additional to the above the stability data and batches kept on stability testing were checked.

(i) *Firm could not provide accelerated stability study data reports provided to DRAP at the time of registration.*

(ii) *Stability studies protocol was not developed.*

(iii) *Only first two commercial batches of Atrofate Sulfate Inj. (B. No. AT10118 and AT 10218) were kept in stability chambers even though firm had manufactured more than three batches of Atrofate Sulfate Injection at that time.*

(iv) *Ampoules in stability chamber were not placed in commercial packing instead they were placed in clear plastic packs.*

(v) *AT 10218 batch, stability studies were started on 13/02/18 whereas batch was manufactured in January 2018.*

(vi) *Alarm system was not installed in stability chambers.*

(vii) *Continuous monitoring of stability chambers was not being done.*

		Observed pH
1	*Samples from retention samples*	*3.20*
2	*Samples from stability chamber*	*4.76*

Conclusion:-

On the basis of documents viewed, technical personnel met and the physical inspection of the firm it can be concluded that the stability studies of Atrofate Sulfate Injection were not conducted properly by the firm and the stability of the product could not be verified. However they were directed to submitted compliance report in this regard so panel inspection conducted accordingly.

Proceedings and Decision of Board in its 295th Meeting.

Registration Board considered the facts/available record of the case, Inspection report forwarded by the panel and after thorough deliberation decided as under:

- **Production of Atrofate Sulphate Injection, Reg. No. 085776 shall remain suspended till the firm submit product development data including real time & accelerated stability studies of the said product.**
- **Verification of the stability data by the already constituted panel in 289th meeting of Registration Board.**

Case No.04: **Manufacture & Sale of Substandard Dicmaf 50mg Tablets, Batch No.T-043 Manufactured by M/s Mafins Pharma, Karachi.**

The FID-VI, DRAP Karachi visited the premises of M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi on 15-11-2018 to check the GMP compliance level of the firm and taken the following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name:	Dicmaf Tablet 50mg.
Composition:	Each tablet contains 50mg Diclofenac Sodium.
Registration No:	079884
Batch No:	T-043
Manufacturing Date:	15-11-18
Expiry Date:	15-10-20
Manufactured By:	M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi

The FID-VI, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.ARS-166-167/2018-FID-VI (K) dated 16-11-2018 as required under Section 19(3)(i) of the Drugs Act, 1976.

The Government Analyst, CDL, Karachi declared the sample as of **Sub-standard** quality **on the basis of dissolution** vide test/analysis report **No.KQ.770/2018** dated 12th November, 2018 which is violation of

Section 23 (1) (a) (v) of the Drugs Act, 1976 and rules framed there under. Results of the test are reproduced as under;

Description:	*Orange colored enteric coated tablet.*
Identification:	*Diclofenac Sodium identified.*
Uniformity of Dosage Units	
By Weight Variation:	*Complies.*
Dissolution test:	***Does not comply.***
Assay for Diclofenac Sodium:	
Determined amount/tablet:	*50.3mg*
Stated amount/tablet:	*50mg*
Percentage:	*100.6%*
Limits:	*90.0% to 110.0% Complies.*

Remarks:- The sample is of **Substandard** quality under the Drugs Act, 1976.

The area FID-VI, Karachi vide letter No. ARS-166-167/2018-FID-VI (K) dated 14-10-2018 has asked the firm M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway, Industrial Area, Karachi to explain their position in the matter of manufacturing and selling of substandard drug with direction to recall the above said batch from the market.

M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi submitted their reply vide letter No.MP/CDL/12/18 dated 31-12-2018 wherein they were not satisfied with the results of the Federal Government Analyst, CDL, Karachi and challenge the contents of the report under section 22 of the Drugs Act, 1976 and requested for retesting from Appellate Laboratory, NIH, Islamabad.

On the request of the firm, the sample was sent to appellate laboratory, NIH, Islamabad dated 18-03-2019 as required under section 22 (5) of the Drugs Act, 1976.

The Appellate Laboratory, NIH, Islamabad declared the said sample as of **Substandard** quality vide test report No.08-M/2019 dated 10th April, 2019. Results are reproduced as under;

Description:	*Orange colored triangular shaped, biconvex, coated tablets packed in blister packing further packed in polythene packing.*	
Identification:	*Diclofenac Sodium identified.*	
Dissolution Test:	***Determined:***	***Limits:***
Acid stage:	*Nil*	*Nil*
Buffer stage:	*57.47%*	*Not less than 75% (Q) of label amount. (Five tablets out of six deviated from the limits)* ***(Does not comply with USP 39)***
Assay for Diclofenac Sodium:		
Stated amount/Tablet:	*50mg*	
Determined:		*53.16mg/Tab (106.32%)*
Limits:		*90-110%*
Remarks;	*The sample is of **substandard** quality as defined in the Dug Act, 1976.*	

The FID-IV, DRAP, Karachi in pursuance of Section 19 (7) of the Drugs Act, 1976 submitted complete case for placement in the upcoming meeting of Registration Board and provided the names of responsible which are as under:

i. Mohsin Batala, Managing Director
ii. Muhammad Nadeem, Production Manager
iii. Umair Qayum, Quality Control Manager

The Drugs Licensing Division was requested to verify the names provided by the FID-IV, DRAP, Karachi for further processing of the case and they provided the following names being responsible persons;

M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi	Muhammad Ahmad **(Partner/Director)** M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi
Iqbal Ahmad **(Partner/Director)** M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi	Mohsin Ahmad **(Partner/Director)** M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi

Noor Ahmad **(Partner/Director)** M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi	Sultan Ahmad **(Partner/Director)** M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi
Mrs. Shabana Nafees **(Production Incharge)** M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi	Syed Fida Hussain **(QC Incharge)** M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi

Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-93/2018-(QC) dated 13-05-2019.

M/s Mafins Pharmaceuticals (Pvt.) Ltd., Plot No. A-5, SITE-II, Super Highway Industrial Area, Karachi submitted their reply vide reference No.MP/ADR001 dated 18-05-2019 wherein they have stated that FID visited their factory and draw samples of the said drugs in semi finished form without unit cartons from the in process store area which was not released by the QC department by that time. The genuine manufacturing date from our record is 16-10-18; however the manufacturing date on CDL test report is 15-10-18 which is wrong statement and it may be possible that our sample has been mixed with some other samples and the test report send to us is not valid as it bears wrong manufacturing date. It is very strange to note that the test report from NIH shows date of manufacture; NIL, which doubtfully shows that the sample send to NIH may be mixed with some other samples. Due to controversy of manufacturing date, the sampling has been improper and further that it was packed and sealed in polythene bag without the original outer unit cartons.

The sample has been declared by the CDL, Karachi adopting USP 41 standards while the test report from NIH, Islamabad bears the reference of USP 39. In past the CDL has declared the same product as of standard quality which ensures that we follow the quality standards. They further requested to allow them to present their case before the Board in order to explain the matter personally.

Proceeding of the 290th Meeting of Registration Board.

Mr. Umair Qayum, Q.C. Manager (42101-1795971-5) of M/s Mafins Pharmaceuticals (Pvt.) Ltd., Karachi appeared on behalf of M/s Mafins Pharmaceuticals (Pvt.) Ltd., Karachi to plead the instant case of manufacture & sale of substandard Dicmaf 50mg Tablets, Batch No.T-043, before the Board in its 290th meeting on 04th July, 2019.

Representatives of the firm informed that the sample was taken in semi finished form by the FID which was not released by their Quality Control department. He further stated that it was packed and sealed in polythene bags without the original unit carton, and they believe that the environmental conditions may have changed the parameters of the product. The stock of 50,000 tablets is also placed in their premises as such till to date.

Decision of the 290th Meeting of Registration Board.

The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided as under:

i. Suspension of the Registration of the said product for six (06) months or till the verification of root cause analysis and satisfactory report by the panel whichever is later.
ii. Corrective and preventive action (CAPA) by the firm and product development data.
iii. Product Specific Inspection including verification of product development data and confirmation of CAPA by the following panel:
    - Prof. Ghulam Sarwar.
    - Area Federal Inspector of Drugs.
iv. Destruction of the stock (50,000 Tablets) in the presence of above said panel and certificate of destruction dully signed by the Owner/representative of the firm and the panel members.
v. Inspection report and destruction certificate shall be presented before the Board.

The above said decision was communicated vide letter No.F03-37/2019-QC (290th RB) dated 26th September, 2019 to the panel with request to comply with the decision of the Registration Board.

Current Status of the Case.

FID-VI, DRAP, Karachi vide reference No.F.03-02/2020FID-VI (K) Misc dated 28th January, 2020 regarding the subject of "Pending panel inspections" submitted that the following firm is ready for inspection but unfortunately one of the panel member Dr. Ghulam Sarwar, Member, Drug Registration Board is not feeling well since many days and he is not able to conduct inspections:-

S.NO.	NAME OF FIRM	PURPOSE	DRAP REFERENCE LETTER
01.	M/s. Mafins Pharma, SITE	Product Specific	F. No. 03-37/2019-QC (290th dated 26th

	Super Highway, Karachi	Inspection	September 2019

FID-VI, DRAP, Karachi further requested that another panel member may kindly be nominated to conduct the pending inspections and report for consideration of Registration Board within stipulated time.

Proceedings and Decision of Board in its 295th Meeting.

Registration Board after considering the request of the FID, DRAP, Karachi nominated Dr. Rafiq Alam Khan, Member Registration Board as a panel member in place of late Dr. Ghulam Sarwar.

Case No. 05: **CASE REFERRED BY PQCB, PUNJAB REGARDING DIFFERENT MANUFACTURERS FOR NOT PROVIDING THE METHOD OF ANALYSIS.**

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/F-Isu-11/212/19 dated 30-10-2019 has informed that the following manufacturers have not provided the method of analysis for testing of their products by the Drugs Testing Laboratories;

Sr#	DTL	Name of Drug	Batch No.	Manufactured By	Letters sent
01.	Multan	Inj. Murcobal 500mcg/ml	84	M/S Murfy Pharmaceuticals	Three letters were sent dated: 27-07-19, 21-08-19 and 28-08-19
02.	Lahore	Irosim Syrup 120ml	S1-017	M/S Simz Pharmaceuticals (Pvt.) Ltd	Two letters were sent dated: 29-06--19 and 13-07-19

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Subject matter was considered by the provincial quality control board under section 11 of the Drugs Act, 1976 in its 211th meeting held on 30-09-2019. The board decided to left over the matter due to time constraints.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 212th meeting held on 30-10-2019. Secretary PQCB appraised the Board about background of the subject matter which was discussed at length. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specifications and method of analysis to the Government analyst/ Drug Testing Laboratories as and when required. The need for product specification/method of analysis become more critical when the drug is not available as monograph in official pharmacopeias'&/or the manufacturer has its own customized specifications/method of analysis. In such circumstances it become quite challenging &/or almost impossible for a Government Analyst to conduct testing of the drug sample.

The Board expressed its serious concerns over casual behaviour and-non-cooperation by the above listed firms in this regard. The Board after detailed discussion and deliberation decided to allow the Provincial Drug Testing Laboratories to file the above-mentioned cases. Furthermore, the Board decided to recommend the Drug Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of registration of the drugs enlisted above, in best public interest.

Proceedings and Decision of Board in its 295th Meeting.

Registration Board after detailed discussion & deliberations decided as under:

"To issue the show cause notice and personal hearing for suspension / cancellation of registration to the firm/ responsible persons as provided by the Provincial Quality Control Board (PQCB), Punjab for not providing the method of analysis & standards despite of multiple requests by the Drugs Testing Laboratories i.e. Multan & Lahore."

Case No. 06: CASE REFERRED BY PQCB, PUNJAB REGARDING KAYMAX 75MG SUGAR COATED TABLETS, B# GX1733, MANUFACTURED BY M/S QUAPER (PVT.) LT., 26-A S.I.E LAHORE ROAD, SARGODHA.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-325/2018 dated 17-09-2019 has informed that Provincial Inspector of Drugs Tehsil Jampur Rojhaan, district Rajanpur reported that:

i. He, on 26-06-2018, inspected the business premises of M/S Saleem Medical Store at Bangla Hidayat Tehsil Rojhan District Rajanpur and took samples of two different types of drug on Form No. 04 for the purpose of test and analysis.

ii. One out of these drug samples, after test/ analysis, was declared **Substandard** by Government Analyst Drug Testing Laboratory Multan as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Sugar Coated Tablet. Kaymax 75mg (Diclofenac Potassium 75mg)	GX1733	M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan.	TRA No.01-56001323/DTL dated: 18-08-2018	**Analysis with Specifications:** Manufacturer's Specification **Disintegration Test:** Determined: **18 out of 18 tablets were not disintegrated in specified time** Limit: All the tablets should disintegrate within 30min **Does not comply).** Assay: Percentage: 97.42% Limit: 90-110% Result: The above sample is **Substandard** on the basis of test performed.

iii. M/S Saleem Medical Store at Bangla Hidayat Tehsil Rojhan District Rajanpur provided invoice/ warranty No.025644 dated 05-06-2018 issued by M/S Public Medical Store Whole Sale Chemist Muslim Bazar Kashmore who in turn provided invoice/warranty no.7640 dated 24-04- 2018 issued by M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan as a proof of its purchase.

iv. Warrantor portion was sent to M/S Public Medical Store Whole Sale Chemist Muslim Bazar Kashmore.

v. A copy of test report was sent to M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan with directions to explain their position and provide requisite information in this regard.

vi. In Response, the firm challenged the test/analysis report and requested to re-test the above-mentioned drug sample from Appellate laboratory NIH, Islamabad.

vii. Pursuant to the request of manufacturer the sample was sent to NIH, Islamabad, from where the same was declared as **Sub-standard,** as detailed below: -

Name of drug	Batch no.	Name of manufacturer	NIH Test Report No. & Date	NIH Test Report Results
Kaymax Tablets 75mg	GX1733	M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan	057-P/2019-dated: 09-04- 2019	**Specifications Applied** USP-39 **Dissolution Test:** Determined: **59.73% of the label amount. Five tablets out of six deviated from the limits (Q)** Limit: Not less than 75% (Q) of the label amount

				Does not comply with USP-39 **Result:** The sample is **Sub-standard** quality on the basis of tests performed.

viii. A copy of NIH Test Report was sent to M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan with directions to provide the requisite information and to explain their position in this regard.

Drug Inspector requested for grant of permission for prosecution against the above- mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. **Manufacturing/stocking /selling of Substandard Drug**
b. **Issuance of false warranty**

Show cause/personal hearing notice(s) issued to accused person(s)

REPLY OF THE FIRM TO THE DRUG INSPECTOR:

- *M/S Quaper (Pvt.) Ltd stated that our firm is one of the leading and trusted national company, best known for its high-quality products, which are fully compliant with Drugs Act 1976 and rules framed there under. Its firm commitment to quality and adherence to high standards/ cGMP guidelines is the hallmark of the company to meet the high expectations of the patients as well as Health care providers.*
- *That retained sample of the same batch no. kept under prescribed conditions was tested at our well-equipped QC Lab, which fully complied with approved specifications and was found of standard quality.*
- *That we neither received any warrantors portion of the sample nor manufacturer portion despite the lapse of three months which was required to be required to be received within statutory period of one week.*
- *The storage conditions of the medical store where sample was drawn, not mentioned by the drug inspector.*
- *Our product is sugar coated tablet, the limits defined by the British Pharmacopoeia for disintegration time for sugar coated is not more than 60minutes, but DTL erroneously applied specifications of the film coated tablets which is not justified.*

PROCEEDINGS & DECISION BY THE BOARD:

PQCB 208th meeting held on 27-06-2019:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 208th meeting held on 27-06-2019. Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons. No one appeared before the Board on behalf of M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan. Secretary PQCB apprised the Board that request for adjournment was received from the firm. The Board after discussion decided to adjourn the case in the best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons.

Personal hearing notice(s) issued to accused person(s)
Case is placed before the Board or further necessary action

PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **210th meeting** held on **17-09-2019.** Mr Sadiq Hussain Secretary DQCB District Rajanpur & Mr Muhammad Kaleem Bhutta Drug Inspector Tehsil Jampur Rojhan were present. Drug Inspector briefed the Board about the facts of the case and requested for permission of prosecution. Accused Person Muhammad Saleem (Quality Control Manager) appeared before the Board on the behalf of M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan and submitted that;

a) Quaper Pharmaceutical industry is one of the leading and trusted national Pharmaceutical company, best known by its high-quality products, which are fully compliant with the Drugs Act 1976 and rules framed there under.

b) The storage condition of the medical store from where sample was drawn, not mentioned by the drug inspector.

c) Our sample was sent to NIH Islamabad by this honorable Board but NIH report tested our product applying USP method instead of BP and declared our product Substandard on physical basis for not complying with Dissolution test which was unwarranted and defective report as the whole test was performed without Pancreatic Enzyme without any legal justification which made the whole report doubtful.

d) Both DTL and NIH are contradictory and highly doubtful and benefit of doubt always goes to the accused.

e) He also mentioned that we have recalled all the stock from our distributors as good will gesture and we have also given the public notice through newspaper. So, He requested for the linnet view.

The Board after comprehensive perusal of the records and statements of the representatives of the firm observed that as the monograph of the subject drug product is not mentioned in BP. The label claim is false and the product is misleading in addition to substandard as declared by DTL & NIH, Islamabad. Moreover, the firm provided Manufacturer specifications to DTL Multan and it was declared as substandard based on disintegration test. On request of the firm the sample was sent to NIH, Islamabad for retesting and NIH, Islamabad has declared it substandard based on Dissolution test as it is the mistake on the part of the firm that label claim does not mention that the product is gelatinized sugar coated tablet so NIH, Islamabad applied USP-39 as the notification vide No. F-3-2/2006 DATED 05-06-2006 that stated that *"All the firms shall adopt the specifications mentioned in the official pharmacopoeias for all the formulations except those drugs not included in the official pharmacopoeia. For these drugs manufacturers may adopt their own specifications till the inclusion of that formulation in the official pharmacopoeias. After this decision firms will not be allowed to adopt their own specifications for the drugs, which are included in any of the official pharmacopoeias"* Furthermore honorable members rebutted firm arguments that due to unavailability of monograph in B.P, NIH Islamabad apply U.S.P Specifications. The Board further observed that dissolution is not a minor parameter in the drug testing. There is a linear relationship between bioavailability and dissolution rate of the drug product. Hence, the drug having low dissolution will have lower bioavailability and will be unable to reach up to the therapeutic concentration and therefore, will lead to therapeutic failure and may cause development of resistance as 'well. Keeping in view the foregoing facts, the Board unanimously decided to grant **permission for prosecution** against the following accused persons in the Drug Court:

1. M/S Quaper (Pvt.) Ltd., 26-A S.I.E Lahore Road Sargodha, Pakistan through its Managing Director Muhammad Iftikhar.
2. Muhammad Iftikhar — Managing Director.
3. Fozia Naheed — Production manager/Warrantor.
4. Muhammad Saleem — Quality Control Manager.

Of **M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan** for the offences of:

a). Manufacturing/stocking /selling of Substandard Drug.

b.) Issuance of false warranty.

The Board after due deliberation and discussion at length, decided to send a letter to Registration Board to review the registration documents of the products of M/S Quaper (Pvt.) Ltd 26-A S.I.E Lahore Road Sargodha, Pakistan.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Case No. 07: **CASE REFERRED BY PQCB, PUNJAB REGARDING NON PROVISION OF METHOD OF ANALYSIS.**

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/CF-2-214/19 dated 30-11-2019, received on 30-01-2020, has informed that Government Analyst Drug Testing Laboratory, Faisalabad vide letter no.10358 dated 03-10-19 requested Board to grant permission to file the case pertaining to testing of the following product due to non provision of Method of analysis.

Request for case file by	Name of drug	Mfg. by	Request for	Request dates & Letter #	Letter to CDC, Punjab to ask said firm for provision of method	Reason of case file
DTL Faisalabad	Inj. Uni-Neuro (Mecobalamin)	M/S Unison Pharma	Method of analysis	9998 Dated 19/8/19 10059 Dated 26/8/19 10133 Dated 03/09/19	Letter # 10203/DTL/FSD dated 12-09- 2019	No response from manufacturer yet

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 212th meeting held on 30-10-2019. The matter was left over due to time constraints.

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 213th meeting held on 15-11-2019. The Board after due deliberation and discussion decided to give an opportunity of personal hearing to the above-mentioned firm before recommendation to the DRAP for cancellation of their products registration.

Personal hearing notice issued to the firm.

PROCCEDINGS & DECISION BY THE BOARD:

The subject matter was considered by the Provincial Quality Control Board (PQCB) in its 214th meeting held on 30-11-19.

Mr Saleem Iqbal, CEO/MD appeared before the Board, to defend/justify his position. He stated that the letter sent to the firm did not bear any batch number, and that was the reason why the firm could not respond to the request for provision of method of analysis.

The Board after detailed discussion expressed its concern that the batch number had no concern with the method of analysis. Poor response of the firm is not acceptable, as per the directions given by the Registration Board vide No.F.03-37/2019-QC (290th RB), Dated: 26-September-2019.

The Board thus decided to recommend the subject case for cancellation of registration to the Drug Regulatory Authority of Pakistan.

Proceedings and Decision of Board in its 295th Meeting.

Registration Board after detailed discussion & deliberations decided as under:

"To issue the show cause notice and personal hearing for suspension / cancellation of registration to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Punjab for not providing the method of analysis despite of multiple requests by the Drugs Testing Laboratory Faisalabad."

Case No. 08: **CASE REFERRED BY PQCB, PUNJAB REGARDING NON PROVISION OF METHOD OF ANALYSIS BY M/S UNISON CHEMICAL WORKS.**

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/CF-1-214/19 dated 30-11-2019, received on 30-01-2020, wherein he has informed that Director Drug Testing Laboratory, Bahawalpur vide letter no.1456 and 1628 dated 21-09-19 and 06-11-19 requested Board to grant permission to file the case pertaining to testing of the following products due to non provision of manufacturers specifications.

Request for case file by	Name of drug	Batch #	Mfg. by	Receiving date	Request for	Request dates & Letter #	Reason of case file
DTL Bahawalpur	Tab. Ubrin (Piroxicam Beta Cyclodextrin equivalent to piroxicam 20mg)	1344	M/S Unison Chemical Works	29-07-19	manufacturers specifications	1409 Dated 2/9/19 1374 Dated 22/8/19 1348 Dated 6/08/19	No response from manufacturer yet.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 212th meeting held on 30-10-2019. The matter was left over due to time constraints.

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 213th meeting held on 15-11-2019. The Board after due deliberation and discussion decided to give an opportunity of personal hearing to the above-mentioned firm before recommendation to the DRAP for cancellation of their products registration.

Personal hearing notice issued to the firm.

PROCCEDINGS & DECISION BY THE BOARD:

The subject matter was considered by the Provincial Quality Control Board (PQCB) in its 214th meeting held on 30-11-19.

Mr Saleem Iqbal, CEO/MD appeared before the Board, to defend/justify his position. He stated that the letter sent to the firm did not bear any batch number, and that was the reason why the firm could not respond to the request for provision of method of analysis.

The Board after detailed discussion expressed its concern that the batch number had no concern with the method of analysis. Poor response of the firm is not acceptable, as per the directions given by the Registration Board vide No.F.03-37/2019-QC (290th RB), Dated: 26-September-2019.The Board thus decided to recommend the subject case for cancellation of registration to the Drug Regulatory Authority of Pakistan.

Proceedings and Decision of Board in its 295th Meeting.

Registration Board after detailed discussion & deliberations decided as under:

"To issue the show cause notice and personal hearing for suspension / cancellation of registration to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Punjab for not providing the Manufacturer's Specifications despite of multiple requests by the Drugs Testing Laboratory Bahawalpur."

Case No.09: CASE REFERRED BY PQCB, PUNJAB REGARDING NON PROVISION OF METHOD OF ANALYSIS BY M/S CREST PHARMACEUTICALS (PVT.) LTD.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/FC-01/215/19 dated 14-12-2019, received on 11-02-2020, has informed that Government Analyst Drug Testing Laboratory, Faisalabad reported that they have to file the cases pertaining to testing of the various drug samples due to non-cooperation of manufacturer. This firm failed to provide methods and standards for test/analysis due to which it was not possible to conduct test/analysis of the samples and to report the same in best public interest.

Sr. N0.	DI Area	DTL	DTL Letter No. and Date	Manufacturer	Product Name	Registration No.	Mf g Date	Expiry Date	Reason
1.	Deputy Drug Controller Wazirabad	Faisalabad	10454/DTL/ FSD 15-10-19	M/S Crest Pharmaceuticals (Pvt.) Ltd	Tablet S-Prazole 40mg (Esomeprazole) Batch# 180504	066478	05-2018	05-2020	No response from firm to provide Product Specification & Method of Analysis despite of 2 letters from DTL vide letter no. 10072/DTU FSD dated:27-08-19, 10188/DTL/ FSD dated: 11-09-19 and one letter to CDC, Punjab vide letter no. 10286/DTL/ FSD dated: 19-09-19

PREVIOUS PROCCEDINGS & DECISION BY THE BOARD:

213 Meeting held on 15-11-2019

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act in its **213th meeting held on 15-11-2019. The** Board after due deliberation and discussion decided to give an Opportunity of personal hearing to the above-mentioned firms before recommendation to the DRAP for cancellation t of their products registration.

Personal hearing notice served to the firm.

CURRENT PROCCEDINGS & DECISION BY THE BOARD:

Subject matter was placed before the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **meeting held on 14-12-2019.** Secretary PQCB apprised the Board about background of the subject matter which was discussed at length. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specification and method of analysis to the Government Analyst/Drug Testing Laboratories and Drug Regulatory Authority of Pakistan vide letter no. F. No.03-37/2019-QC(290th RB) dated 26-09-2019 has issued guide under Testing Specifications. The need for product specifications /method of analysis become more critical when the drug is not available in official pharmacopoeias and/or the manufacturer has its own customized specifications/method of analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample without having manufacturer specification / method of test / analysis.

The Board expressed its serious concerns over casual behavior and non-cooperation on the part of above listed firms in this regard. The Board after detailed discussion and deliberation decided to allow the Provincial Testing Laboratory, Faisalabad to file only those cases where Manufacturer Specifications are not provided by respective firm and also not available in official compendia. Furthermore, the Board decided to recommend the Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of

registration of the drug listed above, in best public interest.

Proceedings and Decision of Board in its 295th Meeting.

Registration Board after detailed discussion & deliberations decided as under:

"To issue the show cause notice and personal hearing for suspension / cancellation of registration to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Punjab for not providing method and standards for test/analysis despite of multiple requests by the Drugs Testing Laboratory Faisalabad."

Case No. 10: CASE REFERRED BY PQCB, PUNJAB REGARDING INJECTION SULFAPRIME, BATCH NO. I-109, MANUFACTURED BY M/S ATTABAK PHARMA ISLAMANBAD.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-331/2019 dated 14-12-2019 has informed that Provincial Inspector of Drugs Tehsil & District Sahiwal reported that:

i. She, on 13-07-2019 inspected the premises of Medicine Store of office of Directorate Live Stock, Jogi Chowk, Sahiwal and took samples of four different types of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of these drug samples after test/analysis, was declared **Substandard and Misbranded by** Government Analyst Drug Testing Laboratory, Bahawalpur as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Injection Sulfaprime [(Trimethoprm 80mg Sulfadiazine 400mg)/ml 50ml]	1-109	M/s Attabak Pharmaceutical Industries. 5-C. 1-10/3 Industrial Area, Islamabad	TRA No 01-25004258/DTL dated:28-08-2019	**Analysis with specifications applied:** MS/BP 2018 **Description (MS):** Suspension of almost white solid in pale straw solution filled in sealed amber glass vial (stated volume: 50ml) The label of the product does not bear the name of pharmacopoeia or document according to which product is manufactured (**The product is misbranded).** **Volume (BP) :** Limit: Not less than nominal (50ml) Determined: 50mL **pH (BP):** Limit: 10.0-10.5 Determined: **11.313 (Does not comply)** **Sterility (BP):** The product is sterile. **Assay (MS):** (Trimethoprim) Percentage: 100.72% Limit: 90-110% (Sulfadiazine) Percentage 98.65% Limit: 90-110% **Result:** The sample is **Substandard** on the basis of pH test and **Misbranded** as defined under clause (vi) of sub-section (s) of section 3 of the Drugs Act 1976.

iii. Store keeper, office of Directorate Live Stock, Jogi Chowk, Sahiwal provided invoice/ warranty No. DG-LS-SWL_0005-14-06-2019 dated 14-06-2019 issued by M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad as a proof of its purchase of the said drug, whereas the Drug Inspector accepted the above mentioned bill/warranty.

iv. Whereas, warrantor portion and a copy of test report of the drug sample was sent to M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad with directions to provide the requisite information and to explain their position in this regard.

Drug Inspector requested to grant permission for prosecution against the accused persons nominated in the instant case who have contravened the provisions of Section 23/27 of the Drugs Act, 1976 (as amended) /DRAP Act, 2012 and Rules framed there under by the way of -

i. **Manufacturing/ Selling/ Stocking of Substandard/Misbranded drug**
ii. **Issuance of false warranty**

Show-cause notice(s) were issued to accused person(s).

Reply of The Firm to Showcause Notice:

M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad submitted that:

> *'That the product injection Sulfaprime have manufacturer specification and the PH determined by the DTL Bahawalpur are as per manufacturer specification.*
> *That the PH limit of injection Sulfaprime Is 10— 13 and the PH determined i.e. 11.3 is within limits which are as per manufacturers' specification.*
> *That the chemical assay of both the actives Trimethoprime and Sulphadiazine is with the limits.*
> *That same product injection Sulfaprime is supplied to Gujranwala which is analyzed from DTL Multan and the DTL Multan follow our manufacturers specification and the PH determined by DTL Multan is 11.73 which is as per manufacturers specification.*
> *That how it is possible that on some component of analysis of the same product i.e. Description and Assay manufacturers specification is applied while on some components of analysis i.e. sterility and pH, BP is applied.*
> *That the matter regarding the misbranded of the product we rectify the labels of the said product and a label and an affidavit is already submitted to PQCB Lahore Letter No PQCB/P- 101209/19 "*

Personal hearing notice(s) were issued to accused person(s).

PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **215th meeting** held on **14-12-2019.** Ms. Roquia Parveen, Secretary DQCB Sahiwal and Ms. Sadaf Drug Inspector Tehsil & District Sahiwal were present along with original record of the case. Among accused persons, Sajid Hussain (Quality Control Manager) of M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad was present and submitted that the Government Analyst wrongly applied BP specifications (pH range=10.0-10.5) for pH determination instead of applying manufacturer's specifications (pH range=10-13) and declared the subject drug sample substandard. Thus, he disagreed with the DTL results and requested for lenient view based on application of wrong specifications.

In reply to a query from a Board member, representative of the firm stated that the subject drug sample got registered in 2009, since then they are producing this product according to firm's in-house specifications with pH range 10-13.

The Board, after careful scrutiny of the DTL report and statements of firm representative, observed that the subject drug sample has been declared substandard by the Government Analyst Drug Testing Laboratory on the basis of pH. The determined value of pH (11.313) is greater than the upper permissible limit i.e., **10.0-10.5** as given in British Pharmacopoeia. The Board was of the opinion that injecting more alkaline solutions (above the upper permissible limit of pH) may lead to discomfort, erythema and oedema at the site of injection. The Board further observed that the firm is continuously producing subject drug sample with more alkaline/out of range pH according to their own set, unjustified pH range.

Keeping in view the facts of the case, the Board after due deliberation and discussion, **unanimously** decided **to** grant **permission for prosecution** against the following accused persons in **Drug Court:**

1. **M/s Attabak Pharmaceutical Industries, 5-C, 1-10/3 Industrial Area, Islamabad** through its Managing Director Dr. Israr Hussain Shah
2. Dr. Israr Hussain Shah — Managing Director/Warrantor
3. Shaid Ahmad Yousafzai — Production Incharge
4. Sajid Hussain — Quality Control Manager

of M/s Attabak Pharmaceutical Industries, 5-C. 1-10/3 Industrial Area. Islamabad., for the offences of:

a) Manufacturing/ Selling/ Stocking of Substandard/Misbranded drug
b) Issuance of false warranty

The Board further decided to direct office of secretary PQCB to report to DRAP, the matter of unexplained and unjustified pH range specifications being used by the firm without performing any product development or stability studies.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.
Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.
However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Case No. 11: CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOGIN TABLETS, B# 346, MANUFACTURED BY M/S OPAL LABORATORIES (PVT.) LTD., LC-41, L.I.T.E., LANDHI, KARACHI.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-327/2018 dated 15-11-2019 wherein he has informed that Provincial Inspector of Drugs Tehsil Depalpur, District Okara reported that:

i. He on 04-01-2018 inspected the business premises of M/S Macca Medical Store, Kasur Road Rajowal Depalpur, District Okara and took samples of three different types of drugs on form No 4 for the purpose of test/analysis.

ii. Out of which one drug sample after test/analysis was declared **Substandard** by the Government Analyst Drug Testing Laboratory Punjab, Bahawalpur as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Tabs. Dologin [Mefenamic acid; 250mg]	346	M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan	TRA No: 01-01010653/DTL Dated: 21.03.2018	**Analysis with specifications applied:** Manufacturer's Specifications **Composition:** Each dispersible tablet contains: Mefenamic acid..... 250mg **Description:** A white colored tablet, oblong in shape, bisected on one side and plain on other side. Packed in blister packing of 10 units. **Disintegration:** Eight tablets out of eighteen were not disintegrated within specified time, i.e. 3 minutes. **Limit: 16 tablets out of 18 must be disintegrated within specified time, i.e. not more than 3 minutes** **(Does not comply specifications)** **Identification:** Mefenamic acid is identified. **Assav: (Mefenamic acid)** Stated:……250mg Determined: ……..253.365mg Percentage: ……101.346% Limit:……..95-105 % **Result:** The sample is Substandard on the basis of test performed.

iii. M/S Macca Medical Store Kasur Road Rajowal Depalpur, District Okara provided invoice/warranty No.19853(A) dated 16-10-2017 issued by M/S Asif Trading Corporation, 45 Akbar Road Okara who in turn provided invoice/warranty No. PH-88085 dated 18-09-2017

issued by M/S Opal Laboratories (Pvt.) Ltd., LC-41, L.I.T.E., Landhi, Karachi-Pakistan as a proof of its purchase of the said drug, whereas the Drug inspector accepted the above-mentioned bill/warranty.

iv. Whereas, warrantor portion and a copy of test report was sent to M/S Asif Trading Corporation, 45 Akbar Road Okara.

v. Whereas, a copy of test report of drug sample was sent to M/S Opal Laboratories (Pvt.) Ltd., LC- 41, L.I.T.E., Landhi, Karachi-Pakistan with directions to explain their position and provide requisite information in this regard.

REPLY OF THE FIRM TO DRUG INSPECTOR:

M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan submitted that:

"portion of sealed sample was received on 03-04-2018 after passage of 89 days, although according to law it should have been dispatched within 7 days. Moreover, we had thoroughly checked, upon detail evaluation both warrantor sample and reference sample, found OK and meets specification It is worth noting that we have not been asked for testing method and other required relevant detail for Quality Control laboratory testing. "

Drug Inspector requested for grant of permission for prosecution against the accused persons involved in the subject case who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

a. Manufacturing for sale/Sale of Substandard drug.

b. Issuance of false warranty.

Showcause/personal hearing notice(s) was issued to accused person(s).

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

209th meeting held on 17-07-2019:

Case was considered by the Provincial Quality Control Board, under section 11 of The Drugs Act, 1976 in its 209th meeting held on 17-07-2019 Mr. Zaheer-udin Babar Secretary DQCB Okara and Mr. M Irfan Munir Drug Inspector Tehsil Depalpur & District Okara were present. Drug Inspector briefed the Board about facts of the case and requested to grant permission for prosecution against the accused persons. Secretary PQCB apprised the Board that showcause/personal hearing notice was duly served to the accused persons. Counsels of the firm, Sarnia Khalid (Advocate) and M. Zohaib Shahid (Advocate) were present on behalf of M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan and submitted written request for adjournment of the subject case.

The Board after due deliberation and discussion decided to **adjourn** the case in the best interest of justice and provide another but final opportunity of personal hearing to the accused persons

Personal hearing notice(s) issued to accused person(s).

211th meeting held on 30-09-2019:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act. 1976 in its **211th**meeting held on 30-09-2019. Mr. Zaheer-udin Babar Secretary DQCB Okara was present along with the original case record. Secretary DQCB Okara briefed the Board about facts of the case and requested to grant permission for prosecution against the accused persons. Secretary PQCB apprised the Board that personal hearing notice was duly served to the accused persons. Counsel of the firm, M. Zohaib Shahid (Advocate) appeared before the Board on behalf of M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan and submitted that a similar case of Tablet Dologin [Mefenamic Acid: 250mg] with batch no. 348 was previously considered by the Board. The DTL report of both these cases declared Tablet Dologin [Mefenamic Acid: 250mg] substandard on the basis of Disintegration test. He further stated that inspection of Batch manufacturing record was recommended in the other case and requested that the subject case may be clubbed with case of Tablet Dologin [Mefenamic Acid: 250mg] with batch no. 348

The Board after detailed scrutiny of the record and in light of the arguments raised by the

Counsel of the firm observed that a case of Tablet Dologin [Mefenamic Acid: 250mg] Batch no. 348 with R. no. 36/2018 was considered by the Board in its 207th meeting held on 13-06-2019. The Board further observed that there are similarities in these two cases as both the batches (batch no. 348 & 349) were manufactured in similar time period and they failed on same grounds i.e . Disintegration test. The inspection of Batch manufacturing record was conducted on 23rd September 2019 by the nominated team and the final report is still awaited.

The Board after due deliberation and discussion, unanimously decided to accept the request of the counsel of the firm and directed the office of Secretary PQCB to club the case of Tablet Dologin [Mefenamic Acid. 250mg] Batch no 346 with the other case of Tablet Dologin [Mefenamic Acid 250mg] Batch no 348 of R. no. 36/2018 for further consideration by the Board

INSPECTION REPORT OF M/S OPAL LABORATORIES (PVT.) LTD, LC-41, L.I.T.E., LANDHI, KARACHI.

Panel Members:

Dr. Prof(R) Mahmood Ahmad, Member, PQCB.

Dr. Muhammad Munawar Hayat CDC Punjab

Date of Inspection: 23-09-2019.

Detail of matter and Firm:

- *The management of the firm is changed on 19th December 2017 which was approved in 256th meeting of CLB DRAP on 09 & 10 November 2017.*
- *QA of Firm generated request for change the art work of label on 15-01-2018*
- *Tablet Dologin (Mefenamic acid) 250mg. Batch No. 348 was manufactured on 09/2017*
- *The said drug was declared substandard on basis of Disintegration test by DTL Rawalpindi on 07-05-2018.*

OBSERVATIONS:

a) *The firm is manufacturing **"dispersible"** tablets but having the registration of plain tablets.*
b) *Product Specification of Tablet Dologin is B.P.as mentioned in method and assay is by titration.*
c) *At time of inspection, the production manager of firm informed that firm is now manufacturing the plain dologin tablets from last one year.*
d) *Currently, the firm is using the same formulation as before without any variation.*
e) *API Mefenamic acid is of BP specification.*
f) *On 18/08/2018 firm destroyed the remaining packing material /label bearing dispersible word through Gel Pvt. Ltd.*

Batch Processing Record of specific product:

01. *BMR Record: available.*
02. *QC retain sample: Not available Expired.*
03. *Testing method: available*
04. *Manufacturing started on 29/09/2017 and completed on 09/10/2017.*

Manufacturing Process of tablet Dologin 250mg:

1. *The firm provided the record of process of manufacturing of tablets Dologin, the firm has no reference of dispersible tables of Mefenamic acid of any other firm in the world.*
2. *The firm developed the method of manufacturing of tablet Dologin by using the one disintegrant at 5% percentage only in final blending and found Primogel (Sodium starch glycolate) as suitable for manufacturing of dispersible Dologin tablets.*

Conclusion:

The panel is of the opinion that:

01. *This defect in tablet is due to improper development of dispersible tablet formulation and the firm has not performed any in-vitro tests or study to evaluate the status of dispersible formulation.*
02. *The Firm has given self-life of 3 years to Plain tablets whereas 2 years of shelf-life has been given to dologin DS tablets.*
03. *The firm is performing only Disintegration test and not performing dissolution test.*
04. *The firm has not recalled the drug from the market which is still not expired. The expiry of the drug is 08/2020.*
05. *The firm is manufacturing **"dispersible"** tablets illegally while they have the registration of plain tablets.*
06. *The firm is advised to redesign its formulation to differentiate between plain and dispersible Tablet and stop manufacturing of dispersible tablets.*

Submitted for final decision to Board

Personal hearing notice(s) issued to accused person(s).

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Inspection report was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **213th** meeting held on 15-11-2019. Ms. Barkhoona Waheed Secretary DQCB Jhelum was present along with original record of the case. Counsel of the firm, M Zohaib Shahid (Advocate) appeared before the Board on behalf of M/S Opal Laboratories LC-41, L.I.T.E., Landhi, Karachi and submitted that the statement mentioned on the DTL report that "no monograph of Mefenamic acid dispersible tablet is available in official monographs" as dispersible tablets monograph is available in European Pharmacopeia. He further submitted that Mefenamic acid is commonly used to treat mild to moderate pain and its repeated use can cause serious gastrointestinal toxicity, thus, the clinical justification for manufacturing of dispersible Dologin Tablet is to avoid these adverse effects.

Dr. Munawar Hayat, Chief Drugs Controller, Punjab apprised the Board about the observations made by the inspection team during the visit of the firm. In the light of the facts stated in the inspection report, the Board observed that

- The firm has registration of plain tablets of Mefenamic acid but it was manufacturing dispersible tablet which is illegal. Moreover, the firm is manufacturing Mefenamic acid dispersible tablets, the reference of which is neither available in any pharmacopeia nor such reference is available for its manufacturing by any firm in the world.
- The defect in the tablet was due to improper development of dispersible tablet formulation and that the firm has not performed any in-vitro tests or study to evaluate the stability of dispersible formulation.
- The firm was performing only Disintegration test and not performing dissolution test while according to official pharmacopoeia, both tests are necessary to be performed.
- The expiry date of the subject drug is 08/2020 but the firm has still not recalled it from the market.
- According to the letter from DRAP to M/S Opal Laboratories LC-41, L.I.T.E., Landhi. Karachi, the management of the firm was changed on 19th December 2017 which was approved in 256th meeting of CLB DRAP on 09 & 10 November 2017. However, in PQCB 194th meeting dated 18-10-2018, the current CEO of the firm appeared before the Board and stated that the firm has been acquired by the new management in June 2017. The subject drug was manufactured in September 2017 i.e. after the new management acquired the firm. Moreover, no sale deed has been provided by the firm about handing/taking over of the firm, in support of the claim that on such date they were having the responsibility of this offense or not. Further, in writ petition no 24146/2019, as reflected by the orders of Ayesha A. Malik J dated 16-05-2019 the petitioner has not taken any such stance rather he was in the proper defense of case in the High Court in said writ petition.

Keeping in view the foregoing facts, the Board unanimously decided to grant permission for Prosecution against the following accused persons in the Drug Court

01. M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan through its Chief Executive Officer Dr. Ali Afzal

02.	Dr. Ali Afzal	Chief Executive Officer
03.	Jhanzaib Akram	Managing Director
04.	Rozina Babar	Quality Control Manager/Warrantor
05.	Ikram Zubairi	Production Manager

of M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan for the offences of:

a. Manufacturing for sale/Sale of Substandard drug.
b. Issuance of false warranty.

The Board further decided to recommend the Registration Board, Drug Regulatory Authority of Pakistan for cancellation of registration of Tablet Dologin (Mafenamic acid) 250mg manufactured by M/S Opal Laboratories LC-41, L.I.T.E., Landhi, Karachi.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Case No. 12: CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOGIN TABLETS, B# 348, MANUFACTURED BY M/S OPAL LABORATORIES (PVT.) LTD., LC-41, L.I.T.E., LANDHI, KARACHI.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-36/2018 dated 15-11-2019 has informed that Provincial Inspector of Drugs Tehsil Jhelum reported that:

iii. He on 27-02-2018 inspected the business premises of M/S M/s Tariq Pharmacy, Amin market, Muhammadi chowk, Tehsil Jhelum and took sample of two different type of drugs on Form No. 04 - for the purpose of test and analysis.

iv. One of drug sample after test/ analysis, was declared **Substandard** by Government analyst Drug Testing Laboratory Rawalpindi as detailed below:

<table>
<tr><th>Name of drug</th><th>Batch No.</th><th>Name of manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Test Report Results</th></tr>
<tr><td>Tabs. Dologin [Mefenamic acid; 250mg]</td><td>348</td><td>M/S Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E., Landhi, Karachi-Pakistan</td><td>TRA No: 01-13000725/DTL Dated: 07-05-2018</td><td>
Physical Description
White to off white colored, oblong shaped tablet, bisect line on both sides, packed in Alu-PVC blister (1x10)
Average Weight
<table>
<tr><td>Result</td><td>385.82mg</td></tr>
<tr><td>Limit</td><td>370.409.5mg</td></tr>
</table>
Disintegration Test:
<table>
<tr><td>Stage 1</td><td>4 out of 6 units fail to comply the disintegration test.</td></tr>
<tr><td>Stage 2</td><td>10 out of 18 units fail to comply the disintegration test. (Does not comply)</td></tr>
</table>
If 1 or 2 dosage units fails to disintegrate, repeat the test on 12 additional units, the requirements of the test are met if not less than 16 units tested have disintegrated.
<table>
<tr><td>Limit</td><td>NMT 3 min</td></tr>
</table>
Identification;
Mefenamic Acid identified
Assay:
<table>
<tr><td>Stated:</td><td>250mg/Tablet</td></tr>
<tr><td>Determined:</td><td>253.88mg/Tablet</td></tr>
<tr><td>Percentage:</td><td>101.553%</td></tr>
<tr><td>Limit:</td><td>95-105%</td></tr>
</table>
Result:
Sample is Substandard on the basis of disintegration test.
</td></tr>
</table>

iii. M/s Tariq Pharmacy, Jhelum provided invoice/warranty No.PH-88716, dated 13-10-2017 issued by M/S Opal Laboratories (Pvt.) Ltd., LC-41, L.I.T.E., Landhi, Karachi-Pakistan as the proof of their purchase.

iv. Copy of test/analysis report and warrantor portion was sent to warrantor M/s Opal Laboratories LC-41, L.I.T.E., Landhi, Karachi with the direction to explain their position and provide requisite information in this regard.

v. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976/DRAP Act 2012 and Rules framed there under by the way of: -

(Accused No. 1)

a. Stocking/Selling of Substandard drug

(Accused No. 2-5)

a. Manufacturing for sale/stocking/Selling of Substandard drug

b. Issuance of false warranty

Show-cause/Personal hearing notice(s) issued to accused person(s)

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Qua ty Control Board, under section 11 of the Drugs Act 1976 in its **194th meeting held on 18-10-2018.** Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons Accused Muhammad Qasim (Proprietor) of M/s Tariq Pharmacy, Amin market, Jhelum stated that he purchased the drug directly from manufacturer M/s Opal Pharma and submitted the copy of bill/warranty to the office of Drug Inspector within seven days. Chief Executive Officer of M/s Opal Pharma that the firm was acquired by the new management in June 2017. The said Batch of the drug was manufactured by old management; hence they are not responsible for commission of the offence. In response of a query, QC manager of the firm replied she has been working with the firm since 2016 and the product is being manufactured under B.P specifications. She added that the said drug is registered as a plain tablet not as a dispersible tablet and she raised this issue before the management with the request rectify the label claim. CEO of the firm apprised the Board that in response to the intimation by the QCM the firm has stopped manufacturing of the said drug as dispersible tablet. QC retained portion was tested and its disintegration time was found within required limits. He requested to drop the case.

The Board, after detailed scrutiny of the record, due deliberation and detailed discussion observed that no monograph of Mefenamic acid dispersible tablet is available in official pharmacopoeias. The product was not registered as a dispersible tablet by the **MOH/DRAP.** The said batch of drug was manufactured in September 2017 after acquisition of the firm by the new management. Hence, new management is responsible for manufacturing of the substandard drug in a dosage form not approved by the regulatory authority. In the view of foregoing facts the Board, decided to grant **permission for prosecution** against the following accused persons in the Drug Court:

1. M/S Opal Laboratories LC-41, LITE, Landhi, Karachi through its Chief Executive Officer Dr. Ali Afzal
2. Dr. Ali Afzal — Chief Executive Officer
3. Ikram Zubairi — Production Manager
4. Rozina Baber — Quality Control Manager/Warrantor

of M/S Opal Laboratories LC-41, LITE, Landhi, Karachi for the offences of:

a. Manufacturing for sale/stocking/Selling of Substandard drug

b. Issuance of false warranty

The Board further decided to drop the proceedings against the accused Muhammad Qasim (Proprietor) of M/s Tariq Pharmacy, Amin market, Muhammadi chowk, Tehsil Jhelum.

Review Petition:

The firm has filed the Review Petition against the orders of Provincial Quality Control Board of even No. dated 05-11-2018:

Dr. Ali Afzal Presently CEO of M/s Opal Laboratories (Pvt.) Ltd., LITE, Landhi, Karachi Verses Provincial Drug Inspector, Tehsil Jhelum, Jhelum,

A. That at the time of sampling of the product in question by the Respondent, the Petitioner was not Chief Executive officer of the company the rather Mr Tariq Ikram was the Chief Executive Officer/ Managing Director of the company at that time of manufacturing of the Product in question and the same is evident from the letter dated 19-12-2018 issued by the Central Licensing Board of the DRAP whereby the change of management of the company taken place. As per Section 34 of the Drugs Act, 1976 only those directors may be held responsible within whose knowledge the alleged offence was committed. Had the complainant drug inspector carried out any investigation in the matter or reflected upon status of the Petitioner in the management of the company, he would have certainly excluded his name from the list of accused persons. Therefore, the Petitioner cannot be held liable for the commission of alleged offences and name of the Petitioner as the CEO of the company is liable to be dropped from the instant case

B. That the Petitioner has been charged under section 23 and under 27(4) of the Drugs Act, 1976 in ignorance of the provisions of Section 32 of the Drugs Act which provides that the person not being the manufacturer of the drug in question cannot be held liable for non-fulfillment of responsibility of the manufacturer. He just has to satisfy himself generally to the extent that the drug did not violate the provisions of the act

C. That without prejudice to the above the test report of the DTL Rawalpindi is for various reasons completely in effective, invalid and unfit for the purpose of evaluation of the quality and standard of the drug, either under the law and under the facts, and the same are of no consequence or merit for declaring the Tablet Dologin (Mefenamic Acid) 250 mg as sub-standard.

D That this honorable Board has committed material irregularity while passing the impugned order though giving its observation that "no monograph of Mefenamic acid dispersible tablet is available in official pharmacopeias" it is submitted that this observation is totally wrong as official monograph of dispersible tablet is available. As per 'Ph Eur. monograph 0478' several categories of tablets for oral use are provided which may be distinguished as follows:

i. Uncoated tablets;
ii. Coated tablets;
iii. Effervescent tablets:
iv. Soluble tablets;
v. Dispersible tablets
vi. Orodispersible tablets;
vii. Gastro-resistant tablets;
viii. Modified release tablets
ix. Ablets for use in mouth:
x. Oral lyophilisates;

E. It is clarified that the Dologin Tablet was developed as buffered and dispersible effects, however, it was not mentioned in the brand name, in this regard, a letter dated 24-01-2004 for price revision of the product was sent to the Ministry of Health wherein it was mentioned that the Product is Buffered' and 'Dispersible' to overcome the side effects of GIT. Therefore, this observation by this Honorable Board is wrong that 'the Product was not registered as a dispersible tablet by the MOH/ DRAP'.

F. The clinical justification of the dispersible Dologin Tablets of 'Mefenamic acid' is widely used in the treatment of mild to moderate pain including headache, dental pain, post-operative/ postpartum pain, dysmenorrhea, rheumatic disorders such as osteoarthritis and rheumatoid arthritis. The chemistry and pharmacology of Mefenamic acid is no more hidden from the eyes of the prescribers besides the fact that its usage cause serious gastrointestinal toxicity such as bleeding, ulceration and perforation any time without any warning. The common adverse effects of Mefenamic acid are gastrointestinal disturbances, peptic ulceration and gastrointestinal bleeding The Petitioner/ Opal Laboratories under took studies to eliminate or reduce the above-mentioned side effects of Mefenamic acid during its usage in their Research and Development department. The first idea was to coat the tablet with an acid resistant material but it was dropped, as it will delay the onset action of the drug for almost two hours. During the further studies and review of the published literature another theory was developed that if the drug is made buffered and dispersible, the side effects can be eliminated or at least be minimized. The advantage of buffered Mefenamic Acid is to be antagonize the acidity of stomach to prevent further decrease of pH and hence minimize the serious adverse effects of Mefenamic acid on one hand and on the other hand increases absorption due to lesser acidic environment created in the stomach. Due to the dispersible action the drug is rapidly dispersed throughout the lumen of the gastrointestinal tract and as a result each particle proves its own absorption of Mefenamic acid. The theoretical results were testified at R & D with practical, the approval was received to launch the product with the slogan of buffered Dispersible Mefenamic Acid tablets. As this new idea of dispersion and buffering reached the prescribers the more and more patients were put onto Dologin tablets with buffered and dispersible action and today many are convinced remaining few to touch for their acceptance.

G. That be that as it may and without prejudice to the foregoing, and the legality of the decision of the previous management to add the word 'dispersible' on the label, the new management after taking over the company in Dec 2017 has removed the word 'dispersible' from the label.

H. That without prejudice to the foregoing, the Government Analyst has failed to mention complete protocols of the test applied in the DTL report. It is a trite law that without protocols of the test report is inconclusive and cannot be used as evidence against the accused persons. The Impugned report is liable to be set aside being based on incomplete report.

I. That the petitioner carried out a thorough check on retained samples of Tablet Dologin (Mefenamic acid) 250mg Batch no. 348 and has made similar tests on random samples of the same, no such abnormality was found, the product is well within the limit and is of standard quality. All parameters of test and analysis are within acceptable limits.

J. That Sections 11 (5)(b) and 19(6) of the Act read with Rule 5(3) of the Punjab Drug Rules. 2007 cast a duty upon the Respondent and this honorable Board to take every action under the Impugned reports by applying conscious mind and not in a mechanical manner It is regretted that

the impugned Order has been passed in violation of Section 11 (5)(b) and 19(6) of the Drugs Act and Rule 5(3) of the Punjab Drug Rules. 2007.

K. That it is the duty and obligation of the public functionaries to act justly fairly, equitably, reasonably without any element of discrimination and squarely within the parameters of law as is envisaged by Article 4 of the Constitution.

L. That in addition to above, the Petitioner reserved his right to submit further assistance to this honorable Board during the arguments of the instant petition.

Prayer:

In view of the foregoing, it is most respectfully and humbly submitted that this honorable Board may be pleased to:

i. Accept the instant review petition, delete the name of the Petitioner from the list of accused persons in the case no. PQCB/R-36/2018;

ii. Set aside the Impugned Order dated 05-11-2018 being passed without proper examination of available record;

iii. Suspend the Impugned Order till the decision of the instant review petition

Any other relief which this Honorable Forum deems fit and appropriate in the circumstance of the case may also be allowed.

Review petition:

The following accused have filed the Review Petition against the orders of
Provincial Quality Control Board of even No. dated 05-11-2018:

1. M/s Opal Laboratories (Pvt.) Ltd, LITE, Landhi, Karachi through its authorized officer Ms. Rozina Babar
2. Ms. Rozina Baber d/o Ibarat-ullah- Baber Quality Control Manager/ warrantor of M/s Opal Laboratories (Pvt.) Ltd, LITE, Landhi, Karachi.
3. Mr. Ikram Zubairi Production Manager of M/s Opal Laboratories (Pvt.) Ltd, LITE, Landhi, Karachi.

Verses

Provincial Drug Inspector, Tehsil Jhelum, Jhelum.

A That the test report of the DTL Rawalpindi consists of technical defects and therefore ineffective for the purpose of evaluation of the quality and standard of the drug, either under the law or under the facts, and the same are of no consequence or merit for declaring the Tablet Dologin (Mefenamic Acid) 250mg as sub-standard.

B. That this honorable Board has committed material irregularity while passing the impugned order though giving its observation that "no monograph of Mefenamic acid dispersible tablet is available in official pharmacopeias". It is submitted that this observation is totally wrong as official monograph of dispersible tablet is available. As per 'Ph Eur monograph 0478' several categories of tablets for oral use are provided which may be distinguished as follows;

i. Uncoated tablets;
ii. Coated tablets;
iii. Effervescent tablets;
iv. Soluble tablets;
v. Dispersible tablets:
vi. Orodispersible tablets;
vii. Gastro-resistant tablets;
viii. Modified-released tablets:
ix. Tablets for use in the mouth;
x. Oral lyophilisates.

C. It is clarified that the Dologin Tablet was developed as buffered and dispersible effects, however, it was not mentioned in the brand name, in this regard, a letter dated 24-01-2004 for price revision of the product was sent to the Ministry of Health wherein it was mentioned that the Product is Buffered' and 'Dispersible' to overcome the side effects of GIT Therefore, this observation by this Honorable Board is wrong that 'the Product was not registered as a dispersible tablet by the MOH/ DRAP'.

D. The clinical justification of the dispersible Dologin Tablets of 'Mefenamic acid' is widely used in the treatment of mild to moderate pain including headache, dental pain, post-operative/ postpartum pain, dysmenorrhea, rheumatic disorders such as osteoarthritis and rheumatoid arthritis. The chemistry and pharmacology of mefenamic acid is no more hidden from the eyes of

the prescribers besides the fact that its usage cause serious gastrointestinal toxicity such as bleeding, ulceration and perforation any time without any warning The common adverse effects of mefenamic acid are gastrointestinal disturbances, peptic ulceration and gastrointestinal bleeding The Petitioner/ Opal Laboratories under took studies to eliminate or reduce the above-mentioned side effects of Mefenamic acid during its usage in their Research and Development Department. The first idea was to coat the tablet with an acid resistant material but it was dropped, as it will delay the onset action of the drug for almost two hours During the further studies and review of the published literature another theory was developed that if the drug is made buffered and dispersible, the side effects can be eliminated or at least be minimized. The advantage of buffered Mefenamic Acid is to be antagonize the acidity of stomach to prevent further decrease of pH and hence minimize the serious adverse effects of Mefenamic acid on one hand and on the other hand increases absorption due to lesser acidic environment created in the stomach. Due to the dispersible action the drug is rapidly dispersed throughout the lumen of the gastrointestinal tract and as a result each particle proves its own absorption of Mefenamic acid. The theoretical results were testified at R &D with practical, the approval was received to launch the product with the slogan of buffered Dispersible Mefenamic Acid tablets. As this new idea of dispersion and buffering reached the prescribers the more and more patients were put onto Dologin tablets with buffered and dispersible action and today many are convinced remaining few to touch for their acceptance.

E. That be that as it may and without prejudice to the foregoing, and the legality of the decision of the previous management to add the word 'dispersible' on the label, the new management after taking over the company in Dec 2017 has removed the word dispersible' from the label

F. That without prejudice to the foregoing, the Government Analyst has failed to mention complete protocols of the test applied in the DTL report. It is a trite law that without protocols of the test report is inconclusive and cannot be used as evidence against the accused persons. The Impugned report is liable to be set aside being based on incomplete report

G. That the petitioner carried out a thorough check on retained samples of Tablet Dologin (Mefenamic acid) 250mg Batch no. 348 and has made similar tests on random samples of the same, no such abnormality was found, the product is well within the limit and is of standard quality. All parameters of test and analysis are within acceptable limits.

H. That Sections 11 (5)(b) and 19(6) of the Act read with Rule 5(3) of the Punjab Drug Rules, 2007 casta duty upon the Respondent and this honorable Board to take every action under the Impugned reports by applying conscious mind and not in a mechanical manner It is regretted that the impugned Order has been passed in violation of Section 11 (5)(b) and 19(6) of the Drugs Act and Rule 5(3) of the Punjab Drug Rules, 2007.

I. That it is the duty and obligation of the public functionaries to act justly fairly, equitably, reasonably without any element of discrimination and squarely within the parameters of law as is envisaged by Article 4 of the Constitution.

J. That in addition to above, the Petitioner reserved his right to submit further assistance to this honorable Board during the arguments of the instant petition.

Prayer:

In view of the foregoing, it is most respectfully and humbly submitted that this honorable Board may be pleased to:

i. Accept the instant review petition, delete the name of the Petitioner from the list of accused persons in the case no. PQCB/R-36/2018;

ii. Suspend the Impugned Order til! the decision of the instant review petition.

Any other relief which this Honorable Forum deems fit and appropriate in the circumstance of the case may also be allowed.

The Petitioners also requested for grant of interim relief till the final decision of the titled Review petition.

Personal hearing notice(s) issued to accused person(s)

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

199th meeting held on 31-01-2019:

Subject Review Petition was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 199lhmeeting held on 31-01-2019. Ms Barkhoona Waheed Secretary DQCB District Jhelum and Mr. Naseer Ahmed Drug Inspector Tehsil &District Jhelum were present Counsel of the firm Zohaib Shahid Lodhi (Advocate) appeared before the Board and submitted that the firm was unaware that this case is placed at the agenda of 199th meeting dated 31-01-2019. as they did not receive personal

hearing notice. He agitated his grievances as mentioned in grounds of the review petition submitted by the firm.

The Board after detailed scrutiny of the record and grounds of the review petition submitted by the firm, due deliberation &discussion observed that the current CEO of the firm appeared before the Board in PQCB 194th meeting dated 18-10-2018 and gave the statement that the firm has been acquired by the new management in June 2017 and the subject drug was manufactured in September 2017 after acquisition of the firm by the new management. Government Analyst has tested the subject sample according to the Manufacturer's specifications as provided by the firm and the sample fails to comply with manufacturer's own specifications and the report of Government Analyst is the conclusive evidence of the facts stated therein.

In view of the foregoing facts, the Board unanimously decided to turn-down the subject review petition and uphold its previous decision taken in PQCB 194th meeting held on 18-10-2018 for grant of permission for Prosecution against the following accused in the Drug Court:

1. M/S Opal Laboratories LC-41, LITE, Landhi, Karachi through its Chief Executive Officer Dr. Ali Afzal
2. Dr. Ali Afzal — Chief Executive Officer
3. Ikram Zubairi — Production Manager
4. Rozina Baber — Quality Control Manager/Warrantor

of M/S Opal Laboratories LC-41, LITE, Landhi, Karachi for the offences of

- **a.** Manufacturing for sale/stocking/Selling of Substandard drug
- **b.** Issuance of false warranty

203rd meeting dated 29-03-2019:

Request of the firm to grant fair opportunity of hearing was placed as issue in 203rd meeting dated: 29-03-2019

Request from M/s Opal Laboratories (Pvt.) Ltd. has been received stating that:

1. We write to you on behalf of M/s Opal Laboratories (Pvt.) Ltd. (the "company", our "client").

2. Kindly refer to the previous letter dated 01-02-2019 whereby our client has made a request to your good office for granting of fair opportunity of hearing.

3 That we on the instructions of our Client filed a Review Petition before this honorable Board challenging the Order dated 05-11-2018 of the Provincial Quality Control Board, Punjab. The said Review Petition was lastly fixed for hearing before the honorable Provincial Quality Control Board, Punjab (the "Board") on 31-01-2019 m its 199'" meeting.

4. *That it is pertinent to mention here that no hearing notice for the aforesaid meeting was received by the Company till the date of hearing i.e. 31-01-2019. The associate of the undersigned counsel who was present in the office of the Board to attend hearing of other cases, informed the Company telephonically that their Review Petition is also fixed in the aforesaid hearing*

5. *Since, our Client is based in Karachi, it was impossible for the officials of the Company to reach and attend the hearing on a very short notice. Therefore, our Client gave us instructions to seek adjournment on ground of these unavoidable circumstances, which the honorable Board had flatly refused and directed the associate to plead the case knowing the fact that concerned accused persons and supporting documents were not available with him. However, the honorable Board in absence of the representative of the Company and without conducting a proper hearing of our Client has passed the Order dated 31-01-2019. whereby permission for prosecution has been granted to the Drug Inspector illegally, which is against the principles of natural justice, equity and fair play and also against the principle of Audi Alerm Partem'*

6 Now. through the instant letter we hereby again request you to kindly provide a fair opportunity of hearing to the Company before taking any action against the Company and the accused persons in the titled case, so that we may properly assist the Board in this case.

7. *It is reiterated here that the absence of the Company and its officials in the meeting dated 31-01-2019 was neither intentional nor deliberate rather it was due to the circumstances mentioned in Para 2-4 of the instant Application. No adverse order could have been passed without hearing the stance of the Company.*

8. *We have a strong and good prima facie case in our favor and there is very likelihood of the case being dropped if the honorable Board may grant us a proper opportunity of hearing.*

9. *It in the interests of justice that stance of the Company may be heard in a proper hearing, therefore, it is requested to kindly consider the instant application and fix our review petition in upcoming meeting scheduled.*

PROCEEDINGS & DECISION BY THE BOARD:

Issue was considered by Provincial Quality Control Board under Section 11 of the Drugs Act 1976 in its 20rd meeting dated 29-03-2019. The Board observed that the review petition filed by the firm has already been upheld by the Board in its 199th meeting dated 31-01-2019 and there is no provision to give a chance of personal hearing after review petition, in view of the foregoing facts, the Board unanimously decided to turn-down the request of the firm.

Honourable High Court Judgment dated: 16-05-2019 in Writ Petition No. 24146/2019 Titled as "M/S Opal Laboratories (Pvt.) Vs Provincial Quality Control Board etc."

"The instant Petition is allowed, order dated 31-01-2019 issued by Respondent No.l is set aside. The review petition filed by the Petitioner shall be deemed pending before the respondent No.l (PQCB) who is directed to decide it afresh in accordance with law within six weeks' time of certified copy of this order."

Personal hearing notice(s) issued to accused person(s).

PROCEEDINGS & DECISION BY THE BOARD:

Subject Review Petition was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 207th meeting held on 13-06-2019. Ms. Barkhoona Waheed Secretary DQCB District Jhelum and Mr Naseer Ahmed Drug Inspector Tehsil & District Jhelum were present along with original case file. Counsel of the firm Miss Sarnia Khalid (Advocate) appeared before the Board and agitated his grievances as mentioned in grounds of the review petition submitted by the firm. She added that according to DTL report the product was tested on Manufacturer specifications but the firm was not asked to provide method of testing. Our product is plain tablet instead of dispersible tablet (which was mistakenly printed on the label of the product sampled), so disintegration time limit of plain tablet (i.e NMT15 min) should have been applied on the product. This incorrect printing of dosage form on the label of the product is an offence under Labelling and Packaging Rules and DTL Rawalpindi was supposed to declare it misbranded instead of substandard. She further added that at the time of manufacturing of the product in question, her client was not Chief Executive officer of the company rather Mr. Tariq Ikram was the Chief Executive Officer/ Managing Director of the company the same is evident from the letter dated 19-12-2018 issued by the Central Licensing Board of the DRAP whereby the change of management of the company is mentioned. As per Section 34 of the Drugs Act, 1976 only those directors are held responsible with whose knowledge the alleged offence is committed.

The Board after detailed scrutiny of the record, grounds of the review petition and verbal arguments submitted by the counsel of the firm, due deliberation &discussion observed that in order to dig out whether the product in question was manufactured under new administration/ ownership or not. the Batch manufacturing record of the product need to be evaluated. Therefore, the Board decided to constitute a committee comprising of the following members to visit **M/S Opal Laboratories LC-41, LITE, Landhi, Karachi** for record verification and submit report for consideration by the Board:

1. **Prof Dr. Mehmood Ahmad** Convenor
   (Member PQCB)
2. **Munawar Hayyat** Member
   Chief Drugs Controller Punjab /Member PQCB

INSPECTION REPORT OF M/S OPAL LABORATORIES (PVT.) LTD, LC-41, L.I.T.E., LANDHI. KARACHI.

Panel Members:

Dr. Prof(R). Mahmood Ahmad, Member, PQCB.

Dr. Muhammad Munawar Hayat CDC Punjab

Date of Inspection: 23-09-2019

Detail of matter and Firm:

The management of the firm is changed on 19th December 2017 which was approved in 256th meeting of CLB DRAP on 09 & 10 November 2017.

- QA of Firm generated request for change the art work of label on 15-01-2018
- Tablet Dologin (Mefenamic acid) 250mg, Batch No. 348 was manufactured on 09/2017.
- The said drug was declared substandard on basis of Disintegration test by DTL Rawalpindi on 07- 05-2018

OBSERVATIONS:

1 The firm is manufacturing **"dispersible"** tablets but having the registration of plain tablets.

2 Product Specification of Tablet Dologin is B.P as mentioned in method and assay is by titration

3 At time of inspection, the production manager of firm informed that firm is now manufacturing the plain dologin tablets from last one years.

4. Currently, the firm is using the same formulation as before without any variation.
5. API Mefenamic acid is of BP specification.
6. On 18/08/2018, firm destroyed the remaining packing material /label bearing dispersible word through Gel Pvt. Ltd.

Batch Processing Record of specific product

1. BMR Record: available.
2. QC retain sample: Not available. Expired.
3. Testing method: available
4. Manufacturing started on 29/09/2017 and completed on 09/10/2017

Manufacturing Process of tablet Dologin 250mg:

1. The firm provided the record of process of manufacturing of tablets Dologin, the firm has no reference of dispersible tables of mefenamic acid of any other firm in the world.
2. The firm developed the method of manufacturing of tablet Dologin by using the one disintegrant at 5% percentage only in final blending and found Primogel (Sodium starch glycolate) as suitable for manufacturing of dispersible Dologin tablets.

Conclusion

The panel is of the opinion that:

1. This defect in tablet is due to improper development of dispersible tablet formulation and the firm has not performed any *in-vitro*tests or study to evaluate the status of dispersible formulation.
2. The Firm has given self-life of 3 years to Plain tablets whereas 2 years of shelf-life has been given to dologin DS tablets.
3. The firm is performing only Disintegration test and not performing dissolution test.
4. The firm has not recalled the drug from the market which is still not expired The expiry of the drug is 08/2020.
5 The firm is manufacturing **dispersible"** tablets illegally while they have the registration of plain tablets
6 The firm is advised to redesign its formulation to differentiate between plain and dispersible Tablet and stop manufacturing of dispersible tablets.

Submitted for final decision to Board.

Personal hearing notice(s) issued to accused person(s).

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Inspection report was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **213th**meeting held on 15-11-2019. Ms. Barkhoona Waheed Secretary DQCB Jhelum was present along with original record of the case. Counsel of the firm, M. Zohaib Shahid (Advocate) appeared before the Board on behalf of M/S Opal Laboratories LC-41, LITE, Landhi, Karachi and submitted that the statement mentioned on the DTL report that "no monograph of Mefenamic acid dispersible tablet is available in official monographs" as dispersible tablets monograph is available in European Pharmacopeia. He further submitted that mefenamic acid is commonly used to treat mild to moderate pain and its repeated use can cause serious gastrointestinal toxicity, thus, the clinical justification for manufacturing of dispersible Dologin Tablet is to avoid these adverse effects.

Dr. Munawar Hayat, Chief Drugs Controller. Punjab apprised the Board about the observations made by the inspection team during the visit of the firm. In the light of the facts stated in the inspection report, the Board observed that

- The firm has registration of plain tablets of mefenamic acid but it was manufacturing dispersible tablet which is illegal Moreover, the firm is manufacturing mefenamic acid dispersible tablets, the reference of which is neither available in any pharmacopeia nor such reference is available for its manufacturing by any firm in the world
- The defect in the tablet was due to improper development of dispersible tablet formulation and that the firm has not performed any in-vitro tests or study to evaluate the stability of dispersible formulation.

- The firm was performing only Disintegration test and not performing dissolution test while according to official pharmacopoeia, both tests are necessary to be performed.
- The expiry date of the subject drug is 08/2020 but the firm has still not recalled it from the market.
- According to the letter from DRAP to M/S Opal Laboratories LC-41, LITE, Landhi. Karachi, the management of the firm was changed on 19th December 2017 which was approved in 256th meeting of CLB DRAP on 09 &10 November 2017. However, in PQCB 194thmeeting dated 18-102018, the current CEO of the firm appeared before the Board and stated that the firm has been acquired by the new management in June 2017. The subject drug was manufactured in September 2017 i.e.. after the new management acquired the firm Moreover, no sale deed has been provided by the firm about handing/taking over of the firm, in support of the claim that on such date they were having the responsibility of this offense or not. Further, in writ petition no. 24146/2019 as reflected by the orders of Ayesha A. Malik J dated 16-05-2019, the petitioner has not taken any such stance rather he was in the proper defense of case in the High Court in said writ petition.

Keeping in view the foregoing facts, the Board unanimously decided to uphold its previous decision for grant of permission for Prosecution against the following accused in the Drug Court

1. M/S Opal Laboratories LC-41, LITE, Landhi, Karachi through its Chief Executive Officer Dr. Ali Afzal
2. Dr. Ali Afzal — Chief Executive Officer
3. Ikram Zubairi — Production Manager
4. Rozina Baber — Quality Control Manager/Warrantor

of M/S Opal Laboratories LC-41, LITE, Landhi, Karachi for the offences of:

a. Manufacturing for sale/stocking/Selling of Substandard drug

b. Issuance of false warranty

The Board further decided to recommend the Registration Board, Drug Regulatory Authority of Pakistan for cancellation of registration of Tablet Dologin (Mafenamic acid) 250mg manufactured by M/S Opal Laboratories LC-41, LITE, Landhi, Karachi.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Case No. 13: CASE REFERRED BY PQCB, PUNJAB REGARDING DOLOPRIN TABLETS 75MG, B# 006502L, MANUFACTURED BY M/S PACIFIC PHARMACEUTICALS (PVT.) LTD., 30TH km MULTAN ROAD, LAHORE.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-453-07/2016 dated 30-11-2019 has informed that Provincial Inspector of Drugs Tehsil Rajan Pur reported that:

i. He, on 12-05-2016, inspected the Medical Store Depot, E.D.O (Health) Office Rajan pur and took samples of two different types of drugs on Form No. 04 for the purpose of test and analysis.

ii. One out of two drug samples after test/ analysis was declared as **Sub-standard** by Government Analyst Drug Testing Laboratory Multan, as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Tablet Doloprin 75mg	006502L	M/S Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore, Pakistan.	TRA NO.5598/DTL dated: 18-06-2016	**Test/Analysis with Specifications:** Manufacturer's Specifications **Description:** Round pink tablets, packed in outer carton. Some tablets have spots and irregular surface. **(Does not comply with Specifications).** **Assay: (Aspirin)** Stated: 75mg/Tablet Found: 75.80mg/Tablet Percentage: 101.07% Limit: 90-110% **Result:** The sample is **Sub-Standard** on the basis

iii. Store keeper of Medical Store Depot, E.D.O (Health) Office, Rajan pur provided invoice/ warranty No.PPL/001 dated 04-04-2016 issued by M/S Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore, as a proof of its purchase.

iv. A copy of test report and warrantor portion of drug sample was sent to M/S Pacific Pharmaceutical, (Pvt.) Ltd., 30tn Km, Multan Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard. In response they requested for retest/analysis of drug sample from Appellate Laboratory NIH, Islamabad.

v. Pursuant to their request, the sample was sent to NIH Islamabad, from where the drug sample was declared **Substandard** as detailed below:

Name of drug	Batch no.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results Name of drug
Tablet Doloprin 75mg	006502 L	M/S Pacific Pharmaceutical. (Pvt.) Ltd., 30th Km, Multan Road, Lahore, Pakistan.	No. 0131-P/2016 dated 13-10-2016	**Analysis with Specifications:** B.P 2013 **Description:** Pink colored circular, biconvex, coated, plain tablets, packed in blister packing further packed in outer carton.

Dissolution:	Determined:	Limit:
Acid Phase	3.135	NMT 5.0%
Buffer Phase	**40.37%**	NLT 70.0% of the labeled amount (**Does not comply with BP- 2013).**

				Assay: (Aspirin) Stated: 75mg/Tablet Found: 78.34mg/Tablet Percentage: 104.45% Limit: 95-105% **Result:** The sample is of **Sub-Standard** quality as defined in the Drug Act, 1976.

vi. Copy of NIH report was sent to M/S Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore, Pakistan with directions to explain their position and provide requisite information in this regard.

vii. Drug Inspector requested for grant of permission for prosecution against the above-mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of:

a. Manufacturing for sale/sale of Substandard Drug

b. Issuance of false warranty

PREVIOUS PROCEEDINGS OF THE CASE:

PQCB 194th meeting held on 18-10-2018

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **194th meeting held on 18-10-2018.** Secretary PQCB apprised the Board that the personal hearing notice was duly served to the accused persons through M&P Courier Service.

Counsel of firm Haroon Dugal (Barrister) appeared before the Board and submitted that the appearance of spots on the surface of tablets may be due to temperature or storage conditions of the drug sample. He further added that the QC unit of firm has retested the retained samples and they are according to specifications both physically and chemically. Keeping in view the foregoing facts, the Board with due deliberation and discussion at length unanimously decided to **adjourn the case** in the best interest of justice due to its **incomplete quorum** as the presence of Secretary DQCB is mandatory to complete the quorum of the meeting under law.

Personal hearing notice(s) issued to accused person(s).

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **208thmeeting held on 27-06-2019.** Mr. Sadiq Hussain Secretary DQCB District Rajanpur was present along with original record of the case.

Slama Imran (Representative of the firm) appeared before the Board on the behalf of **M/s Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore** and stated that the same batch no. of subject drug sample has been declared of standard quality from DTL Faisalabad and Rawalpindi. He further added that the drug in question is substandard on the basis of dissolution test. According to USP, if a drug sample failed to comply with its dissolution test it should be repeated. Hence in the instant case, analyst of NIH Islamabad failed to repeat the test.

The Board, after detailed scrutiny of the case record and statement of the representative of the firm, observed that matter for subject drug need to be evaluated. So, in order to dig out the root cause of this defect the Board decided to constitute a committee comprising of the followings for the Product specific inspection of **M/s Pacific Pharmaceutical, (Pvt.) Ltd., 30th Km, Multan Road, Lahore, Pakistan** to submit report within fortnight for consideration by the Board:

1) **Prof. Dr. Mahmood Ahmed** Member PQCB — Convener
2) **Mr. Munawar Hayyat Member PQCB** — Member
3) **Mrs. Rabeea Sultan** — Facilitator

PRODUCT SPECIFIC INSPECTION REPORT

Members of inspection committee:

Prof. (Rtd.) Dr. Mahmood Ahmad — *Member Board (PQCB) Convener*

Dr. Muhammad Munawar Hayat — *CDC Punjab* — *Member*

Ms. Rabeea Sultan	*Incharge Regulatory Wing PQCB*	*facilitator*

Date of Inspection: 31-07-2019

Inspection was conducted with reference to PQCB order no. ***PQCB/R-453-07/2016*** *dated 02-07-2019. Tablet Doloprin 75mg, batch no. 006502L was declared substandard vide DTL test report no. 5598/DTL dated: 18-06-2016 from DTL Multan based on physical specifications i.e. Round pink tablets, packed in outer carton. Some tablets have spots and irregular surface. The sample was sent to NIH on request of the firm from where the sample was declared substandard based on dissolution test i.e., only 40.37% of the labeled amount of the tablet was found in buffer phase however B.P requires that it should not be less than 70.0% of the labeled amount.*

Premises:

The manufacturing unit was established in 1990.lt is MHRA certified pharmaceutical company having 180 finished products and exporting up to 28 countries. It is ISO 1400:2004 certified Pharmaceutical Company by SGS. The manufacturing unit comprises of two main blocks. In first block there is tablet section, capsule section, syrup section and semi-solid section. While in second block there are dedicated sections for narcotics, anti-tuberculosis drugs and hormones. Manufacturing area and Q.C is located on the ground floor while the administration department is on the first floor of the building. The drug in question i.e., Doloprin 75mg tablets enteric coated tablet was registered vide letter No.F.3-2/98-REG.II(M-133) dated 20-05-1998 having registration No.021647.

Detail of Product:

Doloprin 75mg Tablet, Batch No. 006502L, Date of Mfg. 02-16. Exp. Date 01-19

Technical Staff

Designation	*Name*
Director/ Quality Control In charge	*Ahmed Junaid Rashid*
Production In charge	*Imtiaz Hussain*
QC Manager/warrantor	*Imran Shehzad*

Detail of Inspection/Observations:

1. *Product Specification of tablet doloprin 750mg is B.P 2013 specification. Since registration B.P method is used for testing. The primary reference standard available was USP aspirin having Lot no R059RO.*
2. *The temperature and humidity charts were displayed and filled accordingly. At the time of inspection temperature in Raw Material Store was 24°C and humidity was 48%.*
3. *There were proper air showers, cross over bench and separate entrance and change rooms for male and female staff.*
4. *Raw Material Store of the unit has designated dusting area, quarantine area, rejection area and sampling area.*
5. *HVAC system is installed and is operational.*
6. *Mixing area has three rooms for mixers, where two mixers having capacity of 200kg and 1 mixer having capacity of 100kg are present. There is a separate room for fluidized bed dryer having capacity of 100kg and two rooms for wet granulation. The final mixing is done in V-mixer which has a capacity of 700kg. Most of the batches are of 200kg.*
7. *In production area temperature, humidity and differential pressure were properly maintained and manometric devices were in order.*
8. *In compression room-1 compression of tablet plasenzym was in process the temperature and humidity was 26°C and 48% respectively. In compression room-2 compression of tablet Glupac SR in compression room-3 compression of tablet levopraid 25mg was in process the temperature and humidity were well maintained. Compression room no.04 was temporary in process quarantine at the time of inspection.*
9. *In capsule section the temperature and humidity at the time of inspection was 24.9°C and 52% respectively. The capsule filling machine was fully automatic attached with dust collectors etc. having filling capacity of 800cap /min. The section had a portable polisher as well.*
10. *The unit has automatic machines for sugar coating, enteric coating and film coating. During inspection spray coating of tablet Bromelin was in process in coating room no.02.*
11. *General liquid section has 09 storage tanks with different storage capacities. Manometric devices were properly installed and differential pressures were well maintained.*

12. *Personnel and materials entry are separate in manufacturing area.*
13. *There is a proper transfer gallery in manufacturing area.*
14. *There are 03 rooms for blistering and the machines of the blistering area are attached to conveyer belts of the packing area in a proper flow. At the time of inspection packing was in process on the four belts and the temperature and humidity of the packing hall was 27.3°C and 51% respectively.*
15. *The Quality Control Section has wet chemistry lab, in process quality control Lab. microbiological lab and instrumental lab. All the labs are well equipped having 05 HPLC, FTIR. Kai Fischer, viscometer, digital polarimeter, U.V spectrophotometer, atomic absorption spectrophotometer, potentiometer, automatic dissolution apparatus, filtration pump, muffle furnace, disintegration apparatus, friabilator, hardness tester, etc.*
16. *There is a separate stability room having total 05 stability chambers where real time, accelerated and intermediate stability studies are done for hot plate real time stability chamber and accelerated stability chamber etc.*
17. *All 05 HPLC are operational and are fully automated, analysts working on HPLC are assigned specific login id and password and once an analysis is done and result is generated no change can be done.*
18. *During inspection HPLC data of doloprin tablet batch no Al 0212N was checked from record. It was analyzed on HPLC on 30-01-2019.The standard and sample curves of chromatograms were checked and was found to be 6.1 and 6.092 respectively and it was verified with the QC results from the record which was found to be within the specified limits.*
19. *Log book of columns C18 (300x3.9mm) and (250X4.6mm) of the HPLC was checked during inspection it was well maintained.*
20 *Operational safety alarms, air showers, smoke detector and insect killers are installed in all sections.*
21. *SOP for finished product testing having document no. QCFG/03/0017 Revision no.01 dated 26-07-2016 was checked and the method for testing was in accordance with the test and method specified in B.P.*

Batch Processing Record of specific product:

1. *BMR Record: available.*
2. *QC retain sample. Not Available. Expired on 01-2019*
3. *Batch size. 800,000 tablets*
4. *Testing method: B P 2013*
5. *Bulk weight: 132000kg*
6. *Theoretical yield= 800,000tabs*
7. *Practical yield=805,860tabs*
8. *Manufacturing started on 16-02-2016*
9. *Labelling / Packing: 01-03-2016*
10. *Expiry date: 01/2019.*
11. *Percentage purity of API=100.27%*
12. *API issued was 60 kg per batch.*
13 *In process QC: Available*
14 *Reconciliation sheet: available*
15. *Record of in-process testing of Doloprin 75mg tablets and chromatograms of batch no.006502L were thoroughly checked. According to BMR of the subject batch dissolution test was conducted on 16-02-2016 and following results were obtained.*

Tablet	*%age release in 0.1 N HCI in first 02 hours*	*%age release in 6.8 Phosphate buffer after 01 hour*
1	*3.54%*	*85.82%*
2	*3.54%*	*93.85%*
3	*3.96%*	*91.69%*
4	*3.34%*	*92.31%*
5	*2 50%*	*83.66%*
6	*3.34%*	*90.76%*
Average	*3.37%(NMT 5%)*	*89.68%(NLT 70%)*

16. *Record of finished product testing of Doloprin 75mg tablets and chromatograms of batch no.006502L were also thoroughly checked. According to BMR of the subject batch*

dissolution test was conducted on 04-03-2016 and following results were obtained.

Tablet	*%age release in 0.1 N HCI in first 02 hours*	*%age release in 6.8 Phosphate buffer after 01 hour*
1	*2.96%*	*99.49%*
2	*2.75%*	*99 80%*
3	*2.75%*	*100.12%*
4	*2.96%*	*99.80%*
5	*2.53%*	*97.59%*
6	*2.53%*	*99.80%*
Average	*2.75% (NMT 5%)*	*99.43%(NLT 70%)*

18. *Testing of finish product is as per specification and assay of finished product prior to release in FGS was 99.79%.*
19. *Aspirin was purchased from Ali Baba Chemicals and according to COA its assay was 100.27%.*

Conclusion:

The panel is of the opinion that

1. *The drug was declared substandard by Govt. Analyst. Drug Testing Laboratory, Punjab was on physical ground having spots and rough surface of the tablet whereas declared substandard by NIH on dissolution test. From reflecting the different aspects, the inspection was conducted in derail to address all parameters of manufacture to correlate the any defect in manufacturing, but not found.*
2. *Remedial measures were taken by the firm by improving the standards of manufacturing at all levels.*
3. *No record for recalling the drug product was provided by the firm.*
4. *No CAPA was generated by the firm and Root-cause analysis was not performed.*

PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **214th meeting held on 30-11-2019.** Secretary DQCB Rajanpur Mr Sadiq Hussain and Drug Inspector Rajanpur Mr. Rauf Ahmed Meo both were present with original case file. Prof. (R) Dr. Mahmood Ahmad (Convener of PSI Committee) apprised the Board about findings and conclusion of the PSI Committee. Panel was of the opinion that no CAPA was generated by the firm and Root-cause analysis was not performed. Moreover, no record for recalling the drug product was provided by the firm.

Counsel of the firm Advocate Shahzaib Bhatti and accused Imtiaz Hussain (Production Incharge) appeared before the Board and submitted the following grounds/ remedial measures taken by firm.

i. Warrantor and retained sample portion were thoroughly checked and found to be of standard quality in all parameters.
ii. Our Quality Assurance Department is well established and working properly.
iii Each batch is released by QC Department after though examination by international standard test/ analysis via sophisticated HPLC Methods. HPLC Trails are present showing all the results of standard quality.
iv We have proper SOP for batch recall and until now three volunteer recalls have done in the past at different levels.
v. The batch in question was of 8 lakh tablets and supplied to institution as well in market. Upon receipt of substandard report a distributer level recall was done regarding the batch. He requested the Board for lenient view.

The Board, after detailed scrutiny of NIH report and PSI report observed that no CAPA was generated by the firm and Root-cause analysis was not performed. No record for recalling the drug product was provided by the firm. According to NIH report the drug was having a very poor release profile as only 40.37% (instead of >70%) drug was released in buffer Phase. Prof. Dr. Irshad Hussain Qureshi (Professor of Medicine/ Member PQCB) was of the opinion that such low quantity of released drug is unable to produce its therapeutic effect. He was of the opinion that DRAP should review the registration of the product in light of this NIH report and guidelines for manufacturer should be issued to improve release

profiles for such formulations. Moreover, unnecessary use of platelet inhibitors (e.g. Aspirin) should be discouraged as this may increase the risk of brain hemorrhage by causing small capillary rupture by blood thinning effect.

In view of foregoing facts, the Board after due deliberation and discussion decided to grant **permission for prosecution** against the following accused persons in the Drug Court:

i. M/s Pacific Pharmaceuticals, (Pvt.) Ltd., 30th KM, Multan, Lahore through its Director Junaid Rashid.
ii. Ahmad Junaid Rashid — Director/Quality Control Incharge.
iii. Imtiaz Hussain — Production Incharge.
iv. Faisal Imran — Marketing Incharge.
v. Imran Shahzad — Warrantor/QC Manager.

Of M/s Pacific Pharmaceuticals, (Pvt.) Ltd., 30th KM, Multan, Lahore for the offences of

a) **Manufacturing for Sale/ Sale of Substandard Drug**
b) **Issuance of its false warranty**

The Board further endorsed the comments of Prof. Dr. Irshad Hussain Qureshi and decided to recommend DRAP to review the registration of the subject drug in light of the NIH report and guidelines for manufacturers should be issued to improve release profiles for such enteric coated formulations. Moreover, Dispersible formulation of Aspirin instead of enteric coated formulation should be promoted as drug release defects in enteric coated formulations are more common.

The Board further recommended the Director Registration Board, DRAP, Islamabad to review the Registration of the Subject Drug.

Proceeding and Decision of 295th Meeting of Registration Board.

The Board was appraised that similar case was presented in 293rd meeting of the Registration Board wherein the Board decided to take the views comments of the Legal Affairs Division, DRAP, Islamabad.

Legal Affairs Division, DRAP, Islamabad provided their opinion that Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Case No.14: CASE REFERRED BY PQCB, PUNJAB REGARDING INJECTION DANADAX, BATCH NO. 104, MANUFACTURED BY M/S DANAS PHARMACEUTICALS, ISLAMABAD.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-265/2019 dated 18-12-2019 has informed that Provincial Inspector of Drugs Tehsil & District Gujrat reported that:

i. He, on 09-05-2019, inspected the business premises of Medicine Store, Rural Health Centre Karianwala Tehsil & District Gujrat and took four different types of drug samples on Form No. 04 for the purpose of test and analysis.
ii. One out of four drug samples after test/analysis, was declared **Misbranded** by Government Analyst Drug Testing Laboratory, Faisalabad as detailed below:

Name of the Drug	Batch No.	Name of Manufacturer	DTL Report TRA No. & Date	DTL report result
Injection Danadex [Each ampoule (1ml) contains:Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg]	104	M/S Danas Pharmaceuticals (Pvt.) Ltd. Plot# 312, Industrial Triangle, Kahuta Road Islamabad.	TRA No. 01-56002610/DTL dated:09-07- 2019	**Analysis with specifications applied:** BP 2019/MS **Physical Description:** Clear, colorless solution filled in amber colored glass ampoule, packed in hard outer carton. *NOTE: Manufacturer specify BP specs on its label. In BP 2019, Labeling of Dexamethasone Sodium Phosphate injection is "the content of active ingredient*

				is stated as the equivalent amount of Dexamethasone in a suitable dose volume" Whereas manufacturer claim on its label as "Each ampoule (1ml) contains Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg" which is contradictory to BP 2019 and is misleading and in violation to Drugs Act 1976 (Does not Comply) **Assay:** Assay complies with the Manufacturer specifications and is within limits. (95-105%) **Result:** Given sample is **Misbranded** with regards to Labeling as per defined in section 3 (s) (iv) of Drugs Act, 1976.

iii. Store keeper of Medicine Store, Rural Health Centre Karianwala Tehsil & District Gujrat provided Warranty/invoice No. DP/DHA-GUJRAT-020, dated 25-03-2019 issued by M/S Danas Pharmaceuticals (Pvt.) Ltd., Plot # 312, Industrial Triangle, Kahuta Road Islamabad as a proof of their purchase.

iv. Warrantor portion of the drug sample was sent to M/S Danas Pharmaceuticals (Pvt.) Ltd., Plot # 312, Industrial Triangle Kahuta Road Islamabad.

v. A copy of test report of the drug sample was sent to M/S Danas Pharmaceuticals (Pvt.) Ltd., Plot # 312, Industrial Triangle, Kahuta Road Islamabad with directions to provide the requisite information and to explain their position in this regard.

Reply of the Firm to the Drug Inspector:

The firm has submitted the written reply:

i. The Govt. Analyst Drug Testing Laboratory Faisalabad has declared the sample Misbranded. The product Injection Danadex Batch No. 104 is of standard quality as it contains therapeutic active ingredients Dexamethasone within pharmacopoeia limit; inference is that the drug is effective and safe for use on patients.

ii. That the drug is misbranded on the basis of contravention of labeling rules, which is very minor labeling issue, but rectifiable and has no impact on quality, effectiveness and safety of drug for human consumption

iii. That the labeling issue has been rectified in line with BP, and we undertake that the firm will comply with the labeling and packing rules 1986 in letter and spirit in further for the subject drug along with other product of our company

02. Drug Inspector requested for grant of permission for prosecution against the above mentioned accused persons who have contravened the provisions of Section 23/27 of the Drugs Act 1976 (as amended) and Rules framed there under by the way of: -

a) **Manufacturing/Selling Misbranded Drug.**
b) **Issuance of false warranty**

03. Show-cause/personal hearing notice(s) was issued to accused person(s)

Case is placed before the Board for Decision.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

PQCB 212th meeting dated 30-10-2019:

04. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **212th**meeting held on **30-10-2019.** Mr. Waseem Mahmood Secretary DQCB District Gujrat & Mr. Muhammad Amar Drug Inspector Tehsil &District Gujrat were present with original record of the case. Drug Inspector briefed the Board about facts of the case and requested to grant permission for prosecution against the accused persons.

05. Counsel person Rana Maqsood Afzal Khan (Advocate Supreme Court) along with representative Muhammad Naeem Anjum appeared before the Board on behalf of the firm. The counsel person pleaded the case by submitting that the product is registered from Drug Regulatory Authority of Pakistan (DRAP) as "Dexamethasone as sodium Phosphate 4mg He added that if we formulate our product according to BP-2019 specifications then 3.32mg/ml of Dexamethasone base will be present in the formulation that is

not according to registration of product. He further submitted that no other brand with 3.32mg/ml of Dexamethasone base is available in the market. He asked for further guidance from the honorable Board.

06. The Board on scrutiny of the DTL report observed that:

i. The subject drug was declared Misbranded on the basis of physical description only while the percentage of chemical assay of the drug product is according to the specification and is within limits (95-105%).

ii. According to test analysis report DTL has identified "Each ampoule (1ml) contains Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg" on the label while according to BP specs "Labeling of Dexamethasone Sodium Phosphate injection is "the content of active ingredient is stated as the equivalent amount of Dexamethasone in a suitable dose volume".

iii. According to the counsel for the firm, the product is registered with DRAP as "Dexamethasone as sodium Phosphate 4mg. if the product is to be manufactured as Dexamethasone base then it will be required to incorporate 3.32mg/ml Dexamethasone Base.

07. Keeping in view the foregoing facts of the case, the Board decided to **pend the case** with directions to constitute a committee comprising of the followings to evaluate the matter on technical grounds in light of the information given in official books/compendia, DRAP guidelines & technical literature if any, and submit this Board the final recommendations about statement of "Dexamethasone Base (with 3.32mg/ml drug) BP specs" to be written on label of the product or otherwise.

1. Mr. Muhammad Sohail	Additional Secretary (Drugs Control) P&SHD.
2. Dr. Mehmood Ahmed	(Member PQCB)

For information of Board:

It is to inform the Board that the drug product Injection Danadex [Each ampoule (1ml) contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg]" was supplied to different hospitals of the Punjab. Total 23 reports of "Injection Danadex [Each ampoule (1ml) contains: Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mgj" has been received/reported to PQCB on the same grounds i.e. Misbranded.

Sr. No.	Year	R. No.	Drug Inspector	District	TRA No.	Date	DTL	Drug Name	Batch No.	Manufacturer name	DTL Result
1.	2019	R-417/2019	Sialkot	Sialkot	01-69001197	07-12-19	FSD	Injection Danade	110	Danas Pharmaceuticals (Pvt.)	Misbranded
2.	2019	R-418/2019	Sialkot	Sialkot	01-69001199	07-12-19	FSD	Injection Danade	108	Danas Pharmaceuticals (Pvt.)	Misbranded
3.	2019	R- 419/2019	Sialkot	Sialkot	01-69001198	07-12-19	FSD	Injection Danade	109	Danas Pharmaceuticals (Pvt.)	Misbranded
4.	2019	R-413/2019	Chiniot	Chiniot	01-56002889	07-12-19	FSD	Injection Danade	109	Danas Pharmaceuticals (Pvt.)	Misbranded
5.	2019	R- 414/2019	Chiniot	Chiniot	01-56002890	07-12-19	FSD	Injection Danade	111	Danas Pharmaceuticals (Pvt.)	Misbranded
6.	2019	R-415/2019	Chiniot	Chiniot	01-56002891	07-12-19	FSD	Injection Danade	110	Danas Pharmaceuticals (Pvt.)	Misbranded
7.	2019	R-416/2019	Chiniot	Chiniot	01-56002892	07-12-19	FSD	Injection Danade	108	Danas Pharmaceuticals (Pvt.)	Misbranded
8.	2019	R- 432/2019	Iqbal Town	Faisalabad	01-56004342	23/8/2019	FSD	Injection Danade	126	Danas Pharmaceuticals (Pvt.)	Misbranded

9.	2019	R-433/2019	Toba Tek Singh	Toba Tek Singh	01-56004324	23/8/2019	FSD	Injection Danade	127	Danas Pharmaceuticals (Pvt.)	Misbranded
10.	2019	R- 434/2019	Toba Tek Singh	Toba Tek Singh	01-56004165	23/8/2019	FSD	Injection Danade	116	Danas Pharmaceuticals (Pvt.)	Misbranded
11.	2019	R-420/2019	Iqbal Town	Faisalabad	01-56004343	23/8/2019	FSD	Injection Danade	123	Danas Pharmaceuticals (Pvt.)	Misbranded
12.	2019	R-421/2019	Iqbal Town	Faisalabad	01-69001335	23/8/2019	FSD	Injection Danade	117	Danas Pharmaceuticals (Pvt.)	Misbranded
13.	2019	R-422/2019	Iqbal Town	Faisalabad	01-69001350	23/8/2019	FSD	Injection Danade	115	Danas Pharmaceuticals (Pvt.)	Misbranded
14.	2019	R-423/2019	Jaranwala Town	Faisalabad	01-69001381	23/8/2019	FSD	Injection Danade	114	Danas Pharmaceuticals (Pvt.)	Misbranded
15.	2019	R-424/2019	Lyallpur Town	Faisalabad	01-69001362	23/8/2019	FSD	Injection Danade	121	Danas Pharmaceuticals (Pvt.)	Misbranded
16.	2019	R-425/2019	Samundri Town	Faisalabad	01-69001392	23/8/2019	FSD	Injection Danade	116	Danas Pharmaceuticals (Pvt.)	Misbranded
17.	2019	R-427/2019	Lyallpur Town	Faisalabad	01-56004224	23/8/2019	FSD	Injection Danade	121	Danas Pharmaceuticals (Pvt.)	Misbranded
18.	2019	R-426/2019	Lyallpur Town	Faisalabad	01-56004223	23/8/2019	FSD	Injection Danad	122	Danas Pharmaceuticals (Pvt.)	Misbranded
19.	2019	R-428/2019	Toba Tek Singh	Toba Tek Singh	01-56004323	29/8/2019	FSD	Injection Danade	128	Danas Pharmaceuticals (Pvt.)	Misbranded
20.	2019	R- 429/2019	Iqbal Town	Faisalabad	01-56004344	29/8/2019	FSD	Injection Danade	117	Danas Pharmaceuticals (Pvt.)	Misbranded
21.	2019	R-430/2019	Iqbal Town	Faisalabad	01-56004346	30/8/2019	FSD	Injection Danade	124	Danas Pharmaceuticals (Pvt.)	Misbranded
22.	2019	R-431/2019	Alipur	Muzaffarga Rh	01-56009801	30/10/2019	MLTN	Injection Danade	128	Danas Pharmaceuticals (Pvt.)	Misbranded

Note:

Dexamethasone is a life-saving drug and the stock of Dexamethasone injection is indispensable/not useable at various health centers due to Misbranding issue. Hence not available for patients. Abovementioned list of cases has been placed collectively before the Board for decision of their fate so that further delay may be avoided and the patients may not suffer due to shortage of dexamethasone injection.

08. Subject matter along with case is placed before the Board for decision/ necessary action.

PQCB 215th dated 14-12-2019

09. Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its **215th**meeting held on **14-12-2019.** Mr. Waseem Ahmed Secretary DQCB District Gujrat and Mr. M. Amar Drug Inspector Tehsil & District Gujrat were present. Representatives of the firm Muhammad Naeem (Head Quality Control) and Asim Khan appeared before the Board on behalf of **M/S Danas Pharmaceuticals (Pvt.) Ltd., Plot # 312, Industrial Triangle, Kahuta Road Islamabad** along-

with counsel of the firm Rana Maqsood (Advocate Supreme Court).

10. The counsel person pleaded the case by submitting that the product is registered from Drug Regulatory Authority of Pakistan (DRAP) as "Dexamethasone as sodium Phosphate 4mg. He added that if we formulate our product according to BP-2019 specifications then 3.32mg/ml of Dexamethasone base will be present in the formulation that is not according to registration of product. He further submitted that no other brand with 3.32mg/ml of Dexamethasone base is available in the market. He asked for further guidance from the honorable Board.

11. The Board on scrutiny of the DTL report observed that:

i. According to test analysis repod DTL has identified "Each ampoule (1ml) contains Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate 4mg" on the label while according to BP specs "Labelling of Dexamethasone Sodium Phosphate injection is "the content of active ingredient is stated as the equivalent amount of Dexamethasone in a suitable dose volume".

ii. According to the counsel for the firm, the product is registered with DRAP as "Dexamethasone as sodium Phosphate 4mg. if the product is to be manufactured as Dexamethasone base then it will be required to incorporate 3.32mg/ml Dexamethasone Base.

12. Keeping in view the foregoing facts of the case, the Board unanimously decided to **pend the case** in view to incorporate the report submitted by the committee already constituted vide PQCB order of even no. dated 30-10-2019. 12. After 215th meeting dated 14-12-2019 the office of PQCB received minutes of committee with reference to PQCB Punjab Case: PQCB/R-265/2019.

13. Minutes of meeting of committee with reference to PQCB Punjab Case: PQCB/R-265/2019 (PQCB Meeting 212th dated 30-10-2019) a meeting of the committee was held on 17-12-2019 at 03:00 PM at Drug Testing Laboratory Punjab, Lahore

Following members attend the meeting

No.	Name	Designation
1	Mr. Muhammad Sohail	Addition Secretary Drug Control (P&SH Department)
2	Dr. Mehmood Ahmed	Member PQCB
3	Mr. Jamil Anwer	Secretary PQCB

The matter was technically evaluated in light of information given in official books/compendia and British National Formulary (BNF) guidelines.

Product Specification in subject case is BP specs.

- As per Label claim of product, each ampoule contains: Dexamethasone Sodium Phosphate equivalent to Dexamethasone Phosphate .... 4mg/ml.
- According to BP-2019 monograph of Dexamethasone Sodium Phosphate injection 95.0-105.0% of content of Dexamethasone, each 1mg of Dexamethasone phosphate is equivalent to 0.831 mg of Dexamethasone.

- Molecular weight of Dexamethasone: 392.46g/mol
- Molecular weight of Dexamethasone Phosphate: 472.4 g/mol
- Molecular weight of Dexamethasone Sodium phosphate: 516.4 g/mol

Which means 4mg/ml of Dexamethasone Phosphate will furnish 3.323mg/ml of Dexamethasone.

Comparison of Compendial monograph's claim		
BP-2019 monograph Dexamethasone Sodium Phosphate Injection	**USP-2019 monograph** Dexamethasone Sodium Phosphate Injection	**BP-2014 monograph** Dexamethasone Sodium Phosphate Injection
95.0-105.0% of **Dexamethasone**	90.0-115.0% of **Dexamethasone Phosphate**	95.0-105.0% of **Dexamethasone Phosphate**

Conclusion and Recommendations.

14. The Committee after thorough consideration concluded that the iabei of product inj: Danadex, Mfg by M/S Danas Pharmaceuticals (Pvt.) Ltd., Plot# 312, Industrial Triangle, Kahuta Road Islamabad having label claim "Dexamethasone sodium phosphate equivalent to dexamethasone phosphate...4mg/ml" is not according to the most recent edition of British Pharmacopeia (BP 2019). As evident from BNF, the necessary label information for physicians is the "Dexamethasone base" content. Moreover, it creates ambiguity from analytical perspective that dexamethasone injection (separate monograph present in USP)

should be analyzed for what potency. The dexamethasone injection as per USP is lipophilic preparation while dexamethasone sodium phosphate injection is water soluble and hydrophilic product. The latter is mostly available in market in Pakistan. The matter lies for further workup at registration level as the BNF States potency of "dexamethasone" to be provided to consumers/ end users. It is thus proposed to recommend DRAP to review this product and label specifications of all dexamethasone sodium phosphate injectable preparations and direct manufacturer to clearly mention the content of either "Dexamethasone"in case of BP Specifications or "Dexamethasone Phosphate"in case of USP Specifications.

15. Matter is placed before the Board for decision

CURRENT PROCEEDING AND DECISION BY THE BOARD:

PQCB 216th meeting held on 28-12-2019.

16. The matter was considered as an ex-agenda item by Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **216th meeting held on 28-12-2019.** Secretary PQCB briefed the Board about facts of the case. The Board thoroughly evaluated and reviewed the minutes of the meeting of committee with reference to PQCB Punjab Case PQCB/R-265/2019 which was held on 17-12-2019 at 03:00 PM at Drug Testing Laboratory Punjab, Lahore. The Board after keen perusal of the record and minutes of meeting of the committee formed for this purpose observed that product is registered from Drug Regulatory Authority of Pakistan (DRAP) as "Dexamethasone as sodium Phosphate 4mg" if the firm will formulate its product according to BP-2019 specifications then 3.32mg/ml of Dexamethasone base will be present in the formulation that is not according to registration of product.

17. The Board after due deliberation and discussion was of the considered opinion that assay of the subject drug sample Injection Danadex Batch no. 104, lies within the prescribed limit of 95-105% however, it has been declared misbranded by the DTL, Faisalabad and according to Section 5(5) of the Punjab Drug Rules, 2007 warning can be issued in cases of minor contraventions. Keeping in view the facts of the case and in the light of recommendations of the committee formed in this matter, the Board unanimously decided to issue **Warning to** M/S Danas Pharmaceuticals (Pvt.) Ltd., Plot # 312, Industrial Triangle, Kahuta Road Islamabad. It is pertinent to mention that in cases at serial No. 8, 9, 11, 12, 15, 17-23 the firm has challenged the report of the Government Analyst. The Board further directed the Drug Inspector concerned to complete investigation report in cases mentioned at serial No. 1-7, 10, 13, 14 and 16 and submit for further consideration and decision by the Board.

18. The Board further decided to recommend DRAP to review this product and label specifications of all Dexamethasone sodium phosphate injectable preparations and direct manufacturer to clearly mention the content of either "Dexamethasone" in case of BP Specifications or "Dexamethasone Phosphate" in case of USP Specifications as this matter requires further clarification and workup at DRAP level in Drugs Registration Board.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting and also to seek views comments of the PE&R division regarding the labeling of Dexamethasone Sodium Phosphate injection as per pharmacopeial requirements and innovator's product.

Case No. 15:- Manufacture And Sale Of Spurious Drug (Quinozef 250mg Tablets, Batch No. AP0014) – M/S Ambro Pharma (Pvt.) Ltd., Islamabad.

That the FID-I,DRAP, Islamabad stated that he has been notified as a Federal Inspectors of Drugs for area jurisdiction of Industrial Triangle Kahuta Road Islamabad since 31st May, 2018 vide S.R.O. 686 (I)/2018.

That the Federal Government Analyst, Central Drugs Laboratory(CDL) Karachi declared the following sample as **"Spurious"** vide test analysis report No.NAS.111/2018 dated 14.11.2018. The sample was sent by Drug Inspector, Gilgit Baltistan (GB) vide memorandum No.103/DI-GLT/97/298 dated 23.10.2018 to CDL.

Name of Drug	Reg. No.	Batch No.	Date/Mfg	Date/Exp	Claimed to be Mfg By
Quinozef 250mg Tablets	046368	AP0014	08-17	08-20	M/s Ambro Pharma Pvt. Ltd., Islamabad

That Assistant Director (Quality Control) vide letter No.04-74/2018-QC dated 26th November, 2018 conveyed the undersigned about the above said report with the request to look into the matter and submit complete investigation. Undersigned along with FID-IV visited the firm on 26th November, 2018 on the direction of Additional Director, QA&LT. The panel noticed number of serious GMP violations during the inspection. The report was submitted to the Additional (Director), QA&LT vide letter No.F.3-7/2003-FID–I (ISD) dated 28th November, 2019 with the recommendation to carry out a thorough investigation for manufacturing of spurious drugs and inspection of firm by a larger panel (in order to cover all facets/aspects mentioned in the report) and to probe the matter more carefully.

That in response to the above, AD (QC) vide letter No.04-74/2018-QC dated 30th November, 2018 conveyed the approval of following panel to conduct thorough inspection of firm by the competent authority to probe the manufacturing of Spurious product Quinozef (Ciprofloxacin) 250mg Tablets Reg. No. 046368 Batch No.AP0014 and to see overall GMP compliance (Annex - E):

a) Mr.NadeemIqbal, Expert member
b) Mr. Abdul SattarSohrani, Additional Director, QA&LT
c) Mahvash Ansari, FID-IV/DD (QC), QA&LT, DRAP.
d) Area Federal Inspector of Drugs, DRAP, Islamabad.

That the inspection was conducted by the above panel on 03rd December, 2018 and again a number of violations were noticed and conveyed to Secretary, Central Licensing Board and Secretary, Registration Board via the inspection report vide letter No. F.3-7/2003-FID-I dated 24th December, 2018 (Annex - F). It is pertinent to mention here that DML of the firm was cancelled by Central Licensing Board on the basis of gross violations as reported above.

That during the inspection, undersigned took following samples on form-3 (Annex - G) for test/analysis and sent to Federal Government Analyst, CDL, Karachi vide memorandum No.F.3-7/2003-FID-I dated 07th December, 2018 (Annex - H).

Name of Drug	Reg. No.	Batch No.	Date/Mfg.	Date/Exp.	Claimed to be Mfg. by
Quinozef (Ciprofloxacin) 250mg Tablets	046368	AP0014	08/2017	08/2020	M/s Ambro Pharma Pvt. Ltd., Islamabad
Polymal-F Tablet (Iron III hydroxide polymatose complex 100 mg + Folic acid 350 mcg)	045897	AP0028	04/2018	04/2020	-do-

That Federal Government Analyst (FGA), Central Drug Laboratory, Karachi vide test reports No.R.IP.309/2018 dated 11th January, 2019 (Annex - I) declared the drug mentioned at S.No.1 in above table, as **Spurious** with the remarks that the sample is under section 3 (z-b) (i) of the Drugs Act, 1976. While the drug mentioned at S.No.2 in above table, declared as "Standard" by the FGA vide test reports No.R.IP.310/2018 dated 09th January, 2019 with the remarks that "the sample is of standard quality with regard to the tests performed". Results of the test report are reproduced as under:

Description: *Yellow colored oval shaped film coated with line of bisection on one side.*
Identification: *Ciprofloxacin Hydrochloride NOT Identified.*
Remarks: *The sample is under section 3 (z-b) (i) of the Drugs Act, 1976.*

Note:

1) The HPLC and FTIR studies show that the sample contains Levofloxacin (237.3120 mg/tablet) instead of ciprofloxacin HCl as stated on the label.

2) Section 3 (Definition): In this act unless there is anything repugnant in the subject or context 3 (z): "Specification" when applied to a drug:

3 (z-b): Spurious drug means a drug:

i. Which purports to be a drug but does not contain the active ingredient of that drug

The Assistant Director (Quality Control) again requested the undersigned to look into the matter and submit a complete case for further consideration by the concerned Board vide letter No.04-74/2018-QC dated 18th January, 2019. The said reports (certificate of test or analysis) were forwarded/delivered to the firm as required under section 22(3) (a) of Drugs Act, 1976 vide letter No.F.3-7/2003-FID–I (ISD) dated 12th February, 2019. The firm was asked for explaining its position in this regard.

M/s Ambro Pharmaceuticals, Islamabad through its owner Mr. Abdul Majeed Chaudhary replied vide letter No.APL/FID-003/2018-19 dated 19th February, 2019 stated that:

> "…..they are not satisfied above Analytical Report of our product as declared "Spurious". Now, we have challenged in the Appellate Laboratory i.e. National Institute of Health, Islamabad, because we tested our product in Quality Control Laboratory, as per our Q.C. Lab. report the sample is declared up to standard as a Ciprofloxacin. You are requested to kindly send samples of our product to National Institute of Health for further testing please".

In the light of the firm's above request, the Board portion was sent for appellate testing under section 22(5) of Drugs Act, 1976 to Appellate Board. The Appellate Laboratory, NIH, Islamabad also declared the said sample as **"Spurious"** vide test report No.016-M/2019 dated 19th July, 2019. Results are reproduced as under:

Description: *Yellow colored oblong shaped, biconvex, film coated tablets having bisectional line on one side whereas plain from the other side packed in blister packing further contained in an outer carton along with leaflet.*

Identification: *Ciprofloxacin not identified.*
Levofloxacin identified.

Dissolution test: *Determined:*
Ciprofloxacin not identified.
Levofloxacin identified.
Does not comply with manufacturer specifications.

Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Ciprofloxacin as Hydrochloride	*250mg/tab*	*Nil*	*90-110%*	*Nil*

Does not comply with manufacturer specifications and official pharmacopoeia.

In the opinion of the undersigned the sample is of spurious as defined in the Drugs Act, 1976 for the reasons given below:

Dissolution test: *Determined:*
Ciprofloxacin not identified.
Levofloxacin identified.
Does not comply with manufacturer specifications.

Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Ciprofloxacin as Hydrochloride	*250mg/tab*	*Nil*	*90-110%*	*Nil*

During investigation, original warranty and bill invoices confirming the sale/trading of drug under question to Gilgit Baltistan from stock register were traced. It has now proved that product under question was manufactured by M/s Ambro Pharmaceuticals, Islamabad and following persons are responsible for the offence:

a) M/s Ambro pharmaceuticals, Islamabad through owner Ch. Abdul Majeed.
b) Ch. Abdul Majeed, (claimed) Owner of firm.

c) Mr. Muhammad Asif Awan, Production Manager.
d) Ms. Rohi Asif, Quality Control Manager.

That in the light of substantial evidence, it is therefore, requested to grant permission for registration of FIR or direct prosecution in the competent Drug Court against the above mentioned persons responsible for violation of Schedule-II (1) (a) (i) r/w Section 23(1)(a)(i) punishable under Schedule-III(1)(a) read with Section 27(1)(a) which is cognizable offence under Schedule-IV of DRAP Act, 2012 read with Section 30 of the Drugs Act, 1976.

Proceeding and Decision of 292nd meeting of Registration Board.

The case was presented before the Registration Board in its 292nd meeting held on 01st – 02nd October, 2019 and the Board considered and evaluated the following record:

- Test report No.NAS.111/2018 dated 14th November, 2018 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 28th November, 2018 by FID-I, DRAP, Islamabad.
- Test report No.R.IP.309/2018 dated 11th January, 2019 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 24th December, 2018 by FID-I, DRAP, Islamabad.
- Test report No.016-M/2019 dated 19th July, 2019 by the Appellate laboratory, NIH, Islamabad.
- Complete case forwarded by FID-I, DRAP, Islamabad vide No.F.3-7/2003-FID-I dated 23rd September, 2019.

The Board after detailed discussion and deliberation decided as under:

- To serve show cause notice and personal hearing to the firm and responsible persons for manufacturing and sale of Spurious Drug Quinozef 250mg Tablets, Registration number 046368, Batch No. AP0014, manufactured by M/s Ambro pharmaceuticals, Islamabad in violation to Schedule-II (1) (a)(i) r/w Section 23(1)(a)(i) punishable under Schedule-III(1)(a) read with Section 27(1)(a) which is cognizable offence under Schedule-IV of DRAP Act, 2012 read with Section 30 of the Drugs Act, 1976.

As per decision of the Registration Board, show cause notice was served to the firm and accused vide letter No.F.03-46/2019-QC (292nd RB) dated 08-11-2019.

Reply of the firm is still awaited.

Proceedings and Decision of 293rd Meeting of Registration Board.

No one appeared on behalf of the firm before the Registration Board in its 293rd meeting held on 08-01-2020 and the Board was appraised that the personal hearing letters were received back undelivered. The Board considered and evaluated once again the following record:

- Test report No.NAS.111/2018 dated 14th November, 2018 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 28th November, 2018 by FID-I, DRAP, Islamabad.
- Test report No.R.IP.309/2018 dated 11th January, 2019 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 24th December, 2018 by FID-I, DRAP, Islamabad.
- Test report No.016-M/2019 dated 19th July, 2019 by the Appellate laboratory, NIH, Islamabad.
- Complete case forwarded by FID-I, DRAP, Islamabad vide No.F.3-7/2003-FID-I dated 23rd September, 2019.

The Board after detailed discussion and deliberation decided to grant permission of prosecution against the following accused persons in the court of competent jurisdiction for violating the provisions of Schedule-II(1)(a)(i) of the DRAP Act, 2012 read with Section 23(1)(a)(i) of the Drugs Act, 1976 punishable under Schedule-III(1)(a) of the DRAP Act, 2012 read with Section 27(1)(a) of the Drugs Act, 1976:

a) M/s Ambro pharmaceuticals, Plot no. 293, Industrial Triangle, Kahuta Road,Islamabad through owner Ch. Abdul Majeed.
b) Ch. Abdul Majeed, (claimed) Owner of firm (CNIC No.: 37405-9697166- 9; Cell no.:0300-8555655).
c) Mr. Muhammad Asif Awan, Production Manager.
d) Ms. Rohi Asif, Quality Control Manager.

Board directed the FID to lodge complaint for prosecution against the above mentioned accused persons in the court of competent jurisdiction along with all relevant record and submit compliance report thereof.

Current Status of the Case.

It is submitted that personal hearing letters issued to the firm/accused were received back undelivered and at the same time area FID, DRAP, Islamabad could also not been able to deliver personal hearing letter to the firm. In order to avoid any legal complications and give the accused/firm another & final opportunity of personal hearing, the case is once again placed before the Registration Board for further necessary directions.

Proceedings and Decision of Board in its 295th Meeting

Registration Board considered the facts/available record of the case, and after thorough deliberation decided as under:

- **Copies of the CNIC's of the accused shall be obtained from the Drugs Licensing Division as per their available record.**
- **Personal hearing letters shall be issued again to the accused upon addresses on their CINC's.**

Case No. 16: **CASE REFERRED BY PQCB, PUNJAB REGARDING CAPSULE CAPSOL ZOL 40, BATCH NO. 0198, MANUFACTURED BY M/S FESTAL LABORATORIES, JINNAH INDUSTRIAL ESTATE, LINK KATTARBAND RAOD, LAHORE.**

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-52/2018 dated 30-10-2019 has informed that Provincial Inspector of Drugs Jampur/Rojhan reported that:

i. He, on 11-01-2018, inspected the business premises of M/s Tahir Medical Store Main Medicine Store, Opposite THQ Hospital Rojhan and took two different drug samples on Form No 4 for the purpose of test/analysis.

ii. One out of these drug samples, after test/ analysis was declared as **Substandard** by Government Analyst Drug Testing Laboratory Multan, as detailed below:

Name of drug	Batch No.	Name of manufacturer	DTL Report TRA No. & Date	DTL Test Report Results
Capsule Capsol Zol 40 Esomeprazole 40mg	0198	M/s Festal Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore.	TRA No.01-57000126/DTL dated: 31-03-2018	**Analysis with specifications applied:** USP 2017 **Identification:** Esomeprazole identified. **Assay:** Esomeprazole: Stated: 40mg/Cap Determined: **48.82mg/ Cap** Percentage: **122.04%** Limit: 90-110% **Does not comply with the specifications.** **Result:** The sample is Substandard, on the basis of tests performed.

iii. M/S Tahir Medical Store Opposite THQ Hospital Rojhan provided Invoice/ warranty No.7103196 dated 01-01-2018 issued by M/S ALM Pharma Mahmood Abad Colony Street # 5 Khanewal Road, Multan who in turn provided invoice/warranty No. 3486 dated 29-04-2017 issued by M/S Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore as a proof of their purchase of the said drug.

iv. A copy of Test report and Warrantor portion of drug sample was sent to M/S Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore and they were asked to explain their position and provide requisite information in this regard.

v. Drug Inspector requested for grant of permission for prosecution against above mentioned accused person who have contravened the provisions of Section 23/27 of the Drugs Act 1976 and Rules framed there under by the way of: -

   a. **Manufacturing for sale/Sale of sale of Substandard drug**
   b. **issuance of false warranty**

Show cause/personal hearing notice(s) issued to accused person(s)

Reply of the Firm:

M/s Festel laboratory stated that we have checked our retained sample but we find the results within the limits i.e 107% further more your DTL declare the weight variation is within the limits. How it is possible that the assay exceeds the limits other this fact we done our production on automatic machines if we fill this shell 3 manually by force the maximum assay goes up to 108% we cannot fill the pellets more than 108% then how it is possible that assay exceed 110%.

Furthermore, our product is according to company's specification and DTL have checked the product according to USP Specifications.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **196th meeting held on 13-11-2018.** Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons.

Representative of the firm appeared before the board and stated that according to Report of Govt. Analyst DTL Multan the subject drug sample was tested according to U.S.P Specifications however our product is registered as Festel Specifications. We have checked our retained sample and found the results within stated limits i.e 107%. Moreover, Weight variation of subject drug sample was found within limits according to the DTL Report so the assay of the active drug cannot exceed the limits as manufacturing plant is fully automated. We cannot fill the pellets of drug more than 108% then it is impossible for the assay of the product to exceed 110%.

The Board unanimously decided to constitute an inspection committee comprising of the followings to conduct **Product Specific Inspection (PSI)** of **M/S Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore,** and submit report for consideration by the Board:

Prof. Dr. Mahmood Ahmed Member PQCB	Member
Mr. Munawar Hayat CDC Punjab	Member
Area **Drug Inspector Industries**	Facilitator

PRODUCT SPECIFIC INSPECTION (PSI) REPORTOF M/S FESTEL LABORATORIES

Date of Inspection: 25-07-2019

Premises:

Unit started in 2006. Total area (06 Canals), covered area 75% of total). The firm has nine production Sections

1. General Tablet Section.
2. General Capsule Section.
3. General Liquid Section.
4. Psychotropic Section.
5. Eye Drop Section.
6. External Preparation Section.
7. Pyodine Section.
8. Dry powder Suspension (Cephalosporin Section).
9. Dry powder capsule (Cephalosporin Section),

Drug:

Capsol-Zol (Esomeprazole 40mg capsule). Batch No. 0I98
Date of Mfg. 03/2017
Exp. Date 02/2019.

Staff:

Designation	Name
Managing Director	Amir Jahangir
Production Manager	Maqsood Ul Haq
QC Manager	Mubashir Bashir
Warrantor	Akbar Ali

Observations:

DTL Lahore declared substandard on above than the upper limit of assay basis.

1. Product Specification of Capsol- Zol is Manufacturer Specification but it has been present in U.S.P from 2016 but manufacturer still applying its own Specifications.
2. Identification by UV spectrophotometer by the firm for assay.

3. Assay in final release report is 101%
4. One HPLC and one UV Spectrophotometer are available. FTIR not available.
5. IPQC: Weight variation, physical and average weight was performed.
6. Raw material testing performed.
7. Material Test. Vendor source. Vision Pharma, Pakistan
8. Packing Material: Physical testing.
9. Shell testing not performed but started performing from May, 2019.
10. Shift time: 9AM to 5PM.
11. Calibration of UV Spectrophotometer is performed but Internal Calibration not performed on weekly basis.
12. Calibration of Balance performed but calibration certificate docs. not have Confidence limit. Daily calibration record is available from 1st July 2019 to onwards. Calibration of the balance at three different weights showing no deviation even at the fourth decimal point which is astonishing as balance is not in separate cabinet.
13. The weight of the pellets of one capsule was measured during inspection which was I 87mg.
14. The firm not justifies the implementation of the factor in assay of the product.

Batch Processing Record of specific product:

1. BMR Record: available.
2. QC retain sample: available (Wrong Brand Name).
3. Testing method: manufacturer own (U V) method, pharmacopoeial (HPLC) method is not performing.
4. API issued was 25 Kg per batch for 12624 Packs.
5. Batch manufacturing started on 27/03/2017 and completed on 31/03/2017.
6. Batch size: 12624 Packs (finally released 12450 Packs.
7. Production yield: 98.60%.
8. In process QC: Available.
9. Reconciliation sheet: available.
10. Testing of finish product is as per MS.

Conclusion:

The panel is of the opinion that the firm is at fault on the below mentioned POINTS.

1) The firm has produced Certificate of analysis of Esomeprazole raw material which bears expiry date September 2016 whereas; formulation is manufactured on July 2017.
2) The firm has released Esomeprazole in the Quality Control Raw material register without mentioning Batch No., Expiry Date. Manufacturing date and potency of API.
3) In BMR of the said product, it is not confirmed what is the Batch No. of the Raw Material used in manufacturing of the product of that batch.
4) The analysis method of the product was available in USP 2016 on HPLC whereas, the firm is performing the analysis of bulk as well as finished good on manufacturer specification on UV Spectrophotometer.
5) In the filling sheet of the batch manufacturing record shows the wrong data with respect of the time on dated 28-03-17.
6) In Batch manufacturing record blistering date is 29-03-17 whereas the packing date and transfer to finished goods store date is 01-03-17.
7) The firm is printing the name of the product on the label in wrong manner as per registration certificate of the product.
8) FTIR is not available, the release of inactive materials were also in question.
9) The firm was not performing any test on the shell of capsule which is pharmacopeial requirement.
10) The calculation of the assay by the firm with factor is doubtful and not having any official reference.
11) The production and QC Manager of the firm are symbolic, not having any practical experience which is very alarming situation.

The panel is of the opinion that the firm fails to justify the matter, therefore, it is recommended to forward the case to the trial court as well as to DRAP for necessary action in the matter.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its 212th meeting held on 30-10-2019. Mr. Sadiq Hussain Secretary DQCB Rajanpur, was present along with original case file. Dr. Muhammad Munawar Hayat (Member of PSI Committee/ Member of PQCB)

briefed the Board about facts of the Product Specific Inspection along with finding and conclusion by the PSI committee. He apprided the Board that the inspection panel is of the opinion that the firm is violating the necessary provision of GMP as required by the Schedule II-B of the Drugs (L.R&A) Rules 1976. The firm used the expired Active Pharmaceutical Ingredients (API) for the manufacture of drug product in question. Moreover, the FTIR was not available with the firm which is essentially required for the identification of the APIs etc. These are the sheer violations of the requirements of the GMP and equivalent to putting the public at the risk of severe/serious adverse event/ mortality/ morbidity.

Secretary PQCB apprised the Board that a letter from the firm M/S Festel Laboratories, Lahore has been received in which they requested to adjourn the case for the next date of hearing as according to them personal hearing notice for the meeting was received on 22-10-2019 and there was insufficient time for them to prepare a suitable defense for the case.

After careful perusal of the above mentioned Inspection report the Board showed serious concerns on GMP violations by the firm. The Board was of the opinion that compliance with Good Manufacturing Practices by the pharmaceutical manufacturers is the best way to ensure quality of medicines being manufactured by them. Such violations/ nonconformance's of GMP guidelines may results in production of compromised quality drugs. The Board after thorough scrutiny of the Product Specific Inspection report observed that that the firm was performing the assay of the finished product on UV-Spectrophotometer. However, the firm was required to adopt the test/analysis method as prescribed in the individual monograph of United States Pharmacopoeia (USP). Whereas the Government Analyst has performed the test/analysis of the product in accordance to the USP specifications through HPLC method. As per the directions of Ministry of Health, Government of Pakistan vide letter No F.3-2/2006-Reg-II-South (M-197) dated 05-06-2006, when a product is contained in any official Pharmacopoeia, then it is mandatory to follow the specifications of that Pharmacopoeia. In present case firm has also violated these direction of Ministry of Health. Moreover, the letter of Personal Hearing was received by the firm eight days before the meeting, so there was sufficient time for them to prepare the defense of the case. Keeping in view the foregoing facts and wilful absence of accused(s), the Board unanimously decided to grant permission for prosecution against the following accused persons in the Drug Court:

1. M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore through its Chief Executive Officer Usman Ghani.
2. Usman Ghani — Chief Executive Officer.
3. Mubarik Ali — Proprietor.
4. Manzoor Ahmad — Quality Control Manger.
5. Akbar Ali — Warrantor.
6. Muhammad Maqsood Ul Haq — Production Incharge.

Of M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore , for the offences of:

a. **Manufacturing for sale/Sale of sale of Substandard drug**
b. **Issuance of false warranty**

The Board further decided to suspend the Drug manufacturing License (DML) of the firm for 15 days w.e.f. the date of receipt of this order, with recommendation to DRAP for de-registration of the Product. Moreover, the Board further decided to direct the Area Drug Inspector industries to re-inspect the factory premises after 15 days to evaluate CAPA and remedial measures taken by the firm and submit report to PQCB for further necessary action.

The Provincial Quality Control Board further recommended the Registration Board to deregister the product capsule capsol zol 40 (Esomeprazole 40mg) of M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Lahore.

Decision of 293rd meeting of Registration Board.

Registration Board deliberated that PQCB has already prosecuted responsible persons in Drug Court and also recommending DRAP for cancellation of registration. The Board decided to seek opinion of Legal Affair Division regarding issuance of show cause notice or otherwise.

Current Status of the Case.

In order to comply the above said decision of the Registration Board, The case file was forwarded to the Legal Affair Division for seeking opinion regarding the issuance of show cause notice or otherwise and the reply of the Legal Affair Division is reproduced as under;

"*That the PQCB granted permission for prosecution against the accused persons mentioned in para 8/N and also recommended to DRAP for cancellation of registration of subject product. The Registration Board deferred the matter for opinion of this Division for issuance of show cause notice or otherwise. In*

view of the above facts, the Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB."

Proceeding and Decision of 295th Meeting of Registration Board.

Registration Board considered the facts of the case and views comments of the Legal Affairs Division, DRAP, Islamabad that the Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:

Registration Board after thorough deliberations decided to defer the case for further deliberations in the upcoming meeting.

Case No. 17: CASE REFERRED BY PQCB, PUNJAB REGARDING SUBSTANDARD MEDIDOL TABLET, MANUFACTURED BY M/S MIDICON PHARMA (PVT.) LTD., PESHAWAR.

Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/R-278/2018 dated 13-06-2019 wherein he has informed that Provincial Inspector of Drugs Tehsil & district Attock reported that:

i. He, on 16-07-2018, inspected the business premises of Ms/ Hafiz Brothers Medicose Sameer Plaza Attock and took three different types of Drugs on Form-4 for the purpose of test and analysis.

ii. One out of three drug samples , after test/analysis was declared substandard by Government Analyst Drug Testing Laboratory, Rawalpindi as detailed below;

<table>
<tr><th>Name of the Drug</th><th>Batch No.</th><th>Name of Manufacturer</th><th>DTL Report TRA No. & Date</th><th>DTL Report results</th></tr>
<tr><td>Tablet Medidol 500mg [Paracetamol: 500mg, Caffeine:65 mg, Chlorpheniramine Maleate:2mg]</td><td>546</td><td>M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar.</td><td>TRA No.01-13001358/DTL Dated: 29-10-2018</td><td>Analysis with specifications:
Manufacturer's specification
Description:
White colored, oblong shaped, biconvex, uncoated tablets engraved word "Medicon" on one side and plain from other side, packed in PVC-ALU blister of 10 tablets.
Identification: Paracetamol, Caffeine and Chlorpheniramine Maleate identified.
Assay:
<table>
<tr><th></th><th>Stated (mg/Tab)</th><th>Determined (mg/Tab)</th><th>%age</th></tr>
<tr><td>Paracetamol</td><td>500</td><td>494.23</td><td>98.85</td></tr>
<tr><td>Caffeine</td><td>65</td><td>62.03</td><td>95.44</td></tr>
<tr><td>Chlorpheniramine Maleate</td><td>2</td><td>1.97</td><td>98.48</td></tr>
</table>
Limit: 90-110%
Dissolution test: (Does not comply with specifications)
<table>
<tr><th></th><th>Average release</th><th>Limit</th></tr>
<tr><td>Paracetamol</td><td>50.75%</td><td>Not less than 75%</td></tr>
</table></td></tr>
</table>

				<table><tr><td>Caffeine</td><td>56.87%</td><td>Not specified</td></tr><tr><td>Chlorphenir amine Maleate</td><td>212.92%</td><td>Not less than 70%</td></tr></table> The percent release of Chlorpheniramine Maleate is not consistent according to manufacturer's method. **Result:** The sample is **substandard** on the basis of dissolution test performed.

iii. M/s Hafiz Brothers Medicose Sameer Plaza Attock provided invoice/warranty No.2037 dated 14-03-2018 issued by M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar as proof of its purchase.

iv. Warrantor portion of the sample was sent to M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar.

v. A copy of test report was sent to M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar with direction to explain their position and provide requisite information in this regard.

Drug inspector requested for grant of permission of prosecution against the nominated accused persons who have contravened the provisions of section 23/27 of the Drugs Act, 1976/DRAP Act, 2012 and Rules framed there under by the way of:-

a) Manufacturing for sale/Sale of substandard drug.
b) Issuance of false warranty.

Show cause/personal hearing notice(s) issued to accused person(s).

Previous proceeding by the Board:

PQCB 205th meeting dated 30-04-2018.

Case was considered by Provincial Quality Control Board under section 11 of the Drugs Act, 1976 in its 205th meeting dated 30-04-2019. Mr Aadil mehmood Secretary DQCB District Attock and Mr. Adnan Aslam Drug Inspector Tehsil Pindi Gheb District Attock was present on behalf of Drug inspector Tehsil Pindi Gheb District Attock with original case record. No one appeared on behalf of M/s Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar. Secretary PQCB appraised the board that written request from Medicon Pharmaceuticals (Pvt.) Ltd., B1/11 Industrial Estate Hayatabad, Peshawar has been received stating that owing to the heart problem faced by the Chief Executive of the firm, they requested the Board to adjourn the case.

In view of the foregoing facts, the Board unanimously decided to adjourn the case in best interest of justice. The Board further decided to provide another/final chance of personal hearing to the accused.

Personal hearing Notice issued to the accused persons.

Proceeding & Decision by the Board.

Case was considered by Provincial Quality Control Board under section 11 of the Drugs Act, 1976 in its 207th meeting dated 13-04-2019. Mr Aadil mehmood Secretary DQCB District Attock and Mr. Tariq Masood Shah Drug Inspector Tehsil & District Attock were present along with the original case record. The complete investigation report submitted by the Drug inspector was scrutinized by the Board under section 11(3) (b) of the Drugs Act, 1976. Show-cause was issued to the firm after detail scrutiny and discussion by the Board in accordance to Rules (5) of the Punjab Drug Rules 2007 (as amended). The Board observed that the Drug inspector on 16-07-2018, having Gazette Notification No. S.O (Dental) 10-11/2014 dated 26-03-2015, in exercise of powers conferred to him under section 18 (b) of the Drugs Act, 1976, inspected the premises of Ms/ Hafiz Brothers Medicose Sameer Plaza Attock and took sample of above mentioned Drugs on Form-4 under section 18 (1) (c) (3) of the Drugs Act, 1976 for the purpose of test and analysis. The sample was sent to DTL vide memorandum No.0000017569, dated 21-07-2018, within the prescribed period of seven days as required under section 19 (3) of the Drugs Act, 1976. The drug sample after test and analysis was declared substandard by the Government Analyst, Drug testing laboratory Rawalpindi under section 22 (1) and report was generated on Form no.07 as required under section 22(2) of the Drugs Act 1976. The said sample was tested according to Manufacturer's specifications as mentioned on the label. The instruments used for testing said sample were calibrated. The calibration status and internal calculation sheets were thoroughly checked and scrutinized. On receipt of the report of Government Analyst the Drug Inspector delivered the test report in accordance to section 22(3) of the Drugs Act 1976.The Drug Inspector conveyed warrantor portion of the drug sample vide

letter no 225/DI/AK/18 dated 01-08-2018 to M/s Medicon Pharmaceuticals (Pvt.) Ltd, B1/11 Industrial Estate, Hayatabad, Peshawar and DTL report vide letter no. 402/DI.AK/18 dated 15-11-2018 to M/s Medicon Pharmaceuticals (Pvt.) Ltd, B1/11 Industrial Estate, Hayatabad, Peshawar and asked for provision of requisite information.

Among accused Dr. Maqbool (Managing Director) of M/s Medicon Pharma (Pvt.) Ltd. B1/11 Industrial Estate Hayatabad, Peshawar was present. Managing Director of the firm appeared before the Board and submitted that chemical assay of the product complies with the specifications. The average release of Chlorpheniramine Maleate is 212.92% which is impossible. He further submitted that the report of Drug Testing Laboratory, Rawalpindi is defective. Their product is registered on Manufacturer's specifications, however, Drug Testing Laboratory, Rawalpindi never asked for provision of method for test/ analysis.

The Board after detailed scrutiny of the record, due deliberation & discussion observed that the Government Analyst, Drug Testing Laboratory, Rawalpindi applied the same method for test/ analysis as provided by the manufacturer. The method provided by M/s Medicon Pharma (Pvt.) Ltd. B1/11 Industrial Estate Hayatabad, Peshawar is incomplete and the drug sample was declared substandard on the basis of analysis performed according to manufacturer's own method. The chemical assay of all the three ingredients present in the formulation lies within prescribed limits i.e., 98.85% for Paracetamol, 95.44% for Caffeine and 98.48% for Chlorpheniramine Maleate. The dissolution profile of all the three ingredients lies outside the limits. Perusal of the method provided by the firm reveals that the method was incomplete. The product that does not comply the dissolution test is unable to produce therapeutic effectiveness. Such product cannot be registered whose method of analysis is faulty or incomplete, tn view of the foregoing facts, the Board unanimously decided to grant permission for prosecution against the following accused in the Drug Court:

i. M/s Medicon Pharma (Pvt.) Ltd. B1/11 Industrial Estate Hayatabad, Peshawar through its Managing Director Farjad Maqbool.
ii. Farjad Maqbool — Managing Director
iii. Arshad Ali — Production Incharge
iv. Raza Khan — Quality Control Incharge
v. Farhad Ali — Warrantor

of M/s Medicon Pharma (Pvt.) Ltd. 81/11 Industrial Estate Hayatabad, Peshawar. For the offences of:

a) Manufacturing for sale/Sale of Sub-standard drug
b) Issuance of false warranty

The Board further decided to recommend cancellation of registration of Tablet Medidol 500mg [Paracetamol: 500mg, Caffeine 65mg, Chlorpheniramine Maleate: 2mg] manufactured by M/s Medicon Pharma (Pvt.) Ltd. B1/11 Industrial "Estate Hayatabad, Peshawar from Drug Regulatory ' Authority of Pakistan (DRAP) for provision of incomplete method of analysis.

Decision of 293rd meeting of Registration Board.

Registration Board deliberated that PQCB has already prosecuted responsible persons in Drug Court and also recommending DRAP for cancellation of registration. The Board decided to seek opinion of Legal Affair Division regarding issuance of show cause notice or otherwise.

Current Status of the Case.

In order to comply the above said decision of the Registration Board, The case file was forwarded to the Legal Affair Division for seeking opinion regarding the issuance of show cause notice or otherwise and the reply of the Legal Affair Division is reproduced as under;

"*That the PQCB granted permission for prosecution against the accused persons mentioned in para 8/N and also recommended to DRAP for cancellation of registration of subject product. The Registration Board deferred the matter for opinion of this Division for issuance of show cause notice or otherwise. In view of the above facts, the Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.*"

Proceeding and Decision of 295th Meeting of Registration Board.

Registration Board considered the facts of the case and views comments of the Legal Affairs Division, DRAP, Islamabad that the Registration Board may issue the show cause notice under rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976 to the firm in the light of recommendations of PQCB.

However, member of the Registration Board from Law & Justice Division (M. Aslam, Deputy Draftsman, Islamabad) was of the opinion that as the Provincial Quality Control Board has already prosecuted the

accused, hence Registration Board cannot take any action in this regard since it will attract double jeopardy.

Decision:
Registration Board decided to defer the case for further deliberations in the next meeting.

Case No.18: **Manufacture & Sale of Counterfeit Zotanil 3mg Tablets, Batch No.055 Manufactured by M/s Zanctok Pharmaceutical Labs, Hyderabad.**

The FID-V, DRAP Karachi visited the premises of M/s Damam Medical Store, Near Sohrab Goth, Karachi on 16th July, 2018 and taken the following sample of drug along with other drugs for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name:	Zotanil 3mg Tablets
Composition:	Each tablet contain 3mg Bromazepam
Registration No:	058631
Batch No:	055
Manufacturing Date:	04-18
Expiry Date:	03-20
Manufactured By:	M/s Zanctok Pharmaceutical Labs, Hyderabad.

The FID-V, DRAP, Karachi has forwarded one sealed portion of sample to Government Analyst, Central Drugs Laboratory, Karachi vide memorandum No.SAA-45-46/2018-FID-V (K) dated 19-07-18 as required under Section 19(3)(i) of the Drugs Act, 1976.

The Federal Government Analyst, CDL, Karachi declared the sample as **Counterfeit** on the basis of **resemblance in the color scheme, text and presentation of outer packaging** with already registered product.

Description: *Pink colored tablets, marked with **"ZPL"** on one side.*
Identification: *Bromazepam identified.*
Disintegration test: *Complies.*
Assay for Bromazepam:
Determined amount/tablet: *3.0723mg*
Stated amount/tablet: *3mg*
Percentage: *102.4%*
Limits: *90.0% to 110.0% Complies.*

Remarks:- *The color scheme, name, text and presentation of outer packaging of the sample **"Zotanil 3mg tablets"** nearly resembles as to be calculated to deceive the label and outer packaging of brand leader drug product **"Lexotanil 3mg tablets"** registration number 001043, manufactured by "Martin Dow Limited Karachi". Hence, sample is declared **"Counterfeit"** under section 3 (f) of the Drugs Act, 1976.*

The FID-V, DRAP, Karachi vide reference No. SAA-45-46/2018-FID-V (K) dated 13-09-18 served an explanation letter to M/s Zanctok Pharmaceutical Labs, Hyderabad that why action may not be taken against them as they have violated the section 3 (f) of the Drugs Act, 1976.

In response to the above said explanation letter, M/s Zanctok Pharmaceutical Labs, Hyderabad submitted their reply vide letter No. Nil dated 27th September, 2018 wherein they have stated that the remarks of the CDL, Karachi should be "The sample is of standard quality with regard to the test performed" instead of the sample is "Counterfeit" under section 3 (f) of the Drugs Act, 1976 which is totally invalid in the eye of law as both the packs are different in respect of (a) front panel, side panel and rear panel (b) text matter (c) product name (well prominent) (d) Company logo (e) Registration number & Manufacturing license and Manufacturer name. They further requested to withdraw the notice as they have not violated the law nor manufactured counterfeit product.

The FID-V, DRAP, Karachi submitted that the firm is involved in contravention/violation of Section 23 (1) (a) (ii) of the Drugs Act, 1976 and recommended that M/s Zanctok Pharmaceutical Labs, Hyderabad may be directed to revise the color scheme of their outer packaging of their registered product "Zotanil tablets 3mg" in order t avoid confusion in the resemblance in the color scheme and compliance of the section 3 (f) of the drugs Act, 1976.

The FID-V, DRAP, Karachi also provided the names of accused persons as under:

i. M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
ii. Mr. Muhammad Saleem (Partner).

iii. Mr. Wazir Ali Lasi (Partner).
iv. Ms. Shabana Yousuf (Production Manager)
v. Ms. Salma Bibi (QC Incharge)

The Division of Drug Licensing, DRAP Islamabad was requested to verify the names provided by the FID-V, Karachi and they provided the following names being responsible persons and technical persons.

M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	Muhammad Saleem **(Partner)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
Wazir Ali Lasi **(Partner)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	Salma Bibi **(Q.C Incharge)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
Shabana Sadiq **(Production Incharge)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	

Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-71/2018-(QC) dated 26-02-2019.

In response to the show cause notice, the firm submitted that their product complies in respect of appearance, Identification of Bromazepam, Disintegration test, Uniformity of dosage unit by content uniformity and Assay of Bromazepam 102.4% (90 -110%). Therefore, remarks of the CDL, Karachi should be "The sample is of standard quality with regards to the test performed" instead of this the Federal Government Analyst declared the sample Counterfeit, which is totally invalid in the eye of law as both the packs are different in respect of (a) front panel, side panel and rear panel (b) text matter (c) product name (well prominent) (d) Company logo (e) Registration number & Manufacturing license and Manufacturer name. Moreover M/s Martin Dow does not having any objection on the resemblance of lexotanil with zotanil packs.

Proceeding of the 289th Meeting of Registration Board.

The Accused were called for personal hearing before the Registration Board on 16th May, 2019 at 12:00 PM vide letter No. 03-31/2019-(QC) dated 13th May, 2019 but no one appeared before the Board.

Decision: Registration Board decided to give second opportunity of personal hearing to the accused in the next meeting and deferred the case.

Proceeding of the 290th Meeting of Registration Board.

Mr. M. Fahim, Manager Regulatory (421010117271-9 appeared on behalf of M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad to plead the instant case of manufacture & sale of Counterfeit Zotanil 3mg Tablets, Batch No.055, before the Board in its 290th meeting on 04th July, 2019.

Representatives of the firm informed that they intend to change the color scheme of their product to the concerned section for better regulatory compliance.

Decision of the 290th Meeting of Registration Board.

The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided as under:

i. The firm will process case for change in color scheme and brand name of the product in question and inform the Board.
ii. Registration shall remain suspended till the approval of color scheme and brand name by the Chairman, Registration Board.
iii. A general advisory will be issued to all manufacturers for refraining from imitating the color scheme of the brand leaders to mislead the peoples. All the Chief Drug Inspectors and Additional Directors of field offices should enforce these directions in true letter and spirit. A comprehensive report may be submitted before the Registration Board.

The said decision was communicated to the firm vide letter No.F03-37/2019-QC (290th RB) dated 26th September, 2019 with directions to comply with te decision of the Registration Board in its true letter and spirit.

M/s Zanctok Pharmaceutical Laboratories vide reference No.ZPL/054/2019 dated 07-10-2019 addressed to Director QA&LT, DRAP, Islamabad submitted their reply and is reproduced as under:

- *We have been manufacturing the Zotanil 3mg Tablet since 10th October, 2009 with our own brand name and packing with distinguished color scheme.*
- *The samples of tablet Zotanil 3mg were drawn from the market for test / analysis by the Central Drug Laboratory (CDL) Karachi and the CDL declared the sample as "counterfeit"*

*merely on the basis of resemblance in the color scheme with another brand but there was no any question raised in CDL report for resemblance in the "**brand name**"*

- *In addition to the report of CDL, the question of brand name was never raised by the concerned FID and the division of Quality Assurance & Lab Testing. During routine correspondence and related submissions thereof.*
- *That the verbal decision of the registration board during the personal hearing was only to change the Color Scheme of the Unit Box as it was already submitted with Prescribed Fee on July 1st, 2019. (Copy Enclosed Annex-A). Suggested artwork was also presented to board, and it was advised to re-submit the artwork with changes of full color scheme, which was also submitted on July 17, 2019. (Copy Enclosed Annex-B)*
- *As per decision of the Registration Board we submitted new color scheme artwork on July 17, 2019, and also mentioned the decision of the Registration Board on our request letter, (Please check attached copy).*

- *During personal hearing, it was never given the decision to change the brand name, it was only decided to change the color scheme. It is only the typing mistake, during the preparation of minutes of 290th meeting.*
- *CDL Karachi declared the sample as "Counterfeit" only on the basis of resemblance in the color scheme with another brand. No other objection is being raised on this matter. The brand name of the product "Zotanil" does not resemble with any of the already registered product for which we have already submitted the undertaking during time of submission of registration application.*

*Since mentioning all the facts and proceedings, it is hereby kindly requested that the decision of **CHANGE NAME OF THE BRAND** may be revoked for the sake of our product market and we have already submitted the amended color scheme and artwork of the unit box for your kind approval. Art work and color scheme may be approved and orders to restore the product may be issued on earlier basis. You kind consideration in this regard will always be highly be appreciated.*

M/s Zanctok Pharmaceutical Laboratories, Hyderabad was issued another letter vide No.F.03-71/2018-QC dated 28-10-2019 wherein it was clarifies that the remarks of the test report of CDL, Karachi clearly mention that the color scheme, **name,** text and presentation of outer packaging of the sample "Zotanil 3mg tablets" nearly resembles as to be calculated to deceive the label and outer packaging of brand leader drug product "Lexotanil 3mg tablets" registration number 001043, manufactured by" Martin Dow Limited Karachi". Hence, sample is declared "Counterfeit" under section 3 (f) of the Drugs Act, 1976. It is therefore you are once again directed to comply with the decision of the Registration Board in its true letter and spirit and submit compliance report before the resumption of the production of the product in question.

M/s Zanctok Pharmaceutical Laboratories vide reference No.ZPL/061/2019 dated 14-11-2019 addressed to the Secretary, Registration Board regarding the subject of "Manufacture & sale of Counterfeit zotanil 3mg tablets B#055" wherein they have referred letter F.No.03-37/2019-QC (290th RB) dated 26th September, 2019 received to them on October 02, 2019, In which the decision of the 290th meeting of the Registration Board was communicated to them and submitted their reply which is reproduced as under:

- *As per decision of the Registration Board in 290th meeting, artwork change request was submitted on July 17, 2019 and has been approved on October 23, 2019 vide letter No.F-31-PRVC/2019(PR-I).*
- *We have been manufacturing the Zotanil 3mg tablets since 10th October, 2009 with our own brand name.*
- *That the CDL, Karachi declared the sample of zotanil 3mg tablets B#055on the basis of resemblance of packaging with innovator's brand "Laxotanil 3mg tablets" manufactured by M/s Martin Down Pakistan Limited.*
- *That the brand name of our product doesn't resemble with innovator's brand or any other product.*
- *That by M/s Martin Down Pakistan Limited or any other company has never raised any objection regarding the resemblance of brand name.*

Since mentioning all the facts it is hereby kindly requested that the decision of the **change name of brand** may be revoked for the sake of our product market and orders to restore the product may be issued on earlier basis.

You kind consideration in this regard will always be highly appreciated.

It is submitted that the firm has already been issued a letter in this regard vide No.F.03-71/2018-QC dated 28-10-2019 to comply with the decision of the Registration Board in its true letter and spirit and submit

compliance report before the resumption of the production of the product in question. However the firm requested that the decision of the **change name of brand** may be revoked for the sake of our product market and orders to restore the product may be issued on earlier basis which comes under the preview of the Board.

Decision of 293rd meeting of Registration Board.

The case was presented before the Registration Board in its 293rd meeting held on 08th January, 2019 and the Board after detailed discussion, considering the decision of Registration Board in its 290th meeting and the request of the firm regarding the change name of brand to revoked for the sake of their product market decided as under:

"**The Board regretted the request of the firm (M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad) and upholds the decision of 290th meeting regarding instant case, and directed that the firm shall change the brand name of their product (Zotanil 3mg Tablets, Reg. No.: 058631)."**

The above said decision was communicated to the firm vide letter No.F.03-65/2019-QC (293rd RB) dated 21st April, 2020 with directions to comply with the decision of the Registration Board in its true letter and spirit.

Current Status of the Case.

In response to the above said letter the firm submitted their reply vide reference No. nil dated nil wherein they have stated that they have already got the approval of change of artwork/color scheme of their registered product Zotanil Tablet 3mg vide letter No.F.31-PRVC/2019(PR-I) dated 23-10-2019.

They further informed that change of brand name was also approved vide letter No.F38-PRVC/2020 (PR-I) dated 03-03-2020 as brand name **"Bromatil 3mg Tablet".**

They further requested to "**Cancel the suspension orders**" and resume the production of the said product as compliance has been done.

Proceedings and Decision of Board in its 295th Meeting

Registration Board considered the facts/available record of the case, and after thorough deliberation decided to resume the production of [Zotanil 3mg Tablets (Old name), Bromatil 3mg Tablets (new name)], Registration No. 058631, Manufactured by M/s Zanctok Pharmaceutical Labs, Hyderabad. Registration Board further advised to comply Drugs (Labelling & Packing) Rules, 1986 and conditions of registrations.

Item No.VI: Additional Agenda

A. Division of Pharmaceutical Evaluation & Registration.

Pharmaceutical Evaluation Cell (PEC)

Drug Regulatory Authority of Pakistan in its 85th meeting held on 09th June, 2020 discussed Favipiravir use in COVID-19 management by countries like China, Russia & Saudi Arabia and further its approval in Japan as antiviral against influenza viruses. Keeping in view the current outbreak of COVID-19, the Authority allowed to submit registration applications on Form 5/ Form 5-A/ Form 5-D instead of Form 5F for registration of Favipiravir.

The Authority in the said meeting advised Director (PE&R) to consider the applied registration applications of Favipiravir in the ongoing meeting without waiting for the formal minutes of the Authority.

Keeping in view the above decision and directions of the Authority; the Board considered following applications of Favipiravir and decided as mentioned against each:

1. Favipiravir Tablet 200mg:

Composition

Each Film coated tablet contains:

Favipiravir…….200mg

Availability in RRA:

Avigan 200mg Film coated Tablet by M/s Toyama Chemical Co., Ltd Japan (PMDA Approved)

Me too status: Not confirmed

Specifications: Innovator's specifications

Sr. No.	Name of applicant	Brand Name	composition	Diary no. Date /Fee & Date/ form	Pack size/ Price	Remarks/GMP status	**Decision**
1.	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind, Lahore	Favigen Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir……..…200mg	Dy.No. 6303 dated 08/04/2020Rs. 50,000/- dated 08-04-2020 Form 5D	30's, 50's / As per SRO	The panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance. 29-03-2019	**Approved with innovator's specifications.**
2.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	FAVIXA 200mg Tablet	Each Tablet Contains: Favipiravir……..…200mg	Dy.No. 6199 dated 07/04/2020 Rs. 20,000/- dated 08-04-2020 30,000/- dated 08-06-2018 Form 5	10's & 30's / As per SRO	Panel inspection dated 09-01-2019 recommends grant of GMP certificate.	**Approved with innovator's specifications.**
3.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Favira Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir……..200mg	Dy.No. 5415 dated 31/03/2020Rs. 20,000/- dated 31-03-2020, 30,000/- dated 08-04-2020 Form 5D	20's & 40's / As per SRO	Last GMP inspection was conducted on 17-01-2019 and The report concludes	**Approved with innovator's specifications.**

						satisfactory GMP compliance	
4.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Avegan 200mg Tablet	Each tablet contains: Favipiravir……200mg	Dy.No. 8531 dated 22/04/2020Rs. 50,000/- dated 22-04-2020 Form 5D	As per SRO	Last GMP inspection conducted on 01-01-2020 and report concludes GMP compliance.	**Approved with innovator's specifications.**
5.	M/s Glitz Pharma, Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Influenza Care 200mg Tablet	Each film coated tablet contains: Favipiravir……..200mg	Dy.No. 8103 dated 20/04/2020Rs. 20,000/- dated 20-04-2020 Form 5D	As per SRO	Last inspection report, 16th Jan, 2019, the panel recommended issuance of GMP certificate. Differential fee of Rs. 30,000/- is required to be submitted.	**Deferred for submission of differential fee of Rs. 30,000/-.**
6.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi	Fapivir 200mg Tablet	Each film coated tablet contains: Favipiravir……..200mg	Dy.No. 7311 dated 14/04/2020Rs. 50,000/- dated 14-04-2020 Form 5D	10's, 30's, 100's / As per DPC	10-07-2018./ GMP compliance level is rated as GOOD.	**Approved with innovator's specifications.**
7.	M/s Linz Pharmaceuticals Pvt Ltd. Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area. Karachi	AVIPIR 200mg Tablet	Each film Coated Tablet contains: Favipiravir……..…200mg	Dy. No. 12582 dated 04/06/2020 Rs. 50,000/- dated 04-06-2020 Form 5D	4 × 10's; 10 × 10's; As per PRC	Inspection date 09/01/2020, GMP of the firm is rated as Good.	**Approved with innovator's specifications.**
8.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Favir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir…….200mg	Dy.No. 12581 dated 04/06/2020 Rs. 50,000/- dated 04-06-2020 Form 5D	4 × 10's; 10 × 10's; As per PRC	Inspection dated 17/09/2019, Acceptable level of GMP compliance.	**Approved with innovator's specifications.**
9.	M/s Welwrd Pharmaceuticals , Plot # 3, Block	F-Riva 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir…	Dy.No. 12475 dated 03/06/2020 Rs. 50,000/-	As per SRO	During the inspection, dated 12-11-2018, M/ s	**Approved with innovator's specifications.**

	A, Phase I-II, Industrial Estate Hattar, KPK		……200mg	dated 03-06-2020 Form 5D		Welwrd are considered to be operating at satisfactory level of GMP.	
10.	M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	FP-Vir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 12479 dated 03/06/2020 Rs. 50,000/- dated 03-06-2020 Form 5D	As per SRO	Last panel inspection dated 30-09-2018 & 29-10-2018 recommends grant of GMP certificate.	**Approved with innovator's specifications.**
11.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	FAVIPA 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 12657 dated 04/06/2020 Rs. 50,000/-, dated 04-06-2020 Form 5D	As per SRO	Last inspection report of M/s Weather folds dated 20/02/2019, recommends the grant of GMP certificate.	**Approved with innovator's specifications.**
12.	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	F-RIVA 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 12659 dated 04/06/2020 Rs. 50,000/- dated 04-06-2020 Form 5D	20's & 40's / As per SRO	Keeping in view the overall cGMP compliance status of the firm, the panel unanimously recommend the renewal of DML M/s Wnsfield Pharma Hattar. 18-01-2018.	**Approved with innovator's specifications.**
13.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Vipir 200mg Tablet	Each Film Coated Tablet Contains: Favipiravir……..200mg	Dy.No. 12484 dated 03/06/2020 Rs. 50,000/- dated 03-06-2020 Form 5D	7's, 10's, 14's, 20's, 28's, 30's / As per DPC	GMP inspection Dated 23-02-2018, the firm was operating at an acceptable level of compliance with GMP standards.	**Approved with innovator's specifications.**

14.	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore	Avgan Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 12917 dated 08/06/2020 Rs. 50,000/- dated 08-06-2020 Form 5D	As per DPC	The firm was granted GMP certificate based on inspection dated 24-04-2018.	**Approved with innovator's specifications.**
15.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan	Avira Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 12914 dated 08/06/2020 Rs. 50,000/- dated 08-06-2020 Form 5D	As per DPC	Last inspection report dated 30-01-2019 confirms that firm is operating at a Good level of GMP compliance.	**Approved with innovator's specifications.**
16.	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan	Favir Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 12918 dated 08/06/2020 Rs. 50,000/- dated 08-06-2020 Form 5D	10's, 20's, 50's, 100's / As per DPC	10-07-2019, the firm is operating at good level of GMP compliance.	**Approved with innovator's specifications.**
17.	M/s Bio-Mark Pharmaceuticals , Plot No. 527, Sundar Industrial Estate, Lahore	FAMI TABLET 200mg	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 13114 dated 09/06/2020 Rs. 50,000/- dated 09-06-2020 Form 5D	10's, 20's, 50's, 100's / As per DPC	The firm is granted GMP certificate based on inspection conducted on 13-02-2020.	**Approved with innovator's specifications.**
18.	M/s Getz Pharma (Private) Limited, 29-30/27, Korangi Industrial Area, Karachi	FAVIGET Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 13183 dated 09/06/2020 Rs. 50,000/- dated 09-06-2020 Form 5D	As per DPC	The firm is granted GMP certificate based on inspection conducted on 07-01-2019.	**Approved with innovator's specifications.**
19.	M/s Moringa Pharmaceuticals , 35-A Sundar Industrial Estate, Lahore	EVAGAN Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir……200mg	Dy.No. 13133 dated 09/06/2020 Rs. 20,000/- dated 09-06-2020 Form 5	As per DPC	The firm is granted GMP certificate based on inspection conducted on 30-5-2019. Differential fee of Rs. 30,000/- alongwith Form-5D is required to be	**Deferred for submission of differential fee of Rs. 30,000/- alongwith application on Form-5D.**

						submitted.	
20.	M /s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-industrial triangle kahuta road Islamabad. 44-Industrial Triangle Kahuta Road, Islamabad	FAVIRULZ Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir…..……200mg	Dy.No. 13274 dated 10/06/2020 Rs. 50,000/- dated 10-06-2020 Form 5	10's, 20's, 30's, 40's/ As per DPC	GMP certificate issued on 18/03/2019. Application on Form 5-D is required to be submitted.	**Deferred for submission of application on Form-5D.**
21.	M /s Sami Pharmaceuticals (pvt) limited, F-95,) off Hub River Road SITE Karachi.	FAVIP Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir…..……200mg	Dy.No. 13273 dated 10/06/2020 Rs. 50,000/- dated 10-06-2020 Form 5	As per DPC	Last inspection report dated 7th & 14th February, 2019, Good level of cGMP compliance.	**Approved with innovator's specifications.**
22.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	ZAPIER Tablet 200mg	Each Film Coated Tablet Contains: Favipiravir…..……200mg	Dy.No. 13287 dated 10/06/2020 Rs. 50,000/- dated 10-06-2020 Form 5	As per DPC	On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP inspection. 07/02/18	**Approved with innovator's specifications.**

Priority approval of Azithromycin:

In continuation to Authority's letter No. F.76-DRAP/2020(PE&R) dated 5th May, 2020, Drug Regulatory Authority of Pakistan in its 77th held on 7th April, 2020 has also approved the formulation of Azithromycin in the list of drugs/formulations for priority approval/registration during COVID-19 pandemic along with other drugs.

2. Azithromycin Tablet 500mg:
Composition:
Each Film coated tablet contains:
Azithromycin as dihydrate…….500mg
Availability in RRAs: MHRA Approved
Me too status: "Azic 500mg Tablet by M/s Nabi Qasim (Reg # 055584)
Specifications: USP

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
23.	M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan	Ezonex 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12052 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	1 x 6's	Certificate of cGMP based on the inspection conducted on 20-05-2019	**Approved with USP specifications.**
24.	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Dynamycin 500mg Tablet	Each Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 11728 dated 21/05/2020Rs. 20,000/- dated 21-05-2020 Form 5	3's 6's	Last GMP inspection report dated 04-12-2018 recommends grant of DML	**Approved with USP specifications.**
25.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Atcozit 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12056 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	3's 6's 7's 10's 14's 20's 28's & 30's	Last GMP inspection conducted on 09-07-2019, and the report concludes that the Overall GMP of the firm is rated as good, based on the area inspected, the people met and the documents reviewed.	**Approved with USP specifications.**
26.	M/s AGP Limited. B-23, S.I.T.E. Karachi	Azifex 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 11866 dated 28/05/2020Rs. 20,000/- dated 28-05-2020 Form 5	3's 6's 10's	Last inspection report dated 13-05-2019, concluded good level of GMP compliance.	**Approved with USP specifications.**

27.	M/s Wisdom Pharmaceutical Industries. 78-A, Industrial Estate Hayatabad, Peshawar, Pakistan	Hosrin 500mg Tablet	Each film Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12454 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Last inspection report Not found	**Deferred for updated GMP status of the firm**
28.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Izithol 500mg Tablet	Each film Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12591 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	1 x 3's	Last GMP inspection conducted on 01-01-2020, and the report concludes that the the firm was GMP compliant on the day of Inspection.	**Approved with USP specifications.**
29.	M/s Herbion Pakistan Pvt Ltd. Plot No.30, Sector 28, Korangi Indsutrial Area, Karachi	Azovant 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12730 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	6's	Inspection date 21/05/2019, The panel recommended renewal of DML.	**Approved with USP specifications.**
30.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Azirant 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 11285 dated 18/05/2020Rs. 20,000/- dated 18-05-2020 Form 5	6's 10's	Good GMP compliance, inspection date 24/07/2018. Salt form Azithromycin as monohydrate mentioned.	**Approved with USP specifications.**
31.	M/s Opal Laboratories Pvt Ltd. LC-41, L.I.T.E., Landhi, Karachi	Z-Mac 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 10547 dated 11/05/2020Rs. 20,000/- dated 11-05-2020 Form 5	3's 6's	Good level of GMP, inspection date 19/09/2019.	**Approved with USP specifications.**
32.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Zeemo 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 10550 dated 11/05/2020Rs. 20,000/- dated 11-05-2020 Form 5	3's 6's 12's	Last GMP inspection was conducted on 17-01-2019 and the report concludes satisfactory GMP compliance.	**Approved with USP specifications.**

33.	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan	Zithromax 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin. ..500mg	Dy.No. 12201 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	6's	GMP certificate issued on 06/11/2019. Method of manufacturing not submitted. Salt for of Azithromycin not mentioned.	**Deferred for clarification of salt form of applied formulation and submission of method of manufacturing.**
34.	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan	Zemco 500mg Tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate….. 500mg	Dy.No. 10633 dated 12/05/2020Rs. 20,000/- dated 12-05-2020 Form 5	As per SRO	22-11-2019 Issued cGMP certificate.	**Approved with USP specifications.**
35.	M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore	Rezoxin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as dihydrate ……500mg	Dy.No. 10631 dated 12/05/2020Rs. 20,000/- dated 12-05-2020 Form 5	6's	Inspection report dated: 13-05-2019 and satisfactory GMP compliance	**Approved with USP specifications.**
36.	M/s Himark Laboratories Pvt Ltd. Plot No. 37-A, Sundar Industrial Estate, Lahore, Pakistan	Azimark 500mg Film Coated Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… ……500 mg	Dy.No. 10738 dated 12/05/2020Rs. 20,000/- dated 12-05-2020 Form 5	6's 12's	11-05-2019 Panel inspection was conducted for grant of new DML. CLB in its 271st meeting approved the DML of the firm.	**Approved with USP specifications.**
37.	M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad	Zaracin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… ……500 mg	Dy.No. 10735 dated 12/05/2020Rs. 20,000/- dated 12-05-2020 Form 5	6's	GMP certificate issued on the basis of inspection conducted on 01/03/2019. Step of film coating not mentioned in manufacturing method	**Deferred for clarification of step of film coating in manufacturing method.**
38.	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat, Islamabad	Azimed 500mg tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate….. 500mg	Dy.No. 10732 dated 12/05/2020Rs. 20,000/- dated 12-05-2020 Form 5	6's	Last GMP inspection conducted on 07-11-2018 and report concludes that overall GMP compliance is found Good of today.	**Approved with USP specifications.**

39.	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan	Azi-Dew 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…… ……500mg	Dy.No. 10733 dated 12/05/2020Rs. 20,000/- dated 12-05-2020 Form 5	6's 10's	Last inspection conducted on 16-08-2018 and the report concludes that the panel recommend the grant of DML by way formulation	**Approved with USP specifications.**
40.	M/s Life Pharmaceutical Company. 24-III, Industrial Estate, Multan, Pakistan	Caliz 500mg tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate…. …500mg	Dy.No. 10384 dated 08/05/2020Rs. 20,000/- dated 08-05-2020 Form 5	6's 10's 12's	Inspection date 15/01/2018, satisfactory level of GMP compliance.	**Approved with USP specifications.**
41.	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan	Ziromac 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… ……500mg	Dy.No. 10553 dated 11/05/2020Rs. 20,000/- dated 11-05-2020 Form 5	As per SRO	Last GMP inspection conducted on 07-02-2018 firm was considered to be operated at acceptable level of compliance with GMP guideline	**Approved with USP specifications.**
42.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan	Azet 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… ……500 mg	Dy.No. 10387 dated 08/05/2020Rs. 20,000/- dated 08-05-2020 Form 5	As per SRO	Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP.	**Approved with USP specifications.**
43.	"M/s Ambrosia Pharmaceuticals. Plot # 18, Street # 09, National Industrial Zone, Rawat, Pakistan	Azomite 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… …500mg"	Dy.No. 10546 dated 11/05/2020Rs. 20,000/- dated 11-05-2020 Form 5	3's 6's	The firm was found working in compliance to GMP, inspection date 08/10/2018.	**Approved with USP specifications.**
44.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Apocine 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… ….500mg	Dy.No. 10952 dated 15/05/2020Rs. 20,000/- dated 15-05-2020 Form 5	6's	GMP certificate issued on 11/07/2019 on the basisi of inspection conducted on 31/07/2019.	**Approved with USP specifications.**

45.	M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura	Azal Tablet 500mg	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 10807 dated 13/05/2020Rs. 20,000/- dated 13-05-2020 Form 5	6's 10's	GMP certificate issued on 03/04/2019 on the basis of inspection conducted on 14/01/2019.	**Approved with USP specifications.**
46.	M/s Legacy Pharmaceuticals pvt Ltd 111-A, Industrial Estate Hayatabad Peshawar	Azo 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate….. 500mg	Dy.No. 10876 dated 14/05/2020Rs. 20,000/- dated 14-05-2020 Form 5	6's 10's	Inspection date 18/07/2019. The Panel recommended renewal of DML.	**Approved with USP specifications.**
47.	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore	Lozith 500mg Oral Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate….. 500mg	Dy.No. 10874 dated 14/05/2020Rs. 20,000/- dated 14-05-2020 Form 5	6's 10's	GMP certificate of dated 18-11-2019	**Approved with USP specifications.**
48.	M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar	Ezill 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg	Dy.No. 10872 dated 14/05/2020Rs. 20,000/- dated 14-05-2020 Form 5	As per SRO	GMP inspection conducted on January 24th, 2019 concluded that firm is operating at satisfactory level of GMP compliance.	**Approved with USP specifications.**
49.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No 5, M2-Pharmazone, 26 Km, Main Sharaqpur Road, Sheikhupura, Pakistan	Varibac 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg	Dy.No. 11288 dated 18/05/2020Rs. 20,000/- dated 18-05-2020 Form 5	6's 12's	Inspection report dated 09-12-2019 & 20-12-2019, the firm is granted DML by way of formulation.	**Approved with USP specifications.**
50.	M/s Olive Laboratories. Plot No. 52, Street S-6, National Industrial Zone, Rawat, Rawalpindi	Azolive 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……..…500mg	Dy.No. 11281 dated 18/05/2020Rs. 20,000/- dated 18-05-2020 Form 5	3's	Last inspection report dated 01-08-2017 shows that firm is operating at good level of GMP as of today	**Approved with USP specifications.**
51.	M/s Medifine Laboratories Pvt Ltd. Plot No A-11, New Industrial	Zithrofast 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as	Dy.No. 11280 dated 18/05/2020Rs. 20,000/- dated 18-05-	3's 6's	Inspection date 09/11/2018, the panel recommended renewal of	**Approved with USP specifications.**

	Area, Mirpur, Azad Kashmir		Dihydrate……500mg	2020 Form 5		DML.	
52.	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore	Acasia 500mg Tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate….. 500mg	Dy.No. 11279 dated 18/05/2020Rs. 20,000/- dated 18-05-2020 Form 5	10's 14's 28's	The firm was granted GMP certificate based on inspection dated 24-04-2018.	**Approved with USP specifications.**
53.	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi	Aziver 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg	Dy.No. 11495 dated 19/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	6's 10's	The firm has submitted copy of GMP certificate based on inspection conducted on 19-09-2019.	**Approved with USP specifications.**
54.	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab	Macazit 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate..… 500mg	Dy.No. 11497 dated 19/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	6's 10's	03/05/2019 inspection dated. The panel recommended renewal of DML. Method of manufacturing not submitted	**Deferred for submission of method of manufacturing.**
55.	M/s Hoover Pharmaceuticals Pvt Ltd. Plot No. 16, Zain Park, Industrial Area, Saggian Bypass Road, Lahore	Trazacin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg	Dy.No. 11492 dated 19/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	6's	Inspection report of dated 12-02-2018 and fair level of GMP compliance,	**Approved with USP specifications.**
56.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi	Azitrax 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg	Dy.No. 11373 dated 19/05/2020Rs. 20,000/- dated 18-05-2020 Form 5	As per SRO	25-9-2019 Panel recommended the renewal of DML.	**Approved with USP specifications.**
57.	M/s Faas Pharmaceuticals (Pvt.) Ltd. F-748/L, S.I.T.E Karachi, Pakistan	Zimy 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg	Dy.No. 11042 dated 18/05/2020Rs. 20,000/- dated 18-05-2020 Form 5	As per SRO	GMP certificate issued on 08-05-2018	**Approved with USP specifications.**
58.	AAA Health Pharmaceuticals Laboratories. Plot# 9A, Street # N-5, National Industrial Zone, Rawat,	Aizomax 500mg Tablet	Each Film Coated Tablet Contains: Aizthromycin as Dihydrate…500mg	Dy.No. 11683 dated 20/05/2020Rs. 20,000/- dated 20-05-2020 Form 5	As per SRO	GMP status Not confirmed Step of film coating not mentioned in manufacturing method	**Deferred for updated GMP status of the firm and clarification of step of film coating in**

	Islamabad						**manufacturing method.**
59.	M/s Stanley Pharmaceuticals Pvt Ltd 84-B, Industrial Estate, Hayatabad, Peshawar	Covimax 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 11681 dated 20/05/2020Rs. 20,000/- dated 20-05-2020 Form 5	6's	Inspection of conducted on 09-05-18, and GMP compliance satisfactory.	**Approved with USP specifications.**
60.	M/s Linz Pharmaceuticals Pvt Ltd. Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area. Karachi	Azax 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… ……500mg	Dy.No. 11722 dated 21/05/2020Rs. 20,000/- dated 21-05-2020 Form 5	6's	Inspection dated 09-01-2020, the GMP of the firm is rated GOOD.	**Approved with USP specifications.**
61.	M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan	Azocal 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate..… 500mg	Dy.No. 11808 dated 21/05/2020Rs. 20,000/- dated 21-05-2020 Form 5	As per SRO	Inspection date 06-11-2018 panel recommended renewal of DML and grant of additional section	**Approved with USP specifications.**
62.	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Azigold 500mg tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 11861 dated 28/05/2020Rs. 20,000/- dated 28-05-2020 Form 5	10's	Inspection date 24/10/2019, panel recommended renewal of DML.	**Approved with USP specifications.**
63.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan	Aztrix 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 11858 dated 28/05/2020Rs. 20,000/- dated 28-05-2020 Form 5	As per SRO	Inspection date 19/07/2019, GMP compliance level is rated as good.	**Approved with USP specifications.**
64.	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore	Cyzit 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 11594 dated 20/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	6's 10's	GMP Certificate issued on 15-03-2018. Step of film coating not mentioned in manufacturing method	**Deferred for clarification of step of film coating in manufacturing method.**
65.	M/s ICI Pakistan Limited. 32/2A Phase 3,	Azocyd 500mg tablet	Each Film Coated Tablet Contains: Azithromycin	Dy.No. 11931 dated 29/05/2020Rs. 20,000/-	6's	07-05-2018 and report concludes good level of cGMP	**Approved with USP specifications.**

	Industrial Estate,Hattar		as Dihydrate …500mg	dated 28-05-2020 Form 5		compliance.	
66.	M/s Curatech Pharma Pvt Ltd. 35 Km, Multan Road, Lahore	Zicure 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 11917 dated 29/05/2020Rs. 20,000/- dated 29-05-2020 Form 5	6's 10's	The panel recommended renewal of DML, inspection date 16/03/2018.	**Approved with USP specifications.**
67.	M/s Zanctok Pharmaceuticals Laboratories Pvt Ltd. F/5 Site Hyderabad, Pakistan	Zanthrocin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 11922 dated 29/05/2020Rs. 20,000/- dated 29-05-2020 Form 5	30's	GMP inspection dated 21-03-2019, current GMP compliance level is rated as Good. Azithromycin dehydrate is mentioned in label claim while dihydrate not mentioned in master formulation	**Deferred for clarification of salt form of applied formulation.**
68.	M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore	Azaltic 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12037 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	6's 10's	Inspection report dated 24-11-2017 Panel recommend grant of renewal of DML	**Approved with USP specifications.**
69.	M/s Oakdale Pharmaceuticals. Plot No. 114, Industrial Estate Jamrud Road, Peshawar	Dalemycin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12044 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	6's	Inspection report of dated 22-01-2019 and satisfactory level of GMP compliance	**Approved with USP specifications.**
70.	M/s Nenza Pharmaceuticals Pvt Ltd. 33-A, Industrial Estate, Hayatabad, Peshawar, Pakistan	Nenzomax DS 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12045-A dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	10's	GMP inspection dated 26-09-2018, overall GMP compliance of the firm is satisfactory	**Approved with USP specifications.**
71.	M/s Murfy Pharmaceuticals Pvt Ltd. 8th Km, Raiwind Road, Lahore	Thromin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to	Dy.No. 12050 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	As per SRO	GMP report not found	**Deferred for updated status of GMP from QA & LT.**

			Azithromycin …500mg				
72.	M/s Regent Laboratories. Plot No. C-20, S.I.T.E Super Highway, North Karachi Industrial Area, Karachi	Azelide 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12047 dated 01/06/2020Rs. 20,000/- dated 28-05-2020 Form 5	6's	Panel inspection dated 09th October, 2019 recommends renewal of DML.	**Approved with USP specifications.**
73.	M/s Pharmatec Pakistan Pvt Ltd. D-86/A, S.I.T.E. Karachi-75700	Mybac 500mg tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12042 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	6's 10's	Last inspection report conducted on 18-07-2017 concluding good level of GMP compliance.	**Approved with USP specifications.**
74.	M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan	Moswell 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12234 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	As per SRO	13/11/2018, Good GMP compliance	**Approved with USP specifications.**
75.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Palthro 500mg Tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate.….500mg	Dy.No. 12235 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	3's 15's	GMP certificate issued on 08-05-2018."	**Approved with USP specifications.**
76.	M/s Friends Pharma Pvt Ltd. 31-km, Ferozepur Road, Lahore, Pakistan	Azithofend 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin …500mg	Dy.No. 12229 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	As per SRO	Last inspection report dated 08/03/2019, the panel recommended renewal of DML. Salt form as dihydrate not mentioned	**Deferred for clarification of salt form of applied formulation alongwith applicable fee.**
77.	M/s Alfalah Pharma Pvt Ltd. 12 km, Sheikhupura Road, Lahore, Pakistan	Milton 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…... .....500mg	Dy.No. 12248 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	6's	GMP certificate not not found Form 5 Attached not attached Method of manufacturing not submitted.	**Deferred for submission of application on approved format of Form-5 and GMP status.**
78.	M/s Maple Pharmaceutical	Mapzit 500mg	Each film coated Tablet	Dy.No. 12231 dated	3's	GMP certificate	**Approved with USP**

	Pvt Ltd. Plot No. 147, Sector 23, Korangi Industrial Area, Karachi	Tablet	Contains: Azithromycin as Dihydrate …500mg	02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5		issued on 22/01/2020 on the basis of inspection conducted on 22/12/2020.	**specifications.**
79.	M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan	Avazit 500mg Tablet	Each film coated Tablet Contains: Azithromycin as dihydrate…… 500mg	Dy.No. 12255 dated 02/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	6's	Inspection conducted on 07-12-17, and the report concludes that the overall rating of GMP was found good at the time of inspection.	**Approved with USP specifications.**
80.	M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.	Axotab 500mg tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12408 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	6's	GMP certificate issued on 31/07/2019 on the basis of inspection conducted	**Approved with USP specifications.**
81.	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad	Aziwiz 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12463 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	10's	Renewal of DML recommended in the inspection dated 13-02-2019 Film coating step not mentioned in manufacturing method	**Deferred for clarification of step of film coating in manufacturing method.**
82.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan	Azil 500mg tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg	Dy.No. 12461 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	3's 6's 10's	GMP certificate issued in 25/04/2019 on the basis on inspection conducted on 07/03/2019.	**Approved with USP specifications.**
83.	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad	Azith 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12465 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	GMP inspection report dated 02-10-2019 is complying satisfactory level of cGMP as of today.	**Approved with USP specifications.**

84.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Azikro 500mg Tablet	Each Film Tablet Contains: Azithromycin as Dihydrate..… 500mg	Dy.No. 12477 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Last panel inspection dated 30-09-2018 & 29-10-2018 recommends grant of GMP certificate.	**Approved with USP specifications.**
85.	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK	Azithrocin 500mg Tablet	Each Film Tablet Contains: Azithromycin as Dihydrate….. 500mg	Dy.No. 12473 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	During the inspection, dated 12-11-2018 M/ s Welwrd are considered to be operating at satisfactory level of GMP.	**Approved with USP specifications.**
86.	M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan	Azomed 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate..… 500mg	Dy.No. 12471 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	6's	Last GMP inspection conducted on 19-11-2019.and report concludes that the panel of inspectors recommend the renewal of DML.	**Approved with USP specifications.**
87.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Azinol 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate..… 500mg	Dy.No. 12468 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	6's 10's	Inspection date 15/02/2019, satisfactory level of GMP compliance.	**Approved with USP specifications.**
88.	M/s Zamko Pharmaceuticals (Pvt) Ltd. 641-A Sundar Industrial Estate, Lahore	Kozivin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate….. 500mg	Dy.No. 12466 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	6's 10's	Inspection date 13/07/2018, panel recommend grant of DML	**Approved with USP specifications.**
89.	M/s OBS Pakistan Private Limited. C-14, S.I.T.E, Karachi, Pakistan	Azthro 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Azithromycin Dihydrate…500mg	Dy.No. 12457 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	3's 6's 10's 12's	GMP inspection conducted at 28-05-18 concluded current level of compliance as good.	**Approved with USP specifications.**
90.	M/s Hizat Pharmaceutical Industries. Plot No. 170 Industrial Estate,Hayatab	Hizethro 500mg Tablet	Each Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin	Dy.No. 12459 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	GMP inspection conducted at 26-12-18 concluded that firm rectify	**Referred to QA Division for updated GMP status**

	ad Peshawar, KPK, Pakistan		…500mg			most of major observations and panel recommends restoration of production activities	
91.	M/s Pakistan Pharmaceutical Products Pvt Ltd. D-122, Sindh Industrial Trading Estate, Karachi	Zentrix 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… ……500mg	Dy.No. 12447 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	GMP certificate issued on 11/03/2019 on the basis of inspection conducted on 05/03/2019.	**Approved with USP specifications.**
92.	M/s Citi Pharma Pvt Ltd. 3-Km Head Balloki Road, Phool Nagar District Kasur, Pakistan	Azocit 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate… ……500mg	Dy.No. 12455 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	3's	Inspection date 19/03/2019 GMP certificate Salt for Azithromycin as dehydrate Mentioned in label claim but not in master formulation and method of manufacturing	**Deferred for clarification of salt form of applied formulation.**
93.	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt.	Winkthro 500mg Tablet	Each Film Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12600 dated 04/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Last GMP inspection conducted on 20-12-2017 and report concludes that The panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest."	**Approved with USP specifications.**
94.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial	Azobrain 500mg tablet	Each Film Tablet Contains: Azithromycin as Dihydrate.…	Dy.No. 12602 dated 04/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Panel Inspection conducted on 03-02-2017 recommends renewal of	**Approved with USP specifications.**

	Estate, Hattar, Pakistan		500mg			DML and grant of four additional sections.	
95.	M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small Industries Estate, Sargodha	Maksin 500mg Tablet	Each Tablet Contains: Azithromycin as Azithromycin Dihydrate…500mg	Dy.No. 12590 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	10's	Last GMP inspection conducted on 22-8-2017 and 12-10-2017 and report concludes that The panel recommend the grant of renewal of DML. In label claim & master formulation film coated not mentioned. While in manufacturing of method step of coating mentioned.	**Deferred for revision of formulation as per reference product alongwith applicable fee.**
96.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Aziglo 500mg tablet	Each Film Coated Tablet Contains: Aziothromycin as Azithromycin Dihydrate….. 500mg	Dy.No. 12586 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	6's 10's	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tabklet General, Capsule General, Liquid Syrup General).	**Approved with USP specifications.**
97.	M/s Sharex Laboratories Pvt Ltd. K.L.P. Road, Sadiqabad.	Azirex 500mg Tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12788 dated 05/06/2020Rs. 20,000/- dated 05-06-2020 Form 5	6's	GMP inspection dated 29-03-2017 concluding satisfactory GMP compliant status	**Approved with USP specifications.**
98.	M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi	Azy-Cin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12739 dated 04/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	As per SRO	GMP inspection dated 11-10-2019 and shows good compliance	**Approved with USP specifications.**

99.	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur	Zirow 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12729 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	3's 6's 10's12's	Last GMP inspection conducted on 03-10-2018 report concludes that firm was considered to be maintaining satisfactory level of the cGMP	**Approved with USP specifications.**
100.	M/s Health Care Pharmaceuticals. 40- K.M. Lahore road, Multan	Azicare 500mg Tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12733 dated 04/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	6's 10's	04-05-2019 Panel inspection for grant of new DML. The DML was granted in 270th meeting of CLB	**Approved with USP specifications.**
101.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi	Azitra 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12735 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 (Deposit slip no# 2014837) Form 5	6's	Inspection date 04/03/2020, Good GMP compliance.	**Approved with USP specifications.**
102.	M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Aziromycin Tablet 500mg	Each Film Coated Tablet Contains: Azithromycin as dihydrate…500mg	Form-5 Dy.No 9392 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019	6's	Good compliance of GMP, inspection date 26/12/2019.	**Approved with USP specifications.**
103.	M/s Ambrosia Pharmaceuticals. Plot # 18, Street # 09, National Industrial Zone, Rawat, Pakistan	Azomite 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate……500mg	Form-5 Dy.No 12561 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019		Another Application with same brand name applied on 11-05-2020 with same strength handed over to Yet to be Marked Sahb/Previous file is not found/Covid-19/Yet to be Marked/18-05-2020	**Deferred for updated status of GMP from QA & LT.**
104.	M/s Biorex Pharmaceuticals	Zithrorex 500mg Tablet	Each tablet contains: Azithromycin	Form-5 Dy.No 13098 dated 06-03-	10's	**Last inspection report is older**	**Deferred for updated status of**

	Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan		as trihydrate…500mg	2019 Rs.20,000/- Dated 06-03-2019		**than 3 years**	**GMP from QA & LT.**
105.	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan	Rocin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg	Form-5 Dy.No 16855 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	10's 14's 20's	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good. Master formulation and method of manufacturing not submitted	**Deferred for submission of master formulation and method of manufacturing.**
106.	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Macrowin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as dehydrate……500mg	Form-5 Dy.No 16767 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019	10's	Inspection conducted on 12-10-2017 & 12-12-2017, and the report concludes that panel recommend grant of DML.	**Approved with USP specifications.**
107.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Mycin Tablet 500mg	Each film coated tablet contains: Azithromycin as dihydrate……500MG	Form-5 Dy.No 15309 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per SRO	The firm was inspected on 12/05/18 concluding Good level of cGMP.	**Approved with USP specifications.**
108.	M/s Palpex Pharmaceuticals Pvt Ltd. FD-46-A8, ST-1, Sector 38, Korangi Creek Industrial Park, Karachi, Pakistan	Palthro 500mg Tablet	Each film Tablet Contains: Azithromycin as Dihydrate……500mg	Form-5 Dy.No 26647 dated 10-12-2019 Rs.20,000/- Dated 10-12-2019	3's 15's	GMP certificate issued on 08-05-2018."	**Approved with USP specifications.**
109.	M/s Marvi Pharmaceuticals. Plot No. 70, Sector 24, Korangi Industrial Area, Karachi From	Renoxin 500mg Tablet	Each film coated tablet contains: Azithromycin …….500mg	Form-5 Dy.No 13722 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per SRO	GMP certificate not found Contract manufacturing differential fee of 30000/- Copy of contract	**Deferred for following observations: GMP certificate not found Contract manufacturing differential**

	Unitech Pharmaceuticals Plot # 4/116, Sec.21, Korangi Industrial Area Karachi					agreement not provided Salt form of Azithromycin not mentioned No of section of applicant could not be verified No of already products on contract manufacturing could not be verified	**fee of 30000/-** **Copy of contract agreement not provided** **Salt form of Azithromycin not mentioned** **No of section of applicant could not be verified** **No of already products on contract manufacturing could not be verified**
110.	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan	Aziwin 500mg Tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate….. 500mg	Form-5 Dy.No 16236 dated 06-03-2019 Rs.20,000/- Dated 07-03-2019 (Duplicate dossier	6's 10's	The panel recommended renewal of DML, inspection date 03/05/2019. Method of manufacturing not submitted.	**Approved with USP specifications.**
111.	M/s Eros Pharmaceuticals Pvt Ltd Plot # 94-95, Sector 23, Korangi Industrial Area Karachi	Zithro 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Azithromycin Dihydrate..… 500mg	Form-5 Dy.No 14632 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (Duplicate dossier	10's	Last inspection report dated 26/03/2018, the panel recommended resumption of production.	**Approved with USP specifications.**
112.	M/s Epoch Pharmaceuticals. Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi	Azicin 500mg Tablet	Each Film Coated Tablet Contains: Azithromycin as dehydrate…… 500mg	Form-5 Dy.No 11414 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019	6's 10's	GMP inspection dated 26th July, 2019, the firm is considered to be operating at satisfactory level of GMP compliance.	**Approved with USP specifications.**

3. Azithromycin Tablet 250mg:
Composition:
Each Film coated tablet contains:
Azithromycin as dihydrate…….250mg
Availability in RRAs: MHRA Approved
ME too status: " Azithrolide tablet of M/s Heal Pharma (Reg. # 084233)
Specifications: USP

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision
113.	M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad	Zaracin 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 10734 dated 12/05/2020Rs. 20,000/- dated 12-05-2020 Form 5	As per SRO 6's	GMP certificate issued on the basis of inspection conducted on 01/03/2019.	**Approved with USP specifications.**
114.	M/s Life Pharmaceutical Company. 24-III, Industrial Estate, Multan, Pakistan	Caliz 250mg tablet	Each Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 10383 dated 08/05/2020Rs. 20,000/- dated 08-05-2020 Form 5	As per SRO 6's 10's 12's 20's 30's	Inspection date 15/01/2018, satisfactory level of GMP compliance.	**Approved with USP specifications.**
115.	M/s Aurik Pharmaceuticals. Plot No. 6 & 7, St No S-9, National Industrial Zone, Rawat, Islamabad	Azirik 250mg Tablet	Each Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 10416 dated 11/05/2020Rs. 20,000/- dated 11-05-2020 Form 5	As per SRO Pack of 6's 10's Pack of 2 blister each blister of 6's (12 tablets)	• Latest Inspection report has not been found. • Film coated description has not been mentioned on Form-5 but it is written in physical parameters.	**Deferred for updated GMP status and revision of salt form of applied formulation alonwith applicable fee.**
116.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan	Azet 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 10386 dated 08/05/2020Rs. 20,000/- dated 08-05-2020 Form 5	As per PRC 6's 10's 20's	Inspection conducted on 23-01-2019 concludes the firm is considered to be operating at good level of GMP.	**Approved with USP specifications.**

117.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Apocine 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 10950 dated 15/05/2020Rs. 20,000/- dated 15-05-2020 Form 5	As per SRO	GMP ceritificate issued on 11/07/2019 on the basis of inspection conducted on 31/07/2018.	**Approved with USP specifications.**
118.	M/s Legacy Pharmaceuticals pvt Ltd 111-A, Industrial Estate Hayatabad Peshawar	Azo 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 10875 dated 14/05/2020Rs. 20,000/- dated 14-05-2020 Form 5	As per SRO 6's 10's	Inspection date 18/07/2019. The Panel recommended renewal of DML.	**Approved with USP specifications.**
119.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No 5, M2-Pharmazone, 26 Km, Main Sharaqpur Road, Sheikhupura, Pakistan	Varibac 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 11288 dated 18/05/2020Rs. 20,000/- dated 18-05-2020 Form 5	As per SRO 10's 2x6's	Inspection report dated 09-12-2019 & 20-12-2019, the firm is granted DML by way of Formulation.	**Approved with USP specifications.**
120.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Azirant 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 11284 dated 18/05/2020Rs. 20,000/- dated 18-05-2020 Form 5	As per SRO 6's 10's	Last GMP inspection report dated 24-7-2018 concluding GOOD compliance to GMP.	**Approved with USP specifications.**
121.	M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi	Aziver 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 11494 dated 19/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	As per SRO 6's 10's	The firm has submitted copy of GMP certificate based on inspection conducted on 19-09-2019.	**Approved with USP specifications.**
122.	M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Road, Layyah, Punjab	Macazit 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 11496 dated 19/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	As per SRO 1X6's 1x10's 10x10's	03/05/2019 Inspection dated. The panel recommended renewal of DML.	**Approved with USP specifications.**
123.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala	Azitrax 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin	Dy.No. 11372 dated 19/05/2020Rs. 20,000/-	As per SRO	Inspection date 25-9-2019 Panel recommended	**Approved with USP specifications.**

	Raod Post Office Daghal, Rawalpindi		as Dihydrate Eq. to Azithromycin …….. 250mg	dated 18-05-2020 Form 5		the renewal of DML.	
124.	M/s Xenon Pharmaceutical Pvt Ltd., 9.5 Km, Sheikhupura Road, Lahore	Azocin 250 mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…… ……250mg	Dy.No. 11720 dated 21/05/2020Rs. 20,000/- dated 21-05-2020 Form 5	As per decision of DPC of DRAP 3's 6's 10's 30's	**Last inspection report is older than 3 Years**.	**Deferred for updated status of GMP from QA & LT.**
125.	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Azigold 250mg tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 11860 dated 28/05/2020Rs. 20,000/- dated 28-05-2020 Form 5	Pack size of 10's As per SRO	Panel inspection for renewal of DML report dated 24/10/2019, the panel recommended for the grant of renewal of DML.	**Approved with USP specifications.**
126.	M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore	Cyzit 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 11593 dated 20/05/2020Rs. 20,000/- dated 19-05-2020 Form 5	As per SRO 6's 10's	Last inspection report dated 30-01-2019 confirms that firm is operating at a Good level of GMP compliance. Firm claim Manufacturer's Specification	**Approved with USP specifications.**
127.	M/s ICI Pakistan Limited. 32/2A Phase 3, Industrial Estate,Hattar	Azocyd 250mg tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 11930 dated 29/05/2020Rs. 20,000/- dated 28-05-2020 Form 5	As per SRO 6's	07-05-2018 and report concludes good level of cGMP compliance.	**Approved with USP specifications.**
128.	M/s Curatech Pharma Pvt Ltd. 35 Km, Multan Road, Lahore	Zicure 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 11918 dated 29/05/2020Rs. 20,000/- dated 29-05-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 16/03/2018.	**Approved with USP specifications.**

129.	M/s Zanctok Pharmaceuticals Laboratories Pvt Ltd. F/5 Site Hyderabad, Pakistan	Zanthrocin 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate…250mg	Dy.No. 11923 dated 29/05/2020Rs. 20,000/- dated 29-05-2020 Form 5	As per SRO 6's	GMP inspection dated 21-03-2019, current GMP compliance level is rated as Good.	**Approved with USP specifications.**
130.	M/s Shrooq Pharmaceuticals Pvt Ltd. 21-km Ferozpur Road, Lahore, Pakistan	Cinzit 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate.….250mg	Dy.No. 12043 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	As per SRO 6's 10's	The firm was Inspected on 22-01-2019.The Panel reported good level of GMP Compliance.	**Approved with USP specifications.**
131.	M/s Nenza Pharmaceuticals Pvt Ltd. 33-A, Industrial Estate, Hayatabad, Peshawar, Pakistan	Nenzomax 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 12045-B dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	As per SRO 1X10's	GMP inspection dated 26-09-2018, overall GMP compliance of the firm is satisfactory	**Approved with USP specifications.**
132.	M/s Murfy Pharmaceuticals Pvt Ltd. 8th Km, Raiwind Road, Lahore	Thromin 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 12049 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	Rs.200.0 per unit of pack (1x6) tablet Rs.330.0 per unit pack of (1x10) tablets	**Last inspection report is older than 3 Years**.	**Deferred for updated status of GMP from QA & LT.**
133.	M/s Pharmatec Pakistan Pvt Ltd. D-86/A, S.I.T.E. Karachi-75700	Mybac 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12041 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	6's &10's As per SRO	Latest GMP inspection report dated 24-02-2020 with the conclusion that firm was considered to be operating at "Good level of compliance"	**Approved with USP specifications.**
134.	M/s Atco Laboratories Limited. B-18, S.I.T.E.	Atcozit 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin	Dy.No. 12055 dated 01/06/2020Rs. 20,000/-	3's 6's 7's 10's	**Last GMP inspection conducted on** 09-07-2019**,**	**Approved with USP specifications.**

	Karachi		as Dihydrate…250mg	dated 01-06-2020 Form 5	12's 14's 20's 28's 30's	**and the report concludes that the** Overall GMP of the firm is rated as good, based on the area inspected, the people met and the documents reviewed.	
135.	M/s AGP Limited. B-23-C, S.I.T.E. Karachi	Azifex 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 11865 dated 28/05/2020Rs. 20,000/- dated 28-05-2020 Form 5	As per SRO 6's 10's	Last inspection report dated 13-05-2019, concluded good level of GMP compliance.	**Approved with USP specifications.**
136.	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Dynamycin 250mg Tablet	Each Tablet Contains: Azithromycin …250mg	Dy.No. 11727 dated 21/05/2020Rs. 20,000/- dated 21-05-2020 Form 5	As per SRO	M/s. Dynatis Pharma Last GMP inspection report dated 04-12-2018 recommends grant of DML Firm applied for uncoated tablet of azithromycin rather film coated azithromycin (as dihydrate)	**Deferred for revision of formulation as per reference alongwith applicable fee.**
137.	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan	Zithromax 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin (as Azithromycin dihydrate)…... 250mg	Dy.No. 12202 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	As per SRO 6's	17-2-2018, Satisfactory level of compliance with GMP	**Approved with USP specifications.**
138.	M/s Friends Pharma Pvt Ltd. 31-km, Ferozepur Road, Lahore, Pakistan	Azithofend 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin …250mg	Dy.No. 12230 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	As per SRO	• GMP certificate issued on 08-05-2018." • Firm applied for Azithromycin rather for Azithromycin (as Dihydrate)	**Deferred for revision of salt form of applied formulation.**

139.	M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.	Axotab 250mg tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 12407 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO 1X6's	GMP certificate issued on 31/07/2019 on the basis of inspection conducted on 03/07/2019.	**Approved with USP specifications.**
140.	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad	Aziwiz 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12462 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Renewal of DML recommended in the inspection dated 13-02-2019 Film coating step not mentioned in manufacturing method	**Deferred for clarification of coating in manufacturing outline.**
141.	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad	Azith 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 12464 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	GMP inspection report dated 02-10-2019 is complying satisfactory level of cGMP as of today.	**Approved with USP specifications.**
142.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Azikro 250mg Tablet	Each Film Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12476 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Last panel inspection dated 30-09-2018 & 29-10-2018 recommends grant of GMP certificate	**Approved with USP specifications.**
143.	M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK	Azithrocin 250mg Tablet	Each Film Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12472 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	During the inspection, dated 12-11-2018 M/ s Welwrd are considered to be operating at satisfactory level of GMP.	**Approved with USP specifications.**
144.	M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan	Azomed 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12470 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO 1X10's	Last GMP inspection conducted on 19-11-2019.and report concludes that the panel of inspectors recommend the renewal of DML.	**Approved with USP specifications.**

145.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Azinol 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12467 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Inspection date 15/02/2019, satisfactory level of GMP compliance	**Approved with USP specifications.**
146.	M/s OBS Pakistan Private Limited. C-14, S.I.T.E, Karachi, Pakistan	Azthro 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Azithromycin Dihydrate…250mg	Dy.No. 12456 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO 3's 6's 10's 12's	GMP inspection conducted at 28-05-18 concluded current level of compliance as good.	**Approved with USP specifications.**
147.	M/s Hizat Pharmaceutical Industries. Plot No. 170 Industrial Estate,Hayatabad Peshawar, KPK, Pakistan	Hizethro 250mg Tablet	Each Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 12458 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	26-12-2018, Restoration of production activities.	**Referred to QA Division for updated GMP status.**
148.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan	Azil 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12460 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO 3's 6's 10's	The firm is granted GMP certificate base on evaluation conducted on 07-03-2019. Firm has attached Eur. Pharmacopeia Monograph for reference of finished product.	**Approved with USP specifications.**
149.	M/s Venus Pharma. 23 km, Multan Road, Lahore	Thromocin-V 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12589 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	As per SRO	GMP certificate issued on 28/11/2019 on the basis of inspection conducted on 05/09/2019.	**Approved with USP specifications.**
150.	M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore	Aziglo 250mg tablet	Each Film Coated Tablet Contains: Aziothromycin as Azithromycin Dihydrate…250mg	Dy.No. 12587 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	6's 10's	Insepction date 16/11/2018, the panel recommended renewal of DML. (Tabklet General, Capsule General, Liquid Syrup General).	**Approved with USP specifications.**

151.	M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan	Izithol 250mg Tablet	Each Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 12592 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	6's	Last GMP inspection conducted on 01-01-2020 and report concludes GMP compliance.	**Approved with USP specifications.**
152.	M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi	Azy-Cin 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12740 dated 04/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	As per SRO	• GMP inspection dated 11-10-2019 and shows good compliance • Firm applied with BP Specifications	**Approved with USP specifications.**
153.	M/s Health Care Pharmaceuticals. 40- K.M. Lahore road, Multan	Azicare 250mg Tablet	Each film coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12732 dated 04/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO 6's 10's	04-05-2019 Panel inspection for grant of new DML. The DML was granted in 270th meeting of CLB	**Approved with USP specifications.**
154.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi	Azitra 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12736 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	As per SRO 1X10's	Inspection date 04/03/2020, Good GMP compliance.	**Approved with USP specifications.**
155.	M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Aziromycin Tablet 250mg	Each Film Coated Tablet Contains: Azithromycin as dihydrate…250mg	Form-5 Dy.No 9391 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019	As per DPC Pack of 6's tablet	M/s Nawan Pharma GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.	**Approved with USP specifications.**
156.	M/s Medera Pharmaceuticals Pvt Ltd. Plot #2, Street #4, National Industrial Zone, Rawat,	Azimed 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Form-5 Dy.No 11037 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019	As per SRO 1X6's	Last GMP inspection conducted on 07-11-2018 and report concludes that overall	**Approved with USP specifications.**

	Islamabad					GMP compliance is found Good of today	
157.	M/s Biorex Pharmaceuticals, Plot No 251-A, Industrial Triangle, Kahuta Road, Islamabad, Pakistan	Zithrorex 250mg Tablet	Each Film coated tablet contains: Azithromycin as dihydrate…250 mg	Form-5 Dy.No 13097 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019	As per SRO 1X10 's per pack	Last inspection report is older than 3 Years.	**Deferred for updated status of GMP from QA & LT.**
158.	M/s Elvin Pharmaceuticals Pvt Ltd 35-Km Raiwind Road, Lahore	AZN 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…250mg	Form-5 Dy.No 16147 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per SRO 10's	Latest inspection report has not found.	**Deferred for updated status of GMP from QA & LT.**
159.	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan	Rocin 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as Dihydrate….. 250mg	**Duplicate** Form-5 Dy.No 16854 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per SRO 10's 14's 20's	M/s: Swiss Pharma Last GMP inspection conducted on 18-10-2018.and report concludes overall current GMP compliance level is rated as good.	**Approved with USP specifications.**
160.	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Macrowin 250mg Tablet	Each Film Coated Tablet Contains: Azithromycin as dihydrate……250mg	Form-5 Dy.No 16766 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019	As per SRO 1x10 's	The firm was granted New Drug Manufacturing License based on inspection Dated 05-12-2017.	**Approved with USP specifications.**
161.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Mycin Tablet 250mg	Each tablet contains: Azithromycin as Azithromycin dihydrate…250mg	Form-5 Dy. No 15354 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per DRAP Policy 6's	The firm was inspected on 12/05/18 concluding Good level of cGMP. Firm applied on Form-5A (for imported drug) while the drug will locally manufacture.	**Deferred for submission of application on approved format of Form-5.**
162.	M/s Eros Pharmaceutical	Zithro 250mg	Each Film Coated Tablet	Form-5 Dy.No 14631	10's	Last inspection report dated	**Approved with USP**

	s Pvt Ltd Plot # 94-95, Sector 23, Korangi Industrial Area Karachi	Tablet	Contains: Azithromycin as Azithromycin Dihydrate…250mg	dated 07-03-2019 Rs.20,000/- Dated 07-03-2019 (Duplicate dossier)		26/03/2018, the panel recommended resumption of production.	**specifications.**

4. Azithromycin powder for oral suspension 200mg/5ml:

Composition:

Each 5ml reconstituted suspension Contains:

Azithromycin dihydrate eq to Azithromycin…200mg

Availability in RRAs:

MHRA Approved.

Me-too status:

Azithrolide Dry Powder Suspension Heal Pharma Hayatabad Industrial Estate, Peshawar 084236

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	**Decision**
163.	M/s Himark Laboratories Pvt Ltd. Plot No. 37-A, Sundar Industrial Estate, Lahore, Pakistan	Azimark 200mg/5ml Oral Suspension	Each 5ml on Reconstitution Contains: Azithromycin Dihydrate Eq. to Azithromycin …200mg	Dy.No. 10736 dated 12/05/2020Rs. 20,000/- dated 12-05-2020 Form 5	As per Sro, As per Sro	11-05-2019 Panel inspection was conducted for grant of new DML. CLB in its 271st meeting approved the DML of the firm.	**Approved with USP specificaiotns.**
164.	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan	Ziromac 200mg/5ml Oral Suspension	Each 5ml Contains: Azithromycin Dihydrate Eq. to Azithromycin …200mg	Dy.No. 10552 dated 11/05/2020Rs. 20,000/- dated 11-05-2020 Form 5	As per Sro, As per Sro	23-4-2019, Satisfactory level of comliance	**Approved with USP specificaiotns.**
165.	M/s Macter International Limited. F-216, S.I.T.E, Karachi, Pakistan	Azet 200mg/5ml Oral Suspension	Each 5ml Contains: Azithromycin Dihydrate Eq. to Azithromycin …200mg	Dy.No. 10385 dated 08/05/2020Rs. 20,000/- dated 08-05-2020 Form 5	15ml, 22.5ml, 25ml, 30ml As per Sro,	27-april-2020-Good level of GMP	**Approved with USP specificaiotns.**
166.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan Contract manufactured By M/s Wenovo	Zeemo 200mg/5ml Dry Suspension	Each 5ml of Reconstituted Suspension Contains: Azithromycin Dihydrate Eq. to Azithromycin …….200mg	Dy.No. 10549 dated 11/05/2020Rs. 50,000/- dated 11-05-2020 Form 5	As per Sro, As per Sro	Applicant name and contract manufacturer name not clear	**Deferred for clarification of applicant and manufacturer on Form-5.**

	Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan						
167.	M/s Linz Pharmaceuticals Pvt Ltd. Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area. Karachi Contract manufactured By M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Azax 200mg/5ml Suspension	Each 5ml Contains: Azithromycin as Dihydrate Eq. to Azithromycin …200mg	Dy.No. 11724 dated 21/05/2020Rs. 50,000/- dated 21-05-2020 Form 5	As per Sro, As per Sro	Bosch: Renewal of DML on 7-2-2020	**Approved with USP specificaiotns.**
168.	M/s Xenon Pharmaceutical Pvt Ltd. 9.5 Km, Sheikhupura Road, Lahore	Azocin 200mg/5ml Dry Suspension	Each 5ml Contains: Azithromycin as Dihydrate…200mg	Dy.No. 11719 dated 21/05/2020Rs. 20,000/- dated 21-05-2020 Form 5	15ml, As per Sro	Granted renewal of DML on 13-october-2017	**Approved with USP specificaiotns.**
169.	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan Contract manufactured By M/s Hygeia Pharmaceuticals. Plot No 295, Industrial Triangle, Kahuta Road, Islamabad	Aziwin 200mg/5ml Dry Suspension	Each 5ml Contains: Azithromycin …200mg/5ml	Dy.No. 11810 dated 21/05/2020Rs. 50,000/- dated 21-05-2020 Form 5	15ml, 30ml, 60ml, As per Sro	Hygeia Pharmaceuticals: 21-9-2017 Satisfactory compliance with c GMP. Salt name is not written. The fee challan contains syp instead of Dry powder for Suspension.	**Deferred for clarification of salt form of applied formulation alongwith applicable fee.**
170.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Azirant 200mg/5ml Suspension	Each 5ml After Reconstitution Contains: Azithromycin Dihydrate Eq. to Azithromycin	Dy.No. 11595 dated 20/05/2020Rs. 20,000/- dated 20-05-2020 Form 5	15ml 22.5ml 25ml, As per Sro	24-7-2018GMP compliance level is good	**Approved with USP specificaiotns.**

			…..200mg				
171.	M/s ICI Pakistan Limited. 32/2A Phase 3, Industrial Estate,Hattar	Azocyd 200mg/5ml Powder for Oral Suspension	Each 5ml Contains: Azithromycin as Dihydrate….. 200mg	Dy.No. 11929 dated 29/05/2020Rs. 20,000/- dated 28-05-2020 Form 5	30ml, As SRO	07-05-2018 and report concludes good level of cGMP compliance.	**Approved with USP specificaiotns.**
172.	M/s Zanctok Pharmaceuticals Laboratories Pvt Ltd. F/5 Site Hyderabad, Pakistan	Zanthrocin 200mg/5ml	Each 5ml Contains: Azithromycin as Monohydrate …200mg	Dy.No. 11921 dated 29/05/2020Rs. 20,000/- dated 29-05-2020 Form 5		31-12-2019 issued cGMP certificate	**Approved with USP specificaiotns.**
173.	M/s OBS Pakistan Private Limited. C-14, S.I.T.E, Karachi, Pakistan Contract Manufactured By M/s Opal Laboratories Pvt Ltd. LC-41, L.I.T.E., Landhi, Karachi	Azthro 200mg/5ml Powder for Oral Suspension	Each 5ml Powder for Oral suspension Contains: Azithromycin Dihydrate Eq. to Azithromycin …200mg	Dy.No. 12038 dated 01/06/2020Rs. 50,000/- dated 01-06-2020 Form 5	15ml, 30ml, 60ml, As per SRO	19-Sep-2019 Good level of GMP	**Deferred for contract agreement, number of sections and products already granted and facility of M/s Opal**
174.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Atcozit 200mg/5ml Oral Suspension	Each 5ml of Suspension Contains: Azithromycin as Dihydrate….. 200mg	Dy.No. 12053 dated 01/06/2020Rs. 20,000/- dated 01-06-2020 Form 5	15ml, 22.5ml, 25ml, 30ml, 35ml, 60ml, 120ml, As per SRO	9-7-2019, good GMP	**Approved with USP specificaiotns.**
175.	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Dynamycin 200mg/5ml Suspension	Each 5ml Contains: Azithromycin …200mg	Dy.No. 11725 dated 21/05/2020Rs. 20,000/- dated 21-05-2020 Form 5		23-12-2019 the firm maintains conformance to cGMP compliance. Suspension section could not be confirmed.	**Deferred for clarification of salt form of applied formulation.**

						Salt form is not written	
176.	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan	Zithromax 200mg/5ml Oral Suspension	Each 5ml Contains: Azithromycin as monohydrate …200mg	Dy.No. 12200 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	15ml, As per SRO,	GMP certificate issued on 06/11/2019.	**Approved with USP specificaiotns.**
177.	M/s Uni-Tech Pharmaceuticals Pvt Ltd. Plot # 4/116-119, Sector 21, Korangi Industrial Area, Karachi-74900, Pakistan	Azogrip 200mg/5ml Oral Suspension	Each 5ml Contains: 204.8mg of Azithromycin Monohydrate Eq. to Azithromycin …200mg	Dy.No. 12236 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	15ml, As per Sro	12-April-2017 Issued cGMP certificate Suspension section is not confirmed	**Deferred for confirmation of required manufacturing facility and composition as per reference regulatory authorities.**
178.	M/s The Searle Company Limited. F-319, S.I.T.E, Karachi, Pakistan Contract manufactured from M/s Searle IV solutions 1.5km Manga Raiwind Road, Lahore	Azitron 200mg/5ml Suspension	Each 5ml Contains: Azithromycin Dihydrate eq to Azithromycin …200mg	Dy.No. 12228 dated 02/06/2020Rs. 50,000/- dated 02-06-2020 Form 5	As per Sro, As per Sro	M/s Searle IV Solutions: Granted cGMP certificate dated 25-3-2019	**Deferred for contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing**
179.	M/s Sharex Laboratories Pvt Ltd. K.L.P. Road, Sadiqabad.	Azirex 200mg/5ml Suspension	Each 5ml Contains: Azithromycin as Dihydrate…200mg	Dy.No. 12480 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per Sro, As per Sro	29-3-2017, Satisfactory level of GMP compliance	**Approved with USP specificaiotns.**
180.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur	Ajicin 200mg/5ml Suspension	Each 5ml Oral Suspension Contains: Azithromycin Dihydrate Eq. to Azithromycin …200mg	Dy.No. 12453 dated 03/06/2020Rs. 50,000/- dated 03-06-2020 Form 5	As per Sro, As per Sro	M/s Novamed: 22-1-2019 Good level of compliance with GMP.	**Deferred for contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing**

	Road, Lahore						
181.	M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad Contract manufactured By M/s Nimrall Laboratories Plot 24, Street SS-3, Rawat, Industrial Area, Islamabad	Aziwiz 200mg/5ml Dry Suspension	Each 5ml Contains: Azithromycin Dihydrate Eq. to Azithromycin …200mg	Dy.No. 12448 dated 03/06/2020Rs. 50,000/- dated 03-06-2020 Form 5	As per Sro, As per Sro		**Deferred for confirmation GMP status of applicant and manufacturer and contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
182.	M/s Pharmawise Labs Pvt Ltd. 25-M, Q.A, Industrial Estate, Kot Lakhpat, Lahore, Pakistan	Azowise 200mg/5ml Oral Powder for Oral Suspension	Each 5ml Contains: Azithromycin as Dihydrate..… 200mg	Dy.No. 12583 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	As per Sro, As per Sro	Certificate of cGMP issued on 13-12-2019	**Approved with USP specificaiotns.**
183.	M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi	Azy-Cin 200mg/5ml Suspension	Each 5ml Contains: Azithromycin as Dihydrate…200mg	Dy.No. 12737 dated 04/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	As per Sro, As per Sro	11-10-2019 Conclusion is not written on the report.	**Deferred for updated status of GMP from QA & LT.**
184.	M/s Fedro Pharmaceuticals Lab Pvt Limited. 149-Industrial Estate, Hayatabad, Peshawar	Zeefed 200mg/5ml Suspension	Each 5ml Contains: Azithromycin as Dihydrate…200mg	Dy.No. 12728 dated 04/06/2020Rs. 20,000/- dated 04-06-2020 Form 5	15ml, 30ml, 22.5ml, 37.5ml	8-2-2019, Approval of additional section i.e. Dry Suspension General	**Approved with USP specificaiotns.**
185.	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan	Rocin 200mg/5ml Oral Powder Suspension	Each 5ml contains: Azithromycin monohydrate …200mg	Form-5 Dy.No 11425 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019	30,60, 120ml.	2018- GMP compliance is rated as good.	**Deferred for correct salt form and fee**

186.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan Contract manufactured By M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	PARA-OFF 200mg Dry Powder Suspension	Each 5ml contains: Azithromycin (as dihydrate) USP …. 200mg	Form-5 Dy.No 14966 dated 07-03-2019 Rs.50,000 Dated 06-03-2019	As per Sro, As per Sro	M/s Novamed: 22-1-2019 Good level of compliance with GMP. Applicant is incorrect as M/s Novamed	**Deferred for clarification of applicant and manufacturer on Form-5 and contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
187.	M/s Neomedix Plot No 5, N/5, National Industrial Zone Rawat Islamabad	Azifine 200mg/5ml Dry Suspension	Each 5ml contains: Azithromycin as Dihydrate…200mg	Form-5 Dy.No 12986 dated 06-03-2019 Rs.20,000/- Dated 05-03-2019	15ml, As per Sro,	14-sep-2017, granted additional section oral dry powder for suspension General	**Deferred for updated status of GMP from QA & LT.**
188.	M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad	Monzit 200mg/5ml Dry Suspension	Each 5ml contains: Azithromycin taste masked granules eq to Azithromycin …200mg	Form-5 Dy.No 14438 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per SRO, As per SRO		**Deferred for updated status of GMP from QA & LT.**
189.	M/s Farmaceutics International F-1-A3, S.I.T.E, Karachi	Azomax Suspension 200mg/15 ml Suspension	Each 15ml contains: Azithromycin …200mg	Form-5 Dy.No 13588 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per Sro, As per Sro	Applied strength is incorrect.	**Deferred for revision of formulation as per reference alongwith applicable fee.**
190.	M/s Farmaceutics International F-1-A3, S.I.T.E, Karachi	Azomax Suspension 200mg/5ml Suspension	Each 5ml contains: Azithromycin as dihydrate…… 200mg	Form-5 Dy.No 13589 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019	As per Sro, As per Sro	GMP report is not present.	**Deferred for updated status of GMP from QA & LT.**
191.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Mycin 200mg/5ml Granules	Each 5ml oral granules for suspension contains: Azithromycin as monohydrate …200mg	Form-5 Dy.No 15289 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019	As per SRO, As per SRO	The firm was inspected on 12/05/18 concluding Good level of cGMP.	**Approved with USP specifications.**

5. Azithromycin for suspension 100mg/5ml:

Composition:

Each 5ml reconstituted suspension Contains:
Azithromycin as dihydrate……..…100mg

Availability in RRAs:

USFDA Approved.

Me-too status:

Azitma 100mg/5ml dry suspension Tablet of M/s Sami Karachi. (Reg.# 074901)

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	**Decision**
192.	M/s Polyfine Chempharma. 51-Industrial Estate, Hayatabad Peshawar, Pakistan	Ziromac 100mg/5ml Oral Suspension	Each 5ml Contains: Azithromycin Dihydrate Eq. to Azithromycin …100mg	Dy.No. 10551 dated 11/05/2020Rs. 20,000/- dated 11-05-2020 Form 5	As per Sro, As per Sro	23-4-2019, Satisfactory level of compliance	**Approved with USP specifications.**
193.	M/s Hygeia Pharmaceuticals. Plot No. 295, Industrial Triangle, Kahuta Road, Islamabad	Hyzitek 100mg/5ml Dry Suspension	Each 5ml Contains: Azithromycin …100mg	Dy.No. 11685 dated 20/05/2020Rs. 20,000/- dated 20-05-2020 Form 5	15ml, 30ml, 60ml, As per Sro,	21-9-2017 Satisfactory compliance with c GMP. Salt name is not written	**Approved with USP specifications.**
194.	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan Contract manufactured By M/s Hygeia Pharmaceuticals. Plot No 295, Industrial Triangle, Kahuta Road, Islamabad	Aziwin 100mg/5ml Dry Suspension	Each 5ml Contains: Azithromycin …100mg	Dy.No. 11809 dated 21/05/2020Rs. 50,000/- dated 21-05-2020 Form 5	15ml, 30ml, 60ml, As per Sro	Hygeia Pharmaceuticals: 21-9-2017 Satisfactory compliance with cGMP. Salt name is not written The fee challan contains syp instead of Dry powder for Suspension.	**Deferred for clarification of salt form of applied formulation and fee challan. contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
195.	M/s ICI Pakistan Limited. 32/2A Phase 3, Industrial Estate,Hattar	Azocyd 100mg/5ml Powder for Oral Suspension	Each 5ml Contains: Azithromycin as Dihydrate…100mg	Dy.No. 11928 dated 29/05/2020Rs. 20,000/- dated 28-05-2020 Form 5	30ml, As SRO	07-05-2018 and report concludes good level of cGMP compliance.	**Approved with USP specifications.**
196.	M/s OBS Pakistan Private Limited. C-14, S.I.T.E, Karachi, Pakistan Contract	Azthro 100mg/5ml Powder for Oral Suspension	Each 5ml Powder for Oral suspension Contains: Azithromycin Dihydrate Eq. to	Dy.No. 12039 dated 01/06/2020Rs. 50,000/- dated 01-06-2020 Form 5	15ml, 30ml, 60ml, As per SRO	19-Sep-2019 Good level of GMP	**Deferred for submission of application on Form-5D. contract agreement, No of existing products on**

	Manufactured By M/s Opal Laboratories Pvt Ltd. LC-41, L.I.T.E., Landhi, Karachi		Azithromycin …100mg				**contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
197.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Atcozit 100mg/5ml Suspension	Each 5ml of Suspension Contains: Azithromycin as dihydrate…100mg	Dy.No. 12233 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	15ml, 22.5ml, 25ml, 30ml, 35ml, 60ml, 120ml, As per SRO	9-7-2019, good GMP	**Approved with USP specifications.**
198.	M/s Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan	Zithromax 100mg/5ml Oral Suspension	Each 5ml Contains: Azithromycin as monohydrate …100mg	Dy.No. 12199 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form 5	15ml, As per SRO,	17-2-2018, Satisfactory level of compliance with GMP	**Approved with USP specifications.**
199.	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi	Azovic 100mg/5ml Dry Powder for Oral Suspension	Each 5ml Reconstituted Suspension Contains: Azithromycin Dihydrate Eq. to Azithromycin …100mg	Dy.No. 12450 dated 03/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	15ml for Rs.300 -30ml for Rs 600-60ml for Rs.900-and 90ml for Rs.1200/	11-Sep-2019, Certificate of GMP issued.	**Approved with USP specifications.**

6. Azithromycin lyophilized/ powder for solution for Infusion 500mg/vial:

Composition:

Each vial Contains:

Azithromycin monohydrate eq to Azithromycin……500mg

Or

Azithromycin dihydrate eq to Azithromycin…….500mg

Availability in RRAs:

MHRA Approved.

The active substance in the proposed product is a monohydrate in contrast to a dihydrate in the reference product. Since both products are powders to be dissolve in water for infusion , the hydrate form is irrelevant and is not expected to affect the in vivo behavior of the active substance. (https://mhraproductsproduction.blob.core.windows.net/docs/f2b573762cc70f20d63585cf7af35401284d5076)

Me-too status:

Macrocap 500mg Dry Powder Injection. Reg. No. 82589

Specifications:

USP

Note: Amperometer electrochemical with dual glassy carbon electrodes is required as per available monograph of USP 42.

Sr No.	Name of applicant	Brand Name	Composition	Diary No./Date/Fee/form	Pack Size/Price	Remarks/ GMP	**Decision:**
200.	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan	Zecmo Lyophilized 500mg Injection	Each Vial Contains: Azithromycin as Dihydrate……500mg	Dy. No. 10632 dated 12/05/2020 Rs. 20,000/- dated 12-05-2020 Form 5	1's vial, As per SRO	22-11-2019 Issued cGMP certificate. Lyophilized vial injectable section is present.	**Approved with USP specifications.**
201.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No 5, M2-Pharmazone, 26 Km, Main Sharaqpur Road, Sheikhupura, Pakistan	Varibac 500mg IV lyophilized sterile powder for Injection	Each Vial Contains: Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 11289 dated 18/05/2020 Rs. 20,000/- dated 18-05-2020 Form 5	1's vial, As per SRO	9,20-12-2019, The panel recommends grant of DML. General Dry powder Injection section (Pre-lyophilized) vial is present	**Deferred for confirmation of required manufacturing facility i.e., Lyophilized vial injectable section.**
202.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi	Azitrax 500mg Injection	Each ml Contains: Azithromycin as Dihydrate (Lyophillized) Eq. to Azithromycin …100mg	Dy.No. 11374 dated 19/05/2020 Rs. 20,000/- dated 18-05-2020 Form 5	1's vial, As per SRO	25-09-2019 panel recommended renewal of DML. Firm has Lyophilized powder for Injection section.	**Approved with USP specifications.**
203.	M/s Hygeia Pharmaceuticals. Plot No. 295, Industrial Triangle, Kahuta Road, Islamabad	Hyzitek 500mg Injection	Each Vial Contains: Azithromycin …500mg	Dy.No. 11687 dated 20/05/2020 Rs. 20,000/- dated 20-05-2020 Form 5	1's vial, As per SRO	21-9-2017 Satisfactory compliance with c GMP. Salt name is not written Vial section is not confirmed	**Deferred for confirmation of required manufacturing facility.**

204.	M/s Linz Pharmaceuticals Pvt Ltd. Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area. Karachi Contract manufactured By M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Azax 500mg injection	Each Vial Contains: Azithromycin as Dihydrate Eq. to Azithromycin …500mg	Dy.No. 11723 dated 21/05/2020 Rs. 50,000/- dated 21-05-2020 Form 5	As per Sro, As per Sro	Bosch: Renewal of DML on 7-2-2020	**Deferred for contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
205.	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan Contract Manufactured By M/s Hygeia Pharmaceuticals . Plot No 295, Industrial Triangle, Kahuta Road, Islamabad	Aziwin 500mg Injection	Each Vial Contains: Azithromycin …500mg	Dy.No. 11811 dated 21/05/2020 Rs. 50,000/- dated 21-05-2020 Form 5	1's vial, As per SRO	Hygeia Pharmaceuticals: 21-9-2017 Satisfactory compliance with c GMP. Salt name is not written The fee challan contains syp instead of Dry powder for Suspension . Vial section is not confirmed	**Deferred for confirmation of required manufacturing facility and for following observations: Salt name is not written. The fee challan contains syp instead of Dry powder for Suspension. contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
206.	M/s Uni-Tech Pharmaceuticals Pvt Ltd. Plot # 4/116-119, Sector 21, Korangi Industrial Area, Karachi-74900, Pakistan	Azogrip 500mg Powder for Injection	Each Vial Contains: 524.03mg of Azithromycin Dihydrate Eq. to Azithromycin …500mg	Dy.No. 12238 dated 02/06/2020 Rs. 20,000/- dated 02-06-2020 Form 5	1's vial, As per SRO	12-April-2017 Issued cGMP certificate Respective section is not confirmed	**Deferred for confirmation of required manufacturing facility.**

207.	M/s Mcolson Research , 24-E, Maulana Shoukat Ali road, Johar town lahore Contract manufactured By M/s Welmark Pharmaceuticals . Plot #122 Phase 5, Block B, Industrial Hattar	Zyson 500mg Injection	Each Vial (5ml) Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12451 dated 03/06/2020 Rs. 50,000/- dated 03-06-2020 Form 5	As per Sro, As per Sro	The various checklist i.e. technical persons list, equipments etc are not confirmed whether these are of Mcolson or Welmark Pharma. Respective section is not confirmed Head office address of Mcolson is written instead of DML address.	**Deferred for confirmation of required manufacturing facility**
208.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore By M/s Welmark Pharmaceuticals . Plot #122 Phase 5, Block B, Industrial Hattar	Azibac 500mg Injection	Each Vial (5ml) Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12452 dated 03/06/2020 Rs. 50,000/- dated 03-06-2020 Form 5	As per Sro, As per Sro	The various checklist i.e. technical persons list, equipments etc are not confirmed whether these are of Mcolson or Welmark Pharma. Respective section is not confirmed	**Deferred for confirmation of required manufacturing facility and contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
209.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Azihon 500mg Injection	Each Vial Contains: Azithromycin lyophilized sterile powder eq to…500mg	Form-5 Dy.No 9965 dated 04-03-2019 Rs.20,000/- Dated 04-03-2019	1's vial, As per SRO	Respective section is not confirmed.	**Deferred for confirmation of required manufacturing facility**
210.	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad	Azi 500mg Injection	Each Vial Contains: Azithromycin ……500mg	Form-5 Dy.No 14297 dated 07-03-2019 Rs.20,000/-	1's vial, As per	24th Oct-2018 Firm was granted additional section i.e.	**Deferred for confirmation of required manufacturing facility**

				Dated 06-03-2019	SRO	Sterile liquid vials General section is present. Salt name is not written	
211.	M/s Adamjee Pharmaceuticals Pvt Ltd, Plot 39, Sector 15, Korangi Industrial Area Karachi Contract manufacturing from Safe Pharmaceuticals Plot No C.I-20, and Sector 6-B North Korangi Industrial Area Karachi	Oxozit Injection 500mg vial	Each Vial Contains: Azithromycin as dihydrate…500mg	Form-5 Dy.No 118 dated 05-03-2019 Rs.50,000/- Dated 05-03-2019	1's vial, As per SRO	Fee challan photocopy attached GMP report is not present	**Deferred for confirmation of required manufacturing facility and for updated status of GMP, contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
212.	M/s Baxter Pharmaceuticals A-1/A Phase-1 SITE Super Highway, Pakistan Contract manufacturing from Safe Pharmaceuticals Plot No C.I-20, and Sector 6-B North Korangi Industrial Area Karachi	Azibex 500mg Injection	Each Vial Contains: Azithromycin as dihydrate…500mg	Form-5 Dy.No 117 dated 04-03-2019 Rs.50,000/- Dated 04-03-2019	1's vial, As per SRO	Fee challan photocopy attached GMP report is not present.	**Deferred for confirmation of required manufacturing facility and for updated status of GMP, contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**

7. Azithromycin capsule 250mg:
Composition:
Each Capsule Contains:
Azithromycin as Dihydrate eq to Azithromycin……...……250mg
Availability in RRAs:
MHRA Approved

ME too status:
Zidor Capsule 250mg of M/s Winthrox Karachi. (Reg.# 074943)
Specifications:
USP
Note: Amperometer electrochemical with dual glassy carbon electrodes is required as per available monograph of USP 42.

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/ GMP status	Decision:
213.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Azirant 250mg Capsule	Each Capsule Contains: Azithromycin dihydrate Eq. to Azithromycin ……250 mg	Dy.No. 11283 dated 18/05/2020Rs. 20,000/- dated 18-05-2020 (#2024202)Form 5	As per SRO	Inspection date 24-07-2019. Good compliance of GMP	**Approved with USP specifications.**
214.	M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Dynamycin 250mg Capsule	Each Capsule Contains: Azithromycin as dihydrate …250mg	Dy.No. 11726 dated 21/05/2020Rs. 20,000/- (# 2028996) dated 21-05-2020 Form 5	6, 10's As per SRO	Inspection date 04-12-2018 recommends grant of DML	**Approved with USP specifications.**
215.	M/s AGP Limited. B-23, S.I.T.E. Karachi	Azifex 250mg capsule	Each Capsule Contains: Azithromycin as Dihydrate..… 250mg	Dy.No. 11867 dated 28/05/2020Rs. 20,000/- (#2006810) dated 28-05-2020 Form 5	6, 10's As per SRO	Inspection date 13-05-2019. Good compliance of GMP.	**Approved with USP specifications.**
216.	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi	Atcozit 250mg capsule	Each Capsule Contains: Azithromycin as Dihydrate..… 250mg	Dy.No. 12054 dated 01/06/2020Rs. 20,000/- (#1908703) dated 01-06-2020 Form 5	3, 6, 7, 10,12, 14, 20, 28 & 30's As per SRO	Inspection date 09-07-2019. Good compliance of GMP	**Approved with USP specifications.**
217.	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi	Azovic 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …….250mg	Dy.No. 12449 dated 03/06/2020Rs. 20,000/- (# 1977553) dated 03-06-2020 Form 5	10,20, 30, 40, 50, 60, 70, 80, 90 & 100's 100 rupees per capsule	Inspection date 24-04-2018. Satisfactory compliance of GMP	**Approved with USP specifications.**
218.	M/s Zanctock Pharmaceuticals Laboratories Pvt Ltd. F/5 Site Hyderabad, Pakistan	Zanthrocin 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 11925 dated 29/05/2020Rs. 20,000/- (# 1978852) dated 29-05-2020 Form 5	30's As per SRO	Inspection date 21-3-2019. Good compliance of GMP	**Approved with USP specifications.**

219.	M/s Regent Laboratories Plot No. C-20, S.I.T.E Super Highway, North Karachi Industrial Area, Karachi	Azelide 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 12046 dated 01/06/2020Rs. 20,000/- (# 0551432) dated 28-05-2020 Form 5	6's As per SRO	Inspection date 01-02-2019. Production Suspension till recommend ation by panel and subsequent approval by the CLB.	**Deferred for updated status of GMP from QA & LT.**
220.	M/s Pharmatec Pakistan Pvt Ltd. D-86/A, S.I.T.E. Karachi-75700	Mybac 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate… …….250mg	Dy.No. 12040 dated 01/06/2020Rs. 20,000/- (0229853) dated 01-06-2020 Form 5	6, 10's As per SRO	Inspection date 30-04-18. Good compliance of GMP	**Approved with USP specifications.**
221.	M/s Himark Laboratories Pvt Ltd. Plot No. 37-A, Sundar Industrial Estate, Lahore, Pakistan	Azimark 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …….250mg	Dy.No. 10737 dated 12/05/2020Rs. 20,000/- (#1943876) dated 12-05-2020 Form 5	6, 12's As per SRO	11-05-2019 Panel inspection was conducted for grant of new DML. CLB in its 271st meeting approved the DML of the firm.	**Approved with USP specifications.**
222.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No 5, M2-Pharmazone, 26 Km, Main Sharaqpur Road, Sheikhupura, Pakistan	Azirant 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 11286 dated 18/05/2020Rs. 20,000/- (#0797741) dated 18-05-2020 Form 5	6, 10's 40.833 per capsul e Or As per SRO	Inspection date 9-12-2019, 20-12-2019. Approval of grant of DML by way of formulation	**Approved with USP specifications.**
223.	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan	J-Mac 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…2 50mg	Dy.No. 11282 dated 18/05/2020Rs. 20,000/- (# 2000272) dated 18-05-2020 Form 5	6, 10's 6's=16 5 10's=2 55	Inspection Dated 03/05/2019 . The panel recommend ed renewal of DML	**Approved with USP specifications.**

224.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi	Azitrax 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate Eq. to Azithromycin …250mg	Dy.No. 11371 dated 19/05/2020Rs. 20,000/- (# 2031378) dated 18-05-2020 Form 5	As per SRO	Inspection date 14-12-2017. The company is found complying CGMP as of today and panel unanimously agreed to issue CGMP certificate for export along with COPP	**Approved with USP specifications.**
225.	M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi	Zio 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin ……250mg	Dy.No. 11043 dated 18/05/2020Rs. 20,000/- (#1956478) dated 18-05-2020 Form 5	As per SRO	Inspection date …. NA	**Deferred for updated status of GMP from QA & LT.**
226.	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore By M/s Bio Mark Pharmaceuticals . Plot No. 527, Sundar Industrial Estate,Lahore	Bizith 250mg Oral Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 10873 dated 14/05/2020Rs. 50,000/- (#2032462) dated 14-05-2020 Form 5	10's As per SRO	Inspection dated 13-2-2020 of M/S Biomark. With compliance of GMP	**Deferred for contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
227.	M/s Farmaceutics International F-1-A3, S.I.T.E, Karachi	Azomax Capsule 250mg	Each capsule contains: Azithromycin ……250 mg	Form-5 Dy.No 13591 dated 07-03-2019 Rs.20,000/- (#0741339) Dated 07-03-2019	10's As per SRO	Inspection date 28-12-2006. New GMP not found Firm applied as Azithromycin but in RRA it is as Dihydrate	**Deferred for clarification of salt form of applied formulation.**
228.	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi,	Elzee Capsule 250mg	Each capsule contains: Azithromycin as dihydrate…250mg	Form-5 Dy.No 15121 07-03-2019 Rs.20,000/- (#0718768) Dated 06-03-2019	12's Rs. 398.11	GMP NA	**Deferred for updated status of GMP from QA & LT.**

229.	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore By M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore Sheikhupura Road, Sheikhupura	Azigon 250mg Capsule	Eachc capsule contains: Azithromycin as dehydrate…. …250mg	Form-5 Dy.No 16111 dated 07-03-2019 Rs.50,000/- (#0844234) Dated 06-03-2019	6's As per SRO	Inspection date 15-02-2018 of M/S Mcolson. With compliance of GMP.	**Deferred for contract agreement, No of existing products on contract manufacturing, total sections and justification if firm has own facility of manufacturing.**
230.	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan	Azomed 250mg Capsule	Eacg hard gelatin capsule contains: Azithromycin as dehydrate…… ….250mg	Form-5 Dy.No 17029 dated 07-03-2019 Rs.20,000/- Dated 28-02-2019	6, 10, 14's As per SRO	GMP NA	**Deferred for updated status of GMP from QA & LT.**
231.	M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan	Zithrosave 250mg Capsule	Each Capsule Contains: Azithromycin dihydrate eq to Azithromycin …250mg	Form-5 Dy.No 9541 dated 01-03-2019 Rs.20,000/- (#0782176) Dated 01-03-2019	10's As per SRO	Inspection date 11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018	**Approved with USP specifications.**
232.	M/s Epoch Pharmaceuticals. Plot # 83-85, Sector 15, Korangi Industrial Area, Karachi	Azicin 250mg Capsule	Each Capsule Contains: Azithromycin 262.5mg dihydrate eq to Azithromycin …250mg	Form-5 Dy.No 11411 dated 05-03-2019 Rs.20,000/- (#0812162) Dated 05-03-2019	6 & 10's As per SRO	Inspection date 28-11-2018 Re commendations: The Director (QA &LT) has granted approval for resumption of production activities in following areas. i) Liquid Injectable ii) Ear/ Eye Drops iii) Cephalosporin Dry Powder Injection iv)	**Deferred for confirmation of manufacturing facility i.e., section for applied dosage form.**

						Cephalosporin Dry Powder suspension, Tablets and Capsules v) Veterinary Injectable vi) Penicillin Dry Syrup and Capsules	
233.	M/s Pakheim international Pharmaceuticals. 28 km, Ferozepur road, Lahore, Pakistan	Azorin 250mg Capsule	Each Capsule Contains: Azithromycin as dihydrate …250mg	Form-5 Dy.No 13666 dated 07-03-2019 Rs.20,000/- (#0829121) Dated 06-03-2019	10's As per SRO	GMP NA	**Deferred for updated status of GMP from QA & LT.**
234.	M/s Amros Pharmaceuticals A-96, S.I.T.E, Super Highway, Karachi	Mycin capsule 250mg	Each capsule contains: Azithromycin as dehydrate…… 250 mg	Form-5A Dy.No 15354 dated 07-03-2019 Rs.20,000/- (#0835977) Dated 07-03-2019	2,4,6's packs As per SRO	The firm was inspected on 12/05/18 Concluding Good level of cGMP.	**Approved with USP specifications.**
235.	M/s Stanley Pharmaceuticals Pvt Ltd 84-B, Industrial Estate, Hayatabad, Peshawar	Covimax 250mg capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin ……250mg	Dy.No. 11682 dated 20/05/2020Rs. 20,000/- (#0784360) dated 20-05-2020 Form 5	2x6's units Per capsule price 42.0/-	The firm was inspected on 09-05-18 Concluding satisfactory level of cGMP.	**Approved with USP specifications.**
236.	M/s Murfy Pharmaceuticals Pvt Ltd. 8th Km, Raiwind Road, Lahore	Thromin 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin ……250 mg	Dy.No. 11679 dated 20/05/2020Rs. 20,000/- (#1962866) dated 20-05-2020 Form 5	255 per unit pack of 1x6 400 per unit pack of 1x10's capsule	The firm was inspected on 16-08-18 concluding fair level of cGMP.	**Approved with USP specifications.**
237.	M/s Linz Pharmaceuticals Pvt Ltd. Plot No. 31-G & 31-H, Sector 15, Korangi	Azax 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate Eq. to Azithromycin	Dy.No. 11721 dated 21/05/2020Rs. 20,000/- (#1962153) dated 21-05-	1x6's As per SRO	GMP NA	**Deferred for updated status of GMP from QA & LT.**

	Industrial Area. Karachi		……250 mg	2020 Form 5			
238.	M/s Heal Pharmaceuticals Pvt Ltd. W-33, Industrial Area, Hayatabad Peshawar	Azithrolide 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 11729 dated 21/05/2020Rs. 20,000/- (#2041470) dated 21-05-2020 Form 5	As per SRO	Inspection date 08/11/2019 . Satisfactory level of GMP	**Approved with USP specifications.**
239.	M/s Alfalah Pharma Pvt Ltd. 12 km, Sheikhupura Road, Lahore, Pakistan	Azolike 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12250 dated 02/06/2020Rs. 20,000/- (#2021872) dated 02-06-2020 Form 5	1x10's As per SRO	GMP NA Form 5 not complete (Just title page attached)	**Deferred for updated status of GMP from QA & LT.**
240.	M/s Maple Pharmaceutical Pvt Ltd. Plot No. 147, Sector 23, Korangi Industrial Area, Karachi	Mapzit 250mg Capsule	Each Tablet Contains: Azithromycin dihydrate as azithromycin …….250 mg	Dy.No. 12232 dated 02/06/2020Rs. 20,000/- (#2001180) dated 02-06-2020 Form 5	10's As per SRO	Inspection date 24-07-2017. Acceptable level of GMP	**Approved with USP specifications.**
241.	M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.	Axomoc 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin ……..250mg	Dy.No. 12406 dated 03/06/2020Rs. 20,000/- (# 2032244) dated 03-06-2020 Form 5	10's As per SRO	GMP certificate issued on 31/07/2019 on the basis of inspection conducted on 03/07/2019 .	**Approved with USP specifications.**
242.	M/s Sharex Laboratories Pvt Ltd. K.L.P. Road, Sadiqabad.	Azirex 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12481 dated 03/06/2020Rs. 20,000/- (#2042360) dated 03-06-2020 Form 5	As per SRO	Inspection date 9-03-2017 satisfactory to GMP compliance	**Approved with USP specifications.**
243.	M/s Unison Chemical Works Post Office Araian, 15 Km Raiwind Road Lahore Pakistan	Azomed 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12469 dated 03/06/2020Rs. 20,000/- (#1909443) dated 03-06-2020 Form 5	As per SRO	GMP NA	**Deferred for updated status of GMP from QA & LT.**
244.	M/s Venus Pharma. 23 km, Multan Road, Lahore	Thromocin-V 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…..	Dy.No. 12588 dated 04/06/2020Rs. 20,000/- (# 2032247)	1x6's 1x10's As per SRO	Inspection date 7/9/2018 GMP Certificate	**Deferred for updated status of GMP from QA & LT.**

			250mg	dated 04-06-2020 Form 5		issued on 27-08-2018	
245.	M/s Pharmawise Labs Pvt Ltd. 25-M, Q.A, Industrial Estate, Kot Lakhpat, Lahore, Pakistan	Azowise 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250 mg	Dy.No. 12584 dated 04/06/2020Rs. 20,000/- (#1975468) dated 04-06-2020 Form 5	6's & 10's As per SRO	GMP certificate issued on 13/12/2019.	**Approved with USP specifications.**
246.	M/s Aneeb Pharmaceuticals Pvt Ltd. 24-Km Bedian Road, Lahore, Pakistan	Thro-Max 250mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …250mg	Dy.No. 12584 dated 04/06/2020Rs. 20,000/- (# 2011409) dated 04-06-2020 Form 5	6x2's As per SRO	Panel inspection dated 29-10-2018 recommended renewal of DML	**Approved with USP specifications.**
247.	M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi	Azy-Cin 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12738 dated 04/06/2020Rs. 20,000/- (# dated 02-06-2020 Form 5	As per SRO	Last GMP inspection was conducted on 04-09-2018 and the report concludes good compliance of the firm	**Approved with USP specifications.**
248.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan	Ajicin 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 12731 dated 04/06/2020Rs. 20,000/- (# 2038758) dated 04-06-2020 Form 5	As per SRO	The firm has maintained conformance to GMP compliance as per inspection report dated 01/04/2019.	**Approved with USP specifications.**
249.	M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi	Mac Azi 250mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…250mg	Dy.No. 11920 dated 29/05/2020Rs. 20,000/- (# 0814873) dated 29-05-2020 Form 5	620/6 capsule AS per SRO	GMP inspection dated 07-11- 2019, the firm is operating at a satisfactory level of GMP compliance.	**Approved with USP specifications.**

8. Azithromycin capsule 500 mg:
Composition:
Each Capsule Contains:
Azithromycin as Dihydrate eq to Azithromycin……...……500mg
Availability in RRAs:
Could not be confirmed
ME too status:
Azithromycin 500mg Capsules Uni pharma (Pvt) Ltd., Lahore. 071422
Specifications:
USP
Note: Amperometer electrochemical with dual glassy carbon electrodes is required as per available monograph of USP 42.

Sr. No.	Name of applicant	Brand Name	composition	Diary no. / Date / fee / form	Pack Size / Price	Remarks/GMP status	**Decision:**
250.	M /s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore	Macromax 500 mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …….500 mg	Dy.No. 12193 dated 02/06/2020Rs. 20,000/- (# 1915450) dated 01-06-2020 Form 5 (Duplicate file)	As per SRO	The firm has submitted copy of GMP certificate based on evaluation conducted on 19-03-2020. The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
251.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan	Azobrain 500mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…500mg	Dy.No. 12601 dated 04/06/2020Rs. 20,000/- dated 03-06-2020 Form 5	As per SRO	Panel Inspection conducted on 03-02-2017 recommends renewal of DML and grant of four additional sections. The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
252.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi	Ziton 500mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate… ……500mg	Dy.No. 12734 dated 04/06/2020Rs. 20,000/- (2014888) dated 04-06-2020 Form 5	1x6's As per SRO	Inspection date 04/03/2020, Good GMP compliance. The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**

253.	M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi	Mac Azi 500mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…….500mg	Dy.No. 11919 dated 29/05/2020Rs. 20,000/- (#0814874) dated 29-05 2020 Form 5	620/6 capsule AS per SRO	GMP inspection dated 07-11-2019, the firm is operating at a satisfactory level of GMP compliance. The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
254.	M/s Curatech Pharma Pvt Ltd. 35 Km, Multan Road, Lahore	Zicure 500mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin ……500mg	Dy.No. 11916 dated 29/05/2020Rs. 20,000/- (#1922296) dated 29-05-2020 Form 5	As per SRO	The panel recommended renewal of DML, inspection date 16/03/2018. The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
255.	M/s Regent Laboratories Plot No. C-20, S.I.T.E Super Highway, North Karachi Industrial Area, Karachi	Azelide 500mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …….500mg	Dy.No. 12048 dated 01/06/2020Rs. 20,000/- (#0551431) dated 28-05-2020 Form 5	As per SRO	Inspection date 01-02-2019. Production Suspension till recommendation by panel and subsequent approval by the CLB. The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
256.	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan	Atizor 500mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …….500mg	Dy.No. 11354 dated 19/05/2020Rs. 20,000/- (2028876)dated 18-05-2020 Form 5	As per SRO	Inspection conducted on 07-09-2017: Satisfactory GMP compliance The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**

257.	M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore	Apocine 500mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate…… ……500mg	Dy.No. 10951 dated 15/05/2020Rs. 20,000/- dated 15-05-2020 Form 5	As per SRO	Inspection conducted on 12-3-2018: Satisfactory GMP compliance The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
258.	M/s Farmaceutics International F-1-A3, S.I.T.E, Karachi	Azomax Capsule 500mg	Each capsule contains: Azithromycin …….500 mg	Form-5 Dy.No 13590 dated 07-03-2019 Rs.20,000(# 0741338) Dated 07-03-2019	10's As per SRO	Inspection date 28-12-2006. New GMP not found Firm applied as Azithromycin but in RRA it is as Dihydrate The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
259.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Romycin 500mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …….500mg	Dy.No. 12251 dated 02/06/2020Rs. 20,000/- (# 2030138)date d 02-06-2020 Form 5	3x6's As per SRO	Inspection report dated 02/08/2018 Concludes the GMP compliance as good. The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
260.	M/s Hygeia Pharmaceuticals . Plot No. 295, Industrial Triangle, Kahuta Road, Islamabad	Hyzitek 500mg Capsule	Each Capsule Contains: Azithromycin …….500mg	Dy.No. 11687 dated 20/05/2020Rs. 20,000/- (#2044650) dated 20-05-2020 Form 5	As per SRO	Date of Inspection: 21-09-2017 Conclusion: Satisfactory The applied strength of formulation could not be verified in RRA.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**

261.	M/s Murfy Pharmaceuticals Pvt Ltd. 8th Km, Raiwind Road, Lahore	Thromin 500mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin ……500mg	Dy.No. 11680 dated 20/05/2020Rs. 20,000/- (# 1962867)date d 20-05-2020 Form 5	As per SRO	The firm was inspected on 16-08-18 Concluding fair level of cGMP.	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
262.	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi	Azirant 500mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin ……500mg	Dy.No. 11596 dated 20/05/2020Rs. 20,000/- (2024203)date d 20-05-2020 Form 5	As per SRO	Inspection date 24-07-2019. Good compliance of GMP	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
263.	M/s Alfalah Pharma Pvt Ltd. 12 km, Sheikhupura Road, Lahore, Pakistan	Azolike 500mg Capsule	Each Capsule Contains: Azithromycin as Dihydrate… ……500mg	Dy.No. 12249 dated 02/06/2020Rs. 20,000/- (2021873)date d 02-06-2020 Form 5	1x10's As per SRO	GMP NA Form 5 not complete (Just title page attached)	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
264.	M/s AGP Limited. B-23, S.I.T.E. Karachi	Azifex 500mg capsule	Each Capsule Contains: Azithromycin as Dihydrate… ……500mg	Dy.No. 11864 dated 28/05/2020Rs. 20,000/- (#2006809) dated 28-05-2020 Form 5	6, 10's As per SRO	Inspection date 13-05-2019. Good compliance of GMP	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.**
265.	M/s Opal Laboratories Pvt Ltd. LC-41, L.I.T.E., Landhi, Karachi	Z-Mac 500mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …….500 mg	Dy.No. 10548 dated 11/05/2020Rs. 20,000/- (# 1926718)date d 11-05-2020 Form 5	As Per SRO	Inspection date 19/09/2019. Good level of GMP	**Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration**

							Board in 275th meeting.

9. Miscellaneous cases:

266.	Name and address of manufacturer / Applicant	M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Azite 1% Opthalmic Solution
	Composition	Each ml Contains: Azithromycin…1%
	Diary No. Date of R& I & fee	Form-5D Dy.No 22189 dated 27-11-2017 Rs.50,000 Dated 24-11-2017 (#0624631)
	Pharmacological Group	Macrolide Antibiotic
	Form	Form-5
	Finished product Specifications	Innovators
	Pack size & Demanded Price	2.5 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Azasite 1% sterile opthalmic solution USFDA Approved.
	Me-too status	Kraze Opthalmic solution 10mg/ml by M/s Meidcaids (Reg#082125)
	GMP status	M/S Remington 15-16th January, 2018 Conclusion: Overall the GMP Compliance of the firm is Good.
	Remarks of evaluator	
	Decision: Approved.	
267.	Name and address of manufacturer / Applicant	M/s Sante Pvt Ltd. A-97, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zithrosan 1% Ophthalmic Solution
	Composition	Each ml Contains: Azithromycin…10mg
	Diary No. Date of R& I & fee	Dy.No. 12227 dated 02/06/2020Rs. 20,000/- dated 02-06-2020 Form (#0316694)
	Pharmacological Group	Macrolide Antibiotic
	Form	Form-5
	Finished product Specifications	Innovators
	Pack size & Demanded Price	2.5 ml As per SRO
	Approval status of product in Reference Regulatory Authorities	Azasite 1% sterile opthalmic solution USFDA Approved.
	Me-too status	Kraze Opthalmic solution 10mg/ml by M/s Meidcaids (Reg#082125)
	GMP status	M/S Sante 02-07-2019 Conclusion: Based on the current practices and keeping in view the attitude of the management towards better compliance of GMP their overall compliance level for the said dosage form is rated as Good.
	Remarks of evaluator	
	Decision: Approved.	

268.	Name and address of manufacturer / Applicant	M/s Caliph Pharmaceuticals Pvt Ltd., Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan
	Brand Name +Dosage Form + Strength	Azocal 1g Sachet
	Composition	Each Sachet Contains: Azithromycin as Dihydrate……1g
	Diary No. Date of R& I & fee	Dy.No. 11807 dated 21/05/2020 Rs. 20,000/- dated 21-05-2020 Rs. 30,000/- dated 11-06-2020
	Pharmacological Group	Macrolide Antibiotic
	Form	Form-5D
	Finished product Specifications	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZITHROMAX (USFDA) supplied in single-dose packets containing azithromycin as dihydrate
	Me-too status	NA
	GMP status	06-11-2018. Recommendations: The panel unanimously recommends the renewal of DML. 00748 by way of formulation, granted to M/s Caliph Pharma KPK are regularization of the layout plan approved vide letter.no.F.3-6/20050Lic dated 16th march 2017 for following sections: others and Sachet section, General (Antibiotic, Non-Antibiotic).
	Remarks of evaluator	Innovator's specifications
	Decision: Approved.	
269.	Name and address of Applicant	M/s Zhangjiakou Dongfang Pharmaceutical Pakistan (Private) Limited, Address: Office # D-2, 2nd Floor, West Land Trade Centre, Plot # C-5, Block 7/8, KCHSU, Shaheed-e-Millat Road, Karachi.
	Detail of Drug Sale License	Address: Validity: Status: Drug License by Way of wholesale
	Name and address of manufacturer	M/s Shijiazhuang No. 4, Pharmaceutical Co., Ltd. Address: No.288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhuang, China
	Name and address of marketing authorization holder (Product license holder)	Not mentioned
	Name of exporting country	People's Republic of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.6662 Dated 21-05-2019
	Fee including differential fee	Rs. 100,000/- Dated 21-05-20178
	Brand Name +Dosage Form + Strength	Azofan 250mg dispersible tablet
	Composition	Each dispersible tablet Contains: Azithromycin ……250 mg
	Finished Product Specification	Manufacturer
	Pharmacological Group	Macrolide antibiotic
	Shelf life	Two years
	Demanded Price	Rs. 35 per tablet
	Pack size	6 dispersible tablets
	International availability	Not confirmed
	Me-too status	Not confirmed

	Detail of certificates attached	**GMP certificate** Photocopy of GMP certificate (HE20150072) for M/s Shijiazhuang No. 4, Pharmaceutical Co., Ltd. China issued by Hebei Food and Drug Administration has been submitted. It is valid until 10/11/2020. **Free sale certificate** Photocopy of free sale certificate confirms the presence of drug on the market of China has been submitted. **Letter of authorization** Not provided
	Remarks of the Evaluator.	The firm has submitted 6 months accelerated and 24 months real time Stability study data for following 3 batches as per Zone IV-A conditions. 350501 350502 350503 Evidence of approval of applied formulation in reference regulatory authority is required. Original letter of authorization / sole agency agreement with product licence holder/ marketing authorization holder is required. Original, legalized CoPP / GMP certificate and free sale certificate are required. The status of product license holder are required to be mentioned. Drug sale license not provided.
	Decision: Deferred for following observations: • **Evidence of approval of applied formulation in reference regulatory authority is required.** • **Original letter of authorization / sole agency agreement with product licence holder/ marketing authorization holder is required.** • **Original, legalized CoPP / GMP certificate and free sale certificate are required.** • **The status of product license holder are required to be mentioned.** • **Copy of Drug sale license is required to be submitted.**	

10. Ascorbic acid chewable tablet 500mg:

Composition:

Each chewable tablet contains:

Ascorbic acid……..500mg

International availability:

Ascorbic acid chewable tablet (50mg, 100mg, 200mg, 500mg) by M/s Ennogen Pharma ltd, MHRA Approved

Me too status:

Cecon 500mg tablet by M/s Abbott.

Specifications: USP

270.	M/s Mega Pharmaceuticals Limited, 27km raiwind road lahore	Mega-C 500mg chewable tablet	Each chewable tablet contains: Ascorbic acid…..500mg	Form-5 Dy.No 117 dated 21-04-2020 Rs.20,000/- Dated 21-04-2020.	As per SRO	Duplicate dossier 30-3-2020, issued cGMP certificate.
Decision: Registration Board approved registration of above application. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

11. Ascorbic acid Injection 500mg/5ml:

Composition:

Each 5ml contains:

Ascorbic acid……..500mg

International availability:

Ascorbic Acid Injection BPC 500mg/5ml (glass ampoule) by M/s Phoenix Labs, MHRA Approved. (product approved by Italy is in glass vial-Vitamin C Salf 500mg/5ml injectable solution-AIC 008194045)

Me too status:

ASCORBIC ACID 500 MG INJ by M/s Schazoo Reg. No. 1629

Specifications: USP

271.	M/s Neutro Pharma 9.5km Sheikhupura road, Lahore	Vitamin-C 500mg ampoule	Each ampoule of 5ml contains: Ascorbic acid…500mg	Form-5 Dy no 8320 dated 20-04-2020 Rs.50,000/- Dated 20-04-2020	5ml, As per SRO	Duplicate dossier 9-5-2020 fair level of GMP compliance.
Decision: Registration Board approved registration of above applications. Conditions regarding validity of registration and data requirement will be same as decided by the Board in its general decision recorded above.						

Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

272.	**Name and address of manufacturer / Applicant**	**M/s Pharm Evo Pvt Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi.**
	Brand Name +Dosage Form + Strength	CanlosTablet 300mg
	Composition	"Each film coated tablet Contains: Canagliflozin as hemihydrate……300mg"
	Diary No. Date of R& I & fee	Dy. No dated 14-7-2015 Rs.50,000/- (Photocopy) Dated 14-07-2015
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5D (Duplicate)
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	N/A
	GMP status	GMP inspection Dated 23-02- 2018, the firm was operating at an acceptable level of compliance with GMP standards.
	Remarks of the Evaluator[II]	

Now the firm has submitted stability data detailed as under:

STABILITY STUDY DATA	
Drug	Canlos Tablet 300mg
Name of Manufacturer	M/s Pharm Evo Pvt Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi.
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., Jiangsu province, China.
API Lot No.	RD-CLF(hemihydrate)-201712031
Description of Pack (Container closure system)	Alu-Alu foil in unit carton
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	18PD-2486-04-T	18PD-2487-05-T	18PD-2488-06-T
Batch Size	2500 tablets	2500 tablets	1000 tablets
Manufacturing Date	11-2018	11-2018	11-2018
Date of Initiation	31-12-2018		
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP Certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd, China issued by nantog Chemical & medical Industry Association , has been submitted, valid upto 05-12-2019.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	• Copy of invoice for Canagliflozin (8Kg), attested by Assistant Director (I & E) DRAP, Karachi dated 08-02-2018 has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has specified Dissolution limit of NLT 80% (Q = 75%) of label claim in 30 minutes, while the FDA Review document of Innovator's product reveal the sampling time of 20 minutes for applied formulation.

273.	Name and address of manufacturer / Applicant	M/s Pharmevo A-29, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Canlos Film Coated Tablets 100mg
	Diary No. Date of R& I & fee	Dy No. 103 , Rs: 50,000/- 14-07-2015
	Composition	Each film coated tablet contains:- Canagliflozin as hemihydrate ….100mg
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors ATC Code: A10BK02 Anti-diabetic
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specs.
	Pack size & Demanded Price	Pack of 30's

	Approval status of product in Reference Regulatory Authorities.	Invokana tablet-USFDA approved
	Me-too status	Not applicable
	GMP status	GMP inspection Dated 23-02- 2018, the firm was operating at an acceptable level of compliance with GMP standards.
	Remarks of the Evaluator.	

STABILITY STUDY DATA			
Drug	Canlos Film Coated Tablets 100mg		
Name of Manufacturer	M/s Pharmevo A-29, North Western Industrial Zone, Port Qasim, Karachi.		
Manufacturer of API	M/s NANTONG Chanyoo Pharmatech Co., Ltd, China		
API Lot No.	RD-CLF(hemihydrate)-201712031		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real time: 0,3,6 (months) Accelerated: 0,3,6 (months)		
Batch No.	18PD-2467-02-T	18PD-2467-03-T	18PD-2467-04-T
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	11-2018	11-2018	11-2018
Date of Initiation	11-2020	11-2020	11-2020
No. of Batches	03		
Date of Submission	22-04-2019 (Dy No. 4154)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
9.	COA of API	Yes RD-CLF(hemihydrate)-201712031
10.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
11.	Protocols followed for conduction of stability study and details of tests.	Yes
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
13.	Documents confirming import of API etc.	Yes
14.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
15.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
16.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has specified Dissolution limit of NLT 80% (Q = 75%) of label claim in 30 minutes, while the FDA Review document of Innovator's product reveal the sampling time of 20 minutes for applied formulation.

Decision of 293rd meeting: Registration Board decided to consider the case after onsite inspection by the panel to be constituted by Chairman Registration Board for verification of authenticity of submitted stability study data.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Canlos (Canagliflozin) 100mg and 300mg Tablets by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.

Reference No:
F.1-2/2020-PEC dated 18th February, 2020 (Canlos 100mg)
F.1-2/2020-PEC dated 24th February, 2020 (Canlos 300mg)
Investigation Date and Time: 4th June, 2020
Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.
Composition of Panel:

1. Dr. Rafeeq Alam Khan, Meritorious Professor & Dean, Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board)
2. Ms, Hira Bhutto Assistant Director, CDL, DRAP, Karachi.
3. Mr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Details of Investigation:
Canlos (Canagliflozin) Tablets 100mg & 300mg

Q.	Question	Observation by panel
1.	Do you have documents confirming the import of Canagliflozin API including approval from DRAP?	The firm has imported Canagliflozin hemihydrate 8.0Kg Batch No: RD-CLF (Hemihydrate)-201712031 vide Invoice No. CYI17457 dated December 18, 2017 from M/s Changzhou Pharmaceutical Factory Co. Ltd. manufactured by M/s Nantong Chanyoo Pharmaceutical Co., Limited for the manufacturing of lab scale batches of Canagliflozin 100mg and 300mg Tablets and taken proper approval of DRAP, Karachi
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation process being implemented by the firm and rationale behind vendor selection is controlled through Postal audit checklist GMP approval by competent authority
3.	Do you have documents confirming the import of Canagliflozin, reference standard and impurity standards?	Firm has imported 20mg of working standard and Impurities CLF -4 and Desfluoro of CLF, Pentatomic ring of CLF and Alpha CLF 5m each and ring opening of CLF 2mg from supplier M/s Changzhou Pharmaceutical Factory Co. Ltd.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, Working standards of the API and impurities standards.
5.	Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate issued by the Nantong Food and Drug Administration, China
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method for testing the API.

7.	Do you have stability studies reports on API?	The firm has stability studies reports on API Canagliflozin hemihydrate conducted by manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and process related impurities have been quantified during stability studies by the API Manufacturer.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has 3.078 KG of the API and 10mg of working standard in hand , however they have consumed all the impurity standards.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients which includes: **Canlos 100mg Tablet:** Microcrystalline cellulose PH.101, Hydroxypropyl Cellulose (Klucel LF), Croscarmellose Sodium, Magnesium Stearate, iron oxide yellow, Super Tab 21AN (Lactose Anhydrous) and Opadry white II 85G68918 and iron oxide yellow has been used for coating. **Canlos 300mg Tablet:** Microcrystalline cellulose PH.101, Hydroxypropyl Cellulose (Klucel LF), Croscarmellose Sodium, Magnesium Stearate, Super Tab 21AN (Lactose Anhydrous) and Opadry white II 85G68918 has been used for coating.
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Canagliflozin 100mg and 300mg Tablets?	The firm has no written protocol however authorized batch record for stability batches of Canagliflozin as hemihydrate 100mg and 300mg Tablets available.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug-excipient Compatibility studies as the composition of their tablets is similar to that of the innovator product (Invokana Tablets 100mg and 300mg manufactured by M/s Janssen-Cilag, Italy).

16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution profile of Canlos 100mg and 300mg Tablet with Invokana Tablets 100mg and 300mg manufactured by M/s Janssen-Cilag respectively. Similarity factor for Canagliflozin 100mg Tablet are as follows: Buffer pH 1.2 (53.908). Acetate Buffer (56.012). Phosphate Buffer (52.123). Similarity factor for Canagliflozin 300mg Tablet are as follows: Buffer pH 1.2 (51.344). Acetate Buffer (55.306). Phosphate Buffer (71.199)
17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, 6 pharmacist and 1 chemist in R&D formulation Laboratory section and two analyst dedicated for R&D testing in QC lab.
18.	Do you have necessary equipment available in product development section for development of Canagliflozin 100mg & 300mg Tablets?	The firm has all necessary equipment related to manufacturing available in R&D section for manufacturing of Canagliflozin 100mg and 300 mg Tablets. The quality control related to development work has been done in the routine quality control laboratory, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product development section qualified?	All the equipment used in product development are qualified.
20.	Do you have proper maintenance /	The firm has proper maintenance / calibration programme. Re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 05 pharmacists and 01 chemist in manufacturing section of product development section currently with suitable knowledge and training in product development. 02 QC Analysts are dedicated for new products testing.
22.	Have you manufactured three stability batches for the stability studies of Canagliflozin 100mg and 300mg Tablets as required?	The firm has manufactured three stability batches for the stability studies of: Canagliflozin 100mg Tablets with Batch Numbers: 18PD-2467-02-T, Mfg Date : 01-11-2018 18PD-2468-03-T Mfg Date : 01-11-2018 18PD-2469-04-T Mfg Date : 01-11-2018 Canagliflozin 300mg Tablets with Batch Numbers: 18PD-2486-04-T, Mfg Date 27-11-2018 18PD-2487-05-T Mfg Date 27-11-2018 18PD-2488-06-T Mfg Date 27-11-2018
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing batch size is of stability batches is the number of tablets per testing frequencies.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.

26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer studies have not been done, however, validation of the method has been performed.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Canagliflozin and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment / instruments being used in the test and analysis of Canagliflozin and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating as supported by forced degradation.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit trail reports on Canagliflozin testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches kept in stability chambers.
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Currently, 12 months studies at real time have been completed with satisfactory results and accelerated stability batches have been completed.
34.	Do you have valid calibration status for the Equipment used in Canagliflozin 100mg & 300mg tablets production and analysis?	The firm has valid calibration status for the equipment used in Canagliflozin as hemihydrate tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as

Conclusions:

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

Recommendations:

4. The firm may kindly be granted necessary registration of Canagliflozin 100mg and 300mg Tablets.

5. Since Canagliflozin falls in BCS Class IV (Low solubility and low permeability), hence will require Bioequivalence Studies. Therefore, post-registration bioequivalence studies are also recommended. **Note:** The firm has submitted written commitment vide letter No. NIL dated NIL for bioequivalence studies on Canlos 100mg and 300mg**.**
Decision: Registration Board decided to approve registration of "Canlos Tablet 300mg (Canagliflozin 300 mg) and Canlos Tablet 100mg (Canagliflozin 100mg) by M/s PharmEvo Pvt Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVa conditions.

274.	**Name and address of manufacturer / Applicant**	**"M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"**
	Brand Name +Dosage Form + Strength	Kay Gone 10gm Sachet
	Composition	Each Sachet Contains: Sodium Polystyrene Sulfonate…10gm
	Diary No. Date of R& I & fee	Dy.No 24563 (16-07-2018) Rs.20,000/- Dated 16-07-2018
	Pharmacological Group	Ion-exchange resin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's" Rs. 1,150/-
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA as 454gm per bottle
	Me-too status	-
	GMP status	Last GMP inspection report dated 23-02-2018 concluding as under: "Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Pharm Evo Pvt. Ltd. Karachi was considered to be operating at acceptable level of compliance with GMP standards as today."
	Remarks of the Evaluator[2]	Evidence of Me-too status required.
	Previous Decision of 286th meeting:	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board.
	Evaluation by PEC	• Firm has submitted 36 months long term & 6 months accelerated stability study reports of three batches of "Polystyrene Sulphonate" from the supplier i.e., M/s Phaex polymers Pvt. Ltd., Maharashtra, India. • Moreover firm has submitted following undertaking: "We, PharmEvo (Pvt) Limited do hereby undertake that we will provide real time stability studies of (Sodium Polystyrene Sulphonate USP according to stability protocol till assigned shelf life of the product."
	Decision of 288th meeting: Deferred for application on Form 5-D along with submission of differential fee and stability study data by the finished product manufacturer as per the requirements of 278th meeting of Registration Board.	
Firm's reply: Firm has submitted 1 month stability data of 3 batches, at both accelerated and long term stability conditions. **Evaluation by PEC:** • Firm has not submitted Form 5-D and differential fee. • Firm has submitted stability data for 100gm jar packing , wherein firm has applied for the 10gm sachet packing		
Decision: Deferred for rectification of following shortcomings:		

- Submission of Form 5-D along with differential fee.
- Submission of complete stability studies at both accelerated and long term conditions.
- Clarification of submitting stability data for jar packaging whereas firm has applied for sachet packaging.

Firm's response:

- Firm has submitted Form 5-D (Dy.# 16421 dated 02-09-2019) along with differential fee of Rs. 30,000/- vide deposit slip# 0833190 dated 02-09-2019.
- Firm has also submitted 3 month long term and accelerated stability data of three batches detailed as under:

Stability Study Data

Drug	Kay Gone 10gm Sachet & 100gm Jar					
Name of Manufacturer	M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi					
Manufacturer of API	M/S Phaex Polymers Pvt. Ltd. Plot No. F10, M.I.D.C., Muraabad-421 40. Dist. Thane. Maharashtra. India.					
API Lot No.	SC25/01/M/18					
Description of Pack (Container closure system)	Sachet.					
Stability Storage Condition	**Accelerated:** 40°C ± 2°C / 75% ± 5%RH **Real Time:** 30°C ± 2°C / 65% ± 5%RH					
Time Period	**Accelerated:** 03 months **Real Time:** 03 months					
Frequency	**Accelerated:** 0, 1, 3, (Months) **Real Time:** 0,1,3 (Months)					
	Sachet	**Jar**	**Sachet**	**Jar**	**Sachet**	**Jar**
Batch No.	**19PD-2762-01-T**	**19PD-2784-01-T**	**19PD-2763-02-T**	**19PD-2784-01-T**	**19PD-2764-03-T**	**19PD-2786-03-T**
Batch Size	500 gm	1500gm	500 gm	1500 gm	500 gm	1500 gm
Manufacturing Date	06-2019		06-2019		06-2019	
Date of Initiation	07-2019		07-2019		07-2019	
No. of Batches	03					

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

Documents to Be Provided	Status
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (Certificate# NEW-WHO-GMP/CERT/KD/75578/2019/11/27124) valid upto 28-02-2022 issued by FDA Maharashtra India.
Protocols followed for conduction of stability study and details of tests.	**Yes**
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	**Yes**
Documents confirming import of API etc.	Copy of License to import Sodium Polystyrene Sulphonate attested by ADC (Karachi) dated 29-05-2019 has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	**Yes**
Commitment to continue real time stability study till assigned shelf life of the product.	**Yes**
Commitment to follow Drug Specification Rules, 1978.	**Yes**

Decision of 293rd meeting: Registration Board decided that case shall be referred to Costing & Pricing Division for fixation of MRP for applied formulation in Sachet & Jar packaging. However, registration application shall be again placed before Registration Board after submission of required stability data of 6 months by the manufacturer for decision.

Firm's response: Now the firm has submitted long term and accelerated stability data of three batches in both 10gm Sachet and 100gm jar packaging for 6th month time point

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Kay Gone (Sodium Polystyrene Sulfonate) 10gm Sachet and 100gm Jar by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.

Reference No: F.1-2/2020-PEC dated 22nd April, 2020
Investigation Date and Time: 04 June, 2020
Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Background:
Chairman Registration Board considered the applications of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi for registration of Kay Gone (Sodium Polystyrene Sulfonate) 10gm Sachet and Kay Gone (Sodium Polystyrene Sulfonate) 100gm Jar and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration. The panel was also advised to verify:

"*The firm has submitted long term and accelerated stability data of three batches in both 10g sachet and 100g jar packaging for 6th months"*

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Meritorious Professor & Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board)
2. Ms. Hira Bhutto, Assistant Director, DRAP, Karachi.
3. Mr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi

Details of Investigation:
Kay Gone (Sodium Polystyrene Sulfonate) 10gm Sachet and 100gm Jar

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of Sodium Polystyrene Sulfonate API including approval from DRAP?	The firm has imported Sodium Polystyrene Sulfonate 6Kg vide Invoice No. T/SODIUM POLY/20/19-20 dated April 30, 2019 from M/s Tricon Enterprises Pvt. Ltd. India manufactured by M/s Phaex Polymers Pvt. Ltd., India for the manufacturing of lab scale batches of Sodium Polystyrene Sulfonate 10gm Sachet and 100gm Jar. The firm has proper approval for the import of the API from DRAP, Karachi dated 29-05-2019.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through • Postal audit checklist • GMP Approval by competent authority
3.	Do you have documents confirming the import of Sodium Polystyrene Sulfonate, reference standard and impurity standards?	Firm has documents confirming the import of 06Kgs of Sodium Polystyrene Sulfonate API, from M/s Tricon Enterprises Pvt. Ltd. India.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API. Reference standard and impurity standards are not imported because only sodium content and potassium exchange capacity is required to analysed which has been performed by the firm as per pharmacopeia reference of API.
5.	Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate issued by the Food and Drugs Administration, Mumbai, Maharashtra State, India.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used USP method for testing the API and verified the same.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per USP method , however no degradation products are reported by USP as well as the manufacturer.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method. There is no impurity reported.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has consumed all and no remaining quantity of the API
11.	Have you used pharmaceutical grade excipients?	Since the product is ready to fill Therefore no excipients used in the formulation.
12.	Do you have documents confirming the import of the used excipients?	There is no excipient used in formulation of finished product.
13.	Do you have test reports and other records on the excipients used?	There is no excipient used in formulation of finished product.

14.	Do you have written and authorized protocols for the development of Sodium Polystyrene Sulfonate 10gm Sachet and 100gm Jar?	The firm has written and authorized protocols for the development of Sodium Polystyrene Sulfonate 10gm Sachet and 100gm Jar.
15.	Have you performed Drug-excipient compatibility studies?	There is no excipient used in formulation of finished product.
16.	Have you performed comparative dissolution studies?	Dissolution not applicable
17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, human resource and utilities.
18.	Do you have necessary equipment available in product development section for development of Sodium Polystyrene Sulfonate 10gm Sachet and 100gm Jar?	It is ready to fill material and filling and sealing machines are available in commercial facility. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product development section qualified?	All the equipments used in product development are qualified.
20.	Do you have proper maintenance / Calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration programme. Re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 05 pharmacists and 01 chemist in manufacturing section of product development section currently with suitable knowledge and training in product development. 03 QC Analysts are dedicated for new products testing.
22.	Have you manufactured three stability batches for the stability studies of Sodium Polystyrene Sulfonate 10gm Sachet and 100gm Jar as required?	The firm has manufactured three stability batches for the stability studies of: Sodium Polystyrene Sulfonate 10gm Sachet with Batch Numbers: 19PD-2762-01-T Mfg: 11th June, 2019 19PD-2763-02-T Mfg: 11th June, 2019 19PD-2764-03-T Mfg: 11th June, 2019 Sodium Polystyrene Sulfonate 100gm Jar with Batch Numbers: 19PD-2784-01-T Mfg: 25th June, 2019 19PD-2785-02-T Mfg: 25th June, 2019 19PD-2786-03-T Mfg: 25th June, 2019
23.	Do you have any criteria for fixing the batch size of stability batches?	Criteria for fixing batch size is based on quantities required as per testing frequencies DRAP guidelines
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. 6month stability studies on real time and 6 month accelerated stability study has been performed
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.

26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated method for testing of their finished product based upon USP method.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer studies is not applicable since the product is in pharmacopeia. (USP)
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Sodium Polystyrene Sulfonate and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment / instruments being used in the test and analysis of Sodium Polystyrene Sulfonate and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating supported by forced degradation.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit trail reports on Sodium Polystyrene Sulfonate testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches kept in stability chambers. Real time stability studies are ongoing
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Currently, 6 months studies accelerated and real time have been completed with satisfactory results.
34.	Do you have valid calibration status for the Equipment used in Sodium Polystyrene Sulfonate 10gm Sachet and 100gm Jar production and analysis?	The firm has valid calibration status for the equipment used in Sodium Polystyrene Sulfonate sachet and jar production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring.
36.	o related manufacturing area, equipment, rsonnel and utilities be rated as GMP ompliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.
37.	ny other query raised by PE&R Division: he firm has submitted long term and ccelerated stability data of three batches in oth 10g sachet and 100g jar packaging for 6th onths	The firm has manufactured in both packaging and data for both packaging was reviewed and found satisfactory by the panel.

	onclusions: On the basis of risk-based approach the genuineness / authenticity of stability data ubmitted by the firm for registration of Kay Gone (Sodium Polystyrene Sulfonate) 10gm Sachet nd 100gm Jar is verifiable to satisfactory level. The related manufacturing area, equipment, personnel and utilities are GMP compliant and ell suited for the manufacturing of Sodium Polystyrene Sulfonate 10gm Sachet and 100gm Jar.
	ecision: Registration Board decided to approve registration of "Kay Gone 10gm Sachet Sodium Polystyrene Sulfonate) by M/s PharmEvo Pvt. Ltd, A-29, North West Industrial one, Light Industrial Zone, Port Qasim, Karachi. Manufacturer will place first three ommercial batches of the products on long term stability studies throughout proposed shelf fe and on accelerated studies for six months as per Zone-IVA conditions.

275.	Name and address of manufacturer / Applicant	M/s PharmEvo (Private) Limited., Plot # A-29, North Western Industrial Zone, Port Qasim Authority, Karachi
	Brand Name +Dosage Form + Strength	VELIX 20mg TABLET
	Composition	Each film coated Tablet contains: Vortioxetine as hydrobromide……..20mg
	Diary No. Date of R& I & fee	4043, 20-04-2017, 50,000/-, 20-04-2017
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished Product Specification	Manufactuer's specifications
	Pack size & Demanded Price	10's, 20's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Trintellix 20mg Tablet of Takeda Pharms (USFDA approved)
	Me-too status	N/A
	GMP status	
	Remarks of Evaluator	

STABILITY STUDY DATA			
Drug	VELIX 20mg TABLET		
Name of Manufacturer	M/s PharmEvo (Private) Limited., Plot # A-29, North Western Industrial Zone, Port Qasim Authority, Karachi		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co. Ltd. China		
API Lot No.	3804-201807001		
Description of Pack (Container closure system)	Alu Alu Blister		
Stability Storage Condition	Accelerated: $40^{o}C \pm 2^{o}C/75\%\pm5\%$ RH Real Time: $30^{o}C \pm 2^{o}C/65\%\pm5\%$ RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Real Time: 0,1,3,6 (06months) Accelerated: 0,1,3,6 (06 months)		
Batch No.	19PD2566-03-T	19PD2567-04-T	19PD2568-05-T
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Jan-2019	Jan-2019	Jan-2019
Date of Initiation	09-03-2019	09-03-2019	09-03-2019
No. of Batches	03		
Date of Submission	23739 (13-11-2019)		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# 3804-201807001) from M/s Jiangsu Yongan Pharmaceutical Co. Ltd. China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued to M/s Jiangsu Yongan Pharmaceutical Co., Ltd, China by Jiangsu Food and Drug administration. Valid up to 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Vortioxetine HBr (900g) attested by ADC, DRAP, Karachi dated 24-09-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR [XIV]

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

276.	Name and address of manufacturer / Applicant	M/s PharmEvo (Private) Limited., Plot # A-29, North Western Industrial Zone, Port Qasim Authority, Karachi
	Brand Name +Dosage Form + Strength	VELIX 10mg TABLET
	Composition	Each film coated Tablet contains: Vortioxetine as hydrobromide……..10mg
	Diary No. Date of R& I & fee	4041, 20-04-2017, 50,000/-, 20-04-2017
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished Product Specification	Manufactuer's specifications
	Pack size & Demanded Price	10's, 20's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Trintellix 10mg Tablet of Takeda Pharms (USFDA approved)
	Me-too status	N/A
	GMP status	
	Remarks of Evaluator	

STABILITY STUDY DATA

Drug	VELIX 10mg TABLET
Name of Manufacturer	M/s PharmEvo (Private) Limited., Plot # A-29, North Western Industrial Zone, Port Qasim Authority, Karachi
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co. Ltd. China
API Lot No.	3804-201807001
Description of Pack (Container closure system)	Alu Alu Blister

Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 06 (months) Real Time: 06 (months)		
Frequency	Real Time: 0,1,3,6 (06months) Accelerated: 0,1,3,6 (06 months)		
Batch No.	19PD2576-01-T	19PD2577-02-T	19PD2578-03-T
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Jan-2019	Jan-2019	Jan-2019
Date of Initiation	22-02-2019	22-02-2019	22-02-2019
No. of Batches	03		
Date of Submission	23739 (13-11-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# 3804-201807001) from M/s Jiangsu Yongan Pharmaceutical Co. Ltd. China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued to M/s Jiangsu Yongan Pharmaceutical Co., Ltd, China by Jiangsu Food and Drug administration. Valid up to 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Vortioxetine HBr (900g) attested by ADC, DRAP, Karachi dated 24-09-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR [XIV]

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

1. Report on Investigation of Authenticity / Genuineness of data submitted for registration of Velix (Vortioxetine) 10mg and 20mg Tablets by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.

Reference No: F.1-2/2020-PEC dated 24th February, 2020
Investigation Date and Time: 04 June, 2020.
Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Background:

Chairman Registration Board considered the applications of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi for registration of Velix (Vortioxetine) 10mg and Velix (Vortioxetine) 20mg Tablets and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration. The panel was also advised to verify:

"The polymorphic form of vortioxetine hydrobromide"

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Meritorious Professor & Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board)
2. Ms, Hira Bhutto Assistant Director, DRAP, Karachi.
3. Mr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Details of Investigation:
Velix (Vortioxetine) Tablets 10mg & 20mg

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of Vortioxetine API including approval from DRAP?	The firm has imported Vortioxetine 900G vide Invoice No. ZY18083101G/W dated August 31, 2018 from M/s Suzhou ZhiYu Biotechnology Co., Ltd. manufactured by M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China for the manufacturing of lab scale batches of Vortioxetine as Hbr10mg and 20mg Tablets. The firm has also manufactured stability batches for Vortioxetine Hbr 5mg and Vortioxetine Hbr 15mg. Remaining quantity of API in-Hand is 297.876gm. The firm has proper approval for the import of the API from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular source of API is the laid down criteria of the firm according to check list and SOP Evaluation procedure include the GMP status of the firm, DMF source and capability to provide API reference standard and impurity standard.
3.	Do you have documents confirming the import of Vortioxetine, reference standard and impurity standards?	Firm has documents including invoice airway bill confirming the import of Vortioxetine, The APIs working standard was imported at the time of import of the APIs and manufacturer has also provided declaration stating that no known impurities are present/detected.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API and Working standards of the API. No Known impurity identified so no impurity standard provided
5.	Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate issued by the Huaian Market supervision Administration, China.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method for testing the API. Test Method ACTM 1108

Q. No.	Question	Observation by panel
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and however no degradation products are reported by the manufacturer.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the unknown impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has 297.876gm quantities of the API only and working standard is consumed.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients and includes: **Velix 10mg Tablet:** Microcrystalline cellulose PH.101, Mannitol, Hydroxypropyl Cellulose (Klucel LF), Sodium starch glycolate, Magnesium stearate and colorcoat FC4WE and iron oxide red has been used for coating. **Velix 20mg Tablet:** Microcrystalline cellulose PH.101, Mannitol, Hydroxypropyl Cellulose (Klucel LF), Sodium starch glycolate, Magnesium stearate and colorcoat FC4WE and iron oxide red has been used for coating.
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Vortioxetine 10mg and 20mg Tablets?	The firm has written and authorized protocols for the development of Vortioxetine 10mg and 20mg Tablets.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug-excipient Compatibility studies as the composition of their tablets is similar to that of the innovator product (Brintellix Tablets 10mg and 20mg manufactured by M/s H. Lundabeck A/S).
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution profile of Velix 10mg and 20mg Tablet with Brintellix Tablets 10mg and 20mg manufactured by M/s H. Lundabeck A/S Denmark respectively. Similarity factor for Vortioxetine 10mg Tablet are as follows: 1. Buffer pH 1.2 (Drug releases more than 85% in 15minutes so no need to calculate F2). 2. Acetate Buffer (Drug releases more than 85% in 15minutes so no need to calculate F2). 3. Phosphate Buffer (55.258). Similarity factor for Vortioxetine 20mg Tablet are as follows: 1. Buffer pH 1.2 (Drug releases more than 85% in 15minutes so no need to calculate F2). 2. Acetate Buffer (Drug releases more than 85% in 15minutes so no need to calculate F2). 3. Phosphate Buffer (52.879).

Q. No.	Question	Observation by panel
17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, 6 pharmacist and 1 chemist in R&D formulation Laboratory section and two analyst dedicated for R&D testing in QC lab.
18.	Do you have necessary equipment available in product development section for development of Vortioxetine 10mg & 20mg Tablets?	The firm has all necessary equipment related to manufacturing available in R&D section for manufacturing of Vortioxetine 10mg and 20 mg Tablets. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product development section qualified?	All the equipment used in product development are qualified. Equipment qualification report not available
20.	Do you have proper maintenance / Calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration programme. Re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 05 pharmacists and 01 chemist in manufacturing section of product development section currently with suitable knowledge and training in product development. 02 QC Analysts are dedicated for new products testing.
22.	Have you manufactured three stability batches for the stability studies of Vortioxetine 10mg and 20mg Tablets as required?	The firm has manufactured three stability batches for the stability studies of: Vortioxetine 10mg Tablets with Batch Numbers: 19PD-2576-01-T, 19PD-2577-02-T 19PD-2578-03-T Vortioxetine 20mg Tablets with Batch Numbers: 19PD-2566-03-T, 19PD-2567-04-T 19PD-2568-05-T
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing batch size of stability batches is the number of tablets per testing frequencies.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches of Vortioxetine 10mg and 20 mg Tablets
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation.

Q. No.	Question	Observation by panel
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer studies have not been done, however, validation of the method has been performed.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Vortioxetine and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment / instruments being used in the test and analysis of Vortioxetine and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating as supported by forced degradation.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit trail reports on Vortioxetine testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches kept in stability chambers.
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Currently, 12 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the Equipment used in Vortioxetine 10mg & 20mg tablets production and analysis?	The firm has valid calibration status for the equipment used in Vortioxetine tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. Adequate monitoring and control are available for stability chamber. All the chambers are provided with continuous power supply and data loggers for continuous monitoring.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.

Q. No.	Question	Observation by panel
37.	Any other query raised by PE&R division: To verify the polymorphic form of Vortioxetine hydrobromide.	As per data available, the firm has used β- form of Vortioxetine hydrobromide.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Velix (Vortioxetine) 10mg and 20mg Tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Vortioxetine 10mg and 20mg Tablets.

Recommendations:

1. The firm may kindly be granted necessary registration of Vortioxetine 10mg and 20mg Tablets.

Decision: Registration Board decided to approve registrations of "Velix (Vortioxetine) 10mg and 20mg Tablets by M/s PharmEvo Pvt. Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi. Manufacturer will place first three commercial batches of the products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
277.	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	TREOW 50mg Tablet Each Film coated tablet contains : Trelagliptin as succinate……..50mg Anti-Diabetic Manufacturer's specs	Form-5D Duplicate 50,000/- dated 28-03-2016 As per PRC	Zafatek by Takeda (PMDA approved) GMP inspection dated 23-02-2018 showed that the firm was considered to be operating at an acceptable level of compliance with GMP standards.

STABILITY STUDY DATA	
Drug	TREOW 50mg Tablet
Name of Manufacturer	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.
Manufacturer of API	M/s Ruyuan HEC Co. Ltd., China.
API Lot No.	TGLT-201803101
Description of Pack (Container closure system)	Alu Alu Foil printed in unit Carton
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C/ 75% ± 5% RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated : 0, 3,6 (months) Real Time: 0,3,6 (Months)

Batch No.	18PD-2413-02-T	18PD-2414-03-T	18PD-2415-04-T
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09-2018	09-2018	09-2018
Date of Initiation	12-10-2018	12-10-2018	12-10-2018
No. of Batches	03		
Date of Submission	8768 (18/06/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA of Trelagliptin succinate (Batch # TGLT-201803101) from M/s Ruyuan HEC Pharm Co., Ltd China is submitted.
2. 0	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Ruyuan HEC Pharm Co., Ltd China issued by Shaouguan Food and Drug Administration. The certificate is valid for 04-12-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Trelagliptin succinate (0.9 Kg) attested by ADC DRAP, Karachi dated 09-05-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR [XIV]

The firm has submitted 6 months accelerated and 6 months real time stability data of three batches.

Observations	Response of the applicant
Reference product is film coated tablet while label claim on Form-5D is uncoated tablet. Revision of formulation as per reference product is required.	Submitted.
Clarification is required regarding rationale behind selection of dissolution parameters such as dissolution medium (i.e., 0.01 N HCL) since the solubility of trelagliptin is 1mg/ml in PBS pH 7.2.	The firm has referred to a patent of trelagliptin for selection of dissolution medium which is as below: Dissolution media: 0.01 N HCl in 900ml.
Justify the dissolution limit NLT 75% without mentioning time since FDA defines value of Q from 75% to 80%.	The firm has submitted we have have set the dissolution specifications NLT 75% (Q) as per USFDA and USP general chapter (1092), and for dissolution medium and release time specifications we have followed the patent of Trelagliptin. Previously submitted specifications data show dissolution specifications NLT 75% without

	mentioning Q.
Valid GMP certificate from relevant authority is required since it is expired on 31-05-2019.	Submitted.
Decision:	

2. Report on Investigation of Authenticity / Genuineness of data submitted for registration of Treow (Trelagliptin) 50mg Tablets by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 26th December, 2019.
Investigation Date and Time: 04 June, 2020
Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Meritorious Professor & Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board)
2. Ms. Sanam Kausar, Assistant Director, CDL, DRAP, Karachi.
3. Mr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Details of Investigation:
Treow (Trelagliptin) Tablets 50mg

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of Trelagliptin API including approval from DRAP?	The firm has imported Trelagliptin 0.9Kg vide Invoice No. WIS180045 dated 13/04/2018 from M/s WIS Pharmtech Co. Ltd. manufactured by M/s Ruyuan HEC Pharm Co. Ltd. for the manufacturing of lab scale batches of Trelagliptin 50mg Tablets. The firm has proper approval for the import of the API from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular source of API is the laid down criteria of the firm in their Vendor Evaluation procedure which include the GMP status of the firm, DMF source and capability to provide API reference standard and impurity standard.
3.	Do you have documents confirming the import of Trelagliptin, reference standard and impurity standards?	Firm has documents confirming the import of Trelagliptin, The APIs working standard was imported at the time of import of the APIs whereas the manufacturer has provided the both impurity standards later free of cost.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, Working standards of the API and impurities standards.
5.	Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate issued by the Shaoguan Food and Drug Administration, China
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method for testing the API.

Q. No.	Question	Observation by panel
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and however no degradation products are reported by the manufacturer. However process related impurities have been quantified during stability studies.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has 381.25g of API and some quantity of working standard, however they have consumed all the impurity standards.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients and include microcrystalline cellulose PH.101, Mannitol, Hydroxypropyl Cellulose (Klucel LF), Cross Carmellose Sodium, Sodium Stearyl Fumarate and Opadry white II 85G68918, iron oxide yellow and iron oxide red has been used for coating.
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Trelagliptin 50mg Tablets?	The firm has written and authorized protocols for the development of Trelagliptin 50mg Tablets.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug-excipient compatibility studies as the composition of their tablets is similar to that of the innovator product (Zafatek Tablets).
16.	Have you performed comparative dissolution studies?	The firm has not performed comparative dissolution profile because they are unable to get pack from Japan without Japanese prescription which is only available in Japan, however the data available with the firm shows that the product is highly soluble and dissolves more than 85% within 15minutes in all three media. Therefore, f2 calculation are not required.
17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, human resource and utilities.

Q. No.	Question	Observation by panel
18.	Do you have necessary equipment available in product development section for development of Trelagliptin 50mg Tablets?	The firm has all necessary equipment related to manufacturing available in R&D section for manufacturing of Trelagliptin 50mg Tablets. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product development section qualified?	All the equipment used in product development are qualified.
20.	Do you have proper maintenance / Calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration programme. Re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 05 pharmacists and 01 chemist in manufacturing section of product development section currently with suitable knowledge and training in product development. 03 QC Analysts are dedicated for new products testing.
22.	Have you manufactured three stability batches for the stability studies of Trelagliptin 50 mg Tablets as required?	The firm has manufactured three stability batches for the stability studies of: Trelagliptin 50mg Tablets with Batch Numbers: 18PD-2413-02-T, 18PD-2414-03-T & 18PD-2415-04-T
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing batch size is according to DRAP guidelines
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer studies have not been done, however, validation of the method has been performed.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Trelagliptin and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment / instruments being used in the test and analysis of Trelagliptin and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating as supported by forced degradation.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit trail reports on Trelagliptin testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches kept in stability chambers.

Q. No.	Question	Observation by panel
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Currently, 12 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the Equipment used in Trelagliptin 50mg Tablets production and analysis?	The firm has valid calibration status for the equipment used in Trelagliptin tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 16 stability chambers, 02 for accelerated and 14 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Treow (Trelagliptin) 50mg Tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Trelagliptin 50mg Tablets.

Recommendations:

1. The firm may kindly be granted necessary registration of Trelagliptin 50mg Tablets.

Decision: Registration Board decided to approve registrations of "Treow (Trelagliptin) 50mg Tablets by M/s PharmEvo Pvt. Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi. Manufacturer will place first three commercial batches of the products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

Case taken from 283rd RB meeting

Human Right Case No. 32007-P of 2018 (Application by Dr. Salman Kazmi)

An application was presented before the Hon'ble Chief Justice of Pakistan in Court at Lahore on 18.6.2018. The court has passed following orders:

"Comments/Report be called from Drug Regulatory Authority."

The Court Associate has directed DRAP vide letter dated 19.06.2018 to comply with the above direction and submit comments/Reports within 15 days.

The application submitted by Dr. Salman Kazmi, General Secretary, YDA Pakistan in the Hon'ble Supreme Court of Pakistan requesting to direct DRAP to register following list of Drugs which are not easily available in Pakistan because of being unregistered in Pakistan and are being sold in black. The list contains **41 drugs** (molecules/brands). Out of these, **25 drugs** (formulations/ alternate brands) are registered with DRAP (including 2 repeated drugs i.e. Penicillamine and phenobarbitone). While, **16 drugs** (formulations)

are not registered in Pakistan (midodrine repeated twice). The status of registered drugs is given in the 1st table while current status of pending / under process applications as per available record is presented in 2nd table presented in 283rd registration board meeting.

The below mentioned molecule is also present in the 16 drugs (formulation): Accordingly as per the direction of Registration Board in 283rd meeting, following pending application alongwith stability data was evaluated and presented before the Board.

Sr. No.	Name &Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary& Date, Fee (including differential fee), Demanded Price/ Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Remarks (IV)
4.	Highnoon Laboratories Limited, 17.5km multan road Lahore.	Pirfenox 200 mg tablets Each Film Coated Tablet contains: Pirfenidone ….. 200 mg Antifibrotic/Antiinflammatory Idiopathic Pulmonary Fibrosis	Form 5D Dy. No. 11045-04/09/2018 Rs. 50000/- 4/07/2018 Pack Size 10's, 20s & 30s tablets Price /- per pack	Glaspia 200 mg (PMDA Japan) Last inspection report Dated **01/01/2019** is attached which confirms the good level of GMP compliance.	

Drug	Pirfenox 200 mg film coated tablets		
Name of Manufacturer	**Highnoon Pharmaceuticals,** 17.5km multan road Lahore.		
Manufacturer of API	**(Pirfenidone) ZCL Chemicals**		
API Lot No.	**FEN 3300118**		
Description of Pack (Container closure system)	Alu – Alu blister		
Stability Storage Condition	**Real Time:** 30'C ± 2'C / 65% ± 5%RH **Accelerated:**40'C ±2'C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months **Accelerated:** 6 Months		
Frequency	**Real Time:**0,3,6, (Months) **Accelerated:** 0,3 6(Months)		
Manufacturing date	10/19	10/19	10/19
Date of Initiation	11/19	11/19	11/19
Batch Nos.	**RD 19080**	**RD 19081**	**RD 19082**
Batch Size	3500 tablets	3500 tablets	3500 tablets
No. of Batches	03 batches		
Stability & exemption application is received on 12-5-2020. DY no 1583 (PEC Drap)			
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

Sr. No.	Documents To Be Provided	Status

1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Yes
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Yes
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

DATA FOR EXEMPTION FROM ON-SITE INVESTIGATION OF SUBMITTED STABILITY DATA
PIRFENOX (PIRFENIDONE) 200 MG TABLET
AS PER 293RD DRB CHECKLIST

01	Reference of previous approval of applications with stability study of the firm	Onsite inspection conducted on 1st january, 2019 for following products • Daplozmet 5/850mg, 5/1000mg which was presented in 288th meeting of Registration board. According to the report following important points were confirmed 1. HPLC is 21 CFR compliant 2. Audit trails of the test reports were available. 3. Related manufacturing area equipment's personals and utilities were found GMP compliant.
02	Certificate of analysis of API from both API manufacturer and finished product manufacturer	• **API manufacturer:** Photocopy of COA of Batch No. FEN 3300118 issued by M/s ZCL chemical limited, Ankleshwar, Gujarat, India is submitted. • **Finished product manufacturer:** Photocopy of COA of Batch No. 19RM0342 issued by M/s Highnoon Laboratories ltd, Pakistan is submitted.
03	Method used for analysis of API from both API manufacturer and finished product manufacturer	Firm has provided the method used for analysis of API from both API manufacturer and Finished product manufacturer.
04	Stability study data of API manufacturer	**Pirfenidone:** The firm has submitted copy of **Accelerated 06 Months** (40°C ± 2°C & 75±5%RH) and **Long Term 24 Months** (30°C ± 2°C & 75±5%RH) stability study reports of 03 batches of Pirfenidone from ZCL chemicals limited.
05	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Pirfenidone:** copy of GMP Certificate issued on 13 August, 2018 by Food & Drug Control Administration, Government of Gujrat, India. **Valid up to: 12th August, 2021.**
06	Documents for the procurement of API with approval from DRAP (in case of import)	**Pirfenidone:** The firm has submitted photocopies of ADC (Lahore) attested, dated 03-05-2019, Commercial Invoice for 5Kg via Invoice # 2219007

<table>
<tr><td></td><td></td><td colspan="4">dated: 17-04-2019 batch no. FEN3300118 from M/s. ZCL chemicals, vide proper approval from DRAP Office, Lahore.</td></tr>
<tr><td>07</td><td>Protocols followed for conduction of stability study</td><td colspan="4">The firm has submitted copy of generalized SOP with the title “PRODUCT STABILTY PROTOCOL”.</td></tr>
<tr><td>08</td><td>Methods used for analysis of FPP</td><td colspan="4">Firm has provided method used for analysis of FPP.
SFPS No. QD8-QA-FPS-P1201
Dissolution criteria: NLT 80% = Q in 30minutes.</td></tr>
<tr><td>09</td><td>Drug-excipients compatibility studies (where applicable)</td><td colspan="4">The firm has submitted Drug-excipients compatibility studies</td></tr>
<tr><td>10</td><td>Complete batch manufacturing record of three stability batches</td><td colspan="4">Firm has provided the complete batch manufacturing record of three stability batches</td></tr>
<tr><td></td><td></td><td colspan="4">PIRFENIDONE 200 MG TABLET</td></tr>
<tr><td></td><td></td><td>BATCH NO.</td><td>BACH SIZE</td><td>MFG. STARTED</td><td>DATE OF PLACEMENT</td></tr>
<tr><td></td><td></td><td>RD19180</td><td>3500</td><td>Oct,2019</td><td>07-11-2019</td></tr>
<tr><td></td><td></td><td>RD19181</td><td>3500</td><td>Oct,2019</td><td>07-11-2019</td></tr>
<tr><td></td><td></td><td>RD19182</td><td>3500</td><td>Oct,2019</td><td>07-11-2019</td></tr>
<tr><td>11</td><td>Record of comparative dissolution data (where applicable)</td><td colspan="4">Firm has submitted comparative dissolution profile with the reference product Pirfenex (Pirfenidone) 200 mg Tablet, by Cipla limited.</td></tr>
<tr><td>12</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.</td><td colspan="4">Firm has provided complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 06 months Real Time Stability Data.</td></tr>
<tr><td>13</td><td>Compliance record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="4">Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.</td></tr>
<tr><td>14</td><td>Record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td colspan="4">Firm has submitted record of digital data logger for temperature and humidity monitoring control for the complete stability period.</td></tr>
<tr><td colspan="6">Decision: Registration Board decided to approve registrations of “Pirfenox 200 mg Tablets by M/s Highnoon Pharmaceuticals, 17.5km multan road Lahore. Manufacturer will place first three commercial batches of the products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.</td></tr>
</table>

Registration applications on CTD Format:

278.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s AGP (Pvt.) Limited, B-23-C, S.I.T.E., Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2096: 17-01-2019
	Details of fee submitted	PKR 20,000/-: 17-01-2019

	The proposed proprietary name / brand name	**Daplazole 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole 22.5% dual delayed release pellets ……. 266.6mg equivalent to 60mg Dexlansoprazole
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Reference to Finished product specifications	AGP specification
	Proposed Pack size	3 x 10's Capsules
	Proposed unit price	Rs. 16/capsule; Rs. 480 /- for 30's
	The status in reference regulatory authorities	Dexilant capsule (oral) approved by USFDA
	For generic drugs (me-too status)	Razodex Capsule by M/s Getz Pharma. (Reg.#086976)
	Name and address of API manufacturer.	M/s Vision Pharma, Islamabad, Pakistan
	Module-II (Quality Overall Summary)	--
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions
279.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s AGP Limited, B-23-C, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s AGP (Pvt.) Limited, B-23-C, S.I.T.E., Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2095: 17-01-2019
	Details of fee submitted	PKR 20,000/-: 17-01-2019
	The proposed proprietary name / brand name	**Daplazole 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole 17% dual delayed release pellets ……. 176.5mg equivalent to 30mg Dexlansoprazole
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor

	Reference to Finished product specifications	AGP specification
	Proposed Pack size	3 x 10's Capsules
	Proposed unit price	Rs. 16/capsule; Rs. 480 /- for 30's
	The status in reference regulatory authorities	Dexilant capsule (oral) 30mg
	For generic drugs (me-too status)	Razodex 30mg Capsule by M/s Getz Pharma.
	Name and address of API manufacturer.	M/s Vision Pharma, Islamabad, Pakistan
	Module-II (Quality Overall Summary)	--
	Module-III Drug Substance:	--
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Daplazole 30mg and 60mg (Dexlansoprazole) Capsules by M/s. AGP Limited, B-23-C, S.I.T.E, Karachi.

Reference No: F.1-2/2020-PEC dated 18th February, 2020.
Investigation Date and Time: 19-03-2020 (Morning).
Investigation Site: Factory premises of M/S. AGP Limited, B-23-C, S.I.T.E, Karachi.
Composition of Panel:

1. Mr. Syed Adnan Rizvi, Director, Drug Testing Laboratory, Government of Sindh, Karachi.
2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
3. Dr. Mahrukh Mughal, Assistant Director, DRAP, Karachi

Details of Investigation:

Q. NO.	QUESTION	OBSERVATION BY PANEL
1.	Do you have documents confirming the import of API including approval from DRAP?	The firm has locally procured 2.0 Kg Dexlansoprazole (17% pellets) & 3.0 Kg(22.5% pellets) from M/s Vision Pharmaceuticals Pvt Limited Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad for the manufacturing of stability batches of Daplazole 30mg & 60mg Capsules.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm has selected the vendor on the basis of authorization for manufacturing of Dexlansoprazole pellets and GMP certificate issued by DRAP

<table>
<tr><td>3.</td><td>Do you have documents confirming the import of reference standard and impurity standards?</td><td>Working Standard & Impurity Standard was provided by M/s Vision Pharmaceuticals Pvt Limited Islamabad.
Details of API working standards:<table><tr><th>Batch No:</th><th>Quantity</th></tr><tr><td>DLP/1706013</td><td>5gm</td></tr><tr><td>RLP0330718</td><td>1gm</td></tr></table>Details of impurity standards:<table><tr><th>Batch No:</th><th>Quantity</th></tr><tr><td>LCZ-1/0090518</td><td>10mg</td></tr><tr><td>LPS/0010419</td><td>10mg</td></tr></table></td></tr>
<tr><td>4.</td><td>Do you have certificate of analysis of API, reference standards and impurity standards?</td><td>The firm has certificate of analysis for Dexlansoprazole Pellets, Dexlansoprazole working standard and impurity standards.</td></tr>
<tr><td>5.</td><td>Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?</td><td>The firm has provided the copy of GMP certificate issued by DRAP vide letter No. F.3-26/2019-Addl.Dir(QA & LT-I)dated July-2019</td></tr>
<tr><td>6.</td><td>Do you use APIs manufacturer method of the testing?</td><td>The firm has used API Manufacturer’s method of testing but initially FDA dissolution method applied only for 17% pellets.</td></tr>
<tr><td>7.</td><td>Do you have stability studies report on APIs?</td><td>The firm has stability studies report of API (Both Strengths) Dexlansoprazole conducted by API manufacturer.</td></tr>
<tr><td>8.</td><td>If yes, whether the stability testing has been performed as per SIM and degradation products have been quantified?</td><td>The manufacturer of API has performed the stability studies of API as per SIM Method and the Related Substance/ impurities have been quantified.</td></tr>
<tr><td>9.</td><td>Do you have methods for quantifying the impurities in API?</td><td>The API manufacturer has developed methods for quantifying the impurities in API. The method is available with AGP also.</td></tr>
<tr><td>10.</td><td>Do you have some remaining quantities of API, the reference standards and impurities?</td><td>The firm has remaining quantity of API i.e 674.55g of 17% Dexlansoprazole pellets, 990.05gm of 22.5% Dexlansoprazole pellets, Some quantity of Dexlansoprazole working standard whereas impurity standard has been consumed.</td></tr>
<tr><td>11.</td><td>Have you used pharmaceutical grade excipients?</td><td>Firm has used empty HGC Shell size no 3 for 30mg and empty HGC Shell size no 2 for 60mg Capsules.</td></tr>
<tr><td>12.</td><td>Do you have documents confirming the import of used excipients?</td><td>Empty HGC Shell were locally procured from M/s Gelcaps Pakistan Limited</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has test reports on empty HGC shell sizes no. 3 and 2.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of products?</td><td>The firm has protocol for the development of Daplazole Capsules 30mg/60mg.</td></tr>
<tr><td>15.</td><td>Have you performed drug-excipient compatibility studies?</td><td>The API manufacturer has performed specificity by placebo method in AMV.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>Firm has performed comparative dissolution studies against dexilant 30mg and 60mg capsules with comparable results.</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section?</td><td>The firm has dedicated product development (R& D) section for manufacturing and analysis of the product.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of product?</td><td>The firm has necessary equipment available for development of Daplazole Capsules 30mg/60mg</td></tr>
</table>

<table>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The available equipment used in product development and analysis of trial batches are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance/ calibration/ requalification program for the equipment used in P&D section?</td><td>There is proper maintenance / calibration program for the equipment used in product development Department.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has proper qualified staff for Product Development including 03 Pharmacists and 02 Chemists with 02 operators.</td></tr>
<tr><td>22.</td><td>Have you manufactured stability batches for the stability studies of the product as required?</td><td>The firm has manufactured three stability batches each of 2500 Capsules of Daplazole 30mg and 60mg.
<table>
<tr><td colspan="3">Daplazole 30mg Capsule</td></tr>
<tr><td></td><td>Mfg: date</td><td>Exp: date</td></tr>
<tr><td>TR-273</td><td>Dec-2017</td><td>Dec-2019</td></tr>
<tr><td>TR-274</td><td>Dec-2017</td><td>Dec-2019</td></tr>
<tr><td>TR-275</td><td>Dec-2017</td><td>Dec-2019</td></tr>
<tr><td colspan="3">Daplazole 60mg Capsule</td></tr>
<tr><td></td><td>Mfg: date</td><td>Exp: date</td></tr>
<tr><td>TR-381</td><td>Mar-2018</td><td>Mar-2020</td></tr>
<tr><td>TR-382</td><td>Mar-2018</td><td>Mar-2020</td></tr>
<tr><td>TR-383</td><td>Mar-2018</td><td>Mar-2020</td></tr>
</table>
The capsules are packed Alu-Alu packs of 3 x 10s.</td></tr>
<tr><td>23.</td><td>Do you have criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches as per DRAP guidelines.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has detailed record of the stability batches of Daplazole Capsules 30mg & 60mg.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability products?</td><td>The firm has protocols for testing of stability batches</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated method of testing of finished product Daplazole Capsules 30mg & 60mg, based on method of testing of API.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing used by your firm is given by another firm?</td><td>Method transfer studies have been done in the form of fall validation.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipment/instruments being used in the test and analysis of API and the finished products?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the Daplazole Capsules 30mg & 60mg.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The method of testing is stability indicating as evidenced & supported by forced degradation studies.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21 CFR compliant?</td><td>The firm has HPLC software which is 21CFR Compliant.</td></tr>
<tr><td>31.</td><td>Can you show audit trail reports on product testing?</td><td>The firm has audit trail Reports on their testing.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm has some remaining quantities of stability batches only.</td></tr>
</table>

33.	Do you have stability batches kept on stability testing?	The firm has three stability batches kept on stability for Real time stability testing. 24 Months Real Time and 6 months Accelerated stability studies of Daplazole 30mg Capsule & 12 Months Real Time and 6 months Accelerated stability studies of Daplazole 60mg Capsule have been conducted & the results are satisfactory.
34.	Do you have valid calibration status for the equipment used in production and analysis?	The firm has valid calibration status for the equipment used in Daplazole Capsules 30mg & 60mg production and analysis
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has online monitoring software available for stability chambers.
36.	Do related manufacturing area, equipment, personnel, and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities can be rated as GMP compliant
37.	<u>Any observation/Quires of PEC.</u> i) Dissolution testing of pellets at pH 5.5 and pH 6.75/7 for confirmation of dual delayed ii) Physical appearance of the pellets for both strengths i.e., 30mg & 60mg.	**Daplazole 60mg Capsule:** The firm has performed dissolution of Daplazole 60mg Capsule at pH 5.5 and pH 7. **Daplazole 30mg Capsule:** Initially, the firm has performed dissolution of Daplazole 30mg Capsule at pH 7 (As per FDA). After DRAP recommendation, the firm has performed dissolution at both pH 5.5 and pH 7 from 9th month stability studies. The 24 months stability studies of Daplazole 30mg Capsule have been successfully completed in Dec-2019. **Daplazole 60mg Capsule:** Bicolored i.e. green and white to off-white pellets **Daplazole 30mg Capsule:** White to off-white pellets.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Daplazole 30mg and 60mg (Dexlansoprazole) Capsules is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Daplazole 30mg and 60mg (Dexlansoprazole) Capsules.

Recommendations:

1. The firm may kindly be granted necessary registration of Daplazole 30mg and 60mg (Dexlansoprazole) Capsules.

2. Since the product is dual release therefore post registration bio-equivalance studies are also recommended.

Note:- Copy of written commitment by the firm is attached herewith

Decision: Registration Board decided to approve registration of "Daplazole 30mg and 60mg (Dexlansoprazole) Capsules by M/s AGP Ltd. Karachi. Manufacturer will place first three commercial batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per Zone-IVA conditions.

14. Miscellaneous cases:

Case No. 01 Registration applications of remaining products of newly granted section (Human)

M/s Liven Pharmaceuticals, Lahore.

CLB in its 259th meeting held on 29th and 30th March 2018 has considered and approved the grant of DML by way of Formulation. 9 molecules / 17 products of the firm were considered by Registration Board in its 282nd meeting. Now the firm has applied for 1 molecule / 1 product

S No.	Section	No. of molecules Considered in 282nd Meeting of RB	Balance molecules	Freshly applied molecule
2.	Tablet (General) Section	09	01	01

Now the firm has requested for consideration of following applications on priority for registration. This application was submitted in DRAP on 07-03-2019.

Tablet (General) Section
1 Products / 1 Molecules

280.	Name and address of manufacture / Applicant	M/s Liven Pharmaceuticals (Pvt) Ltd. 49 KM, Multan Road Lahore.
	Brand Name + Dosage Form and Strength	CARDOVAS 500mg Tablet
	Composition	Each Tablet Contains: Citicoline (as sodium)…….500mg
	Dairy No. date of R &I fee	Dy. No. 16276: 07-03-2019, PKR 20,000/- : 05-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of form	Form-5
	Finished product specifications	Manufacturer specification
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too-status	Citolin 500mg tablet of M/s Global Pharma
	GMP Status	New License (issuance Date: 11th April,2018)
	Remark of the Evaluator III	• Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed.
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.	

B. Division of Biological Evaluation & Research

Sr. No.	Details of application	No. of Cases
A	Locally Manufactured Human Biologicals.	06
B	Miscellaneous/ Deferred cases	01
Total		07

Sr. No.	Assistant Director	Designated No.	No. of Cases
i.	Mr. Khurram Khalid	AD-I	03
i.	Mr. M. Zubair Masood	AD-III	04

A: Locally Manufactured Human Biologicals.

1. Tocilizumab Injection applied by M/s Sami Pharmaceuticals (Pvt) Limited, Karachi:

Registration Board was informed by DBER that they have informed by the firm that they have submitted an applications for local manufacturing of Tocilizumab in R&I section of DRAP. The Board advised DBER to bring up the applications in this meeting. Accordingly, following is the detail of the applications submitted by M/s Sami Pharmaceuticals (Pvt) Limited, Karachi:

1.	**Name & Address of Manufacturer**	**<u>Bulk Manufacturer:</u>** **No source and description of drug substance was provided by the applicant. (Explanation in Remarks of evaluator)** **<u>Local Manufacturer</u>** M/s Sami Pharmaceuticals (Pvt) Limited, F-95, Off Hub River Road, S.I.T.E, Karachi.
	Brand Name +Dosage Form + Strength	Tocab 80mg/4ml Injection
	Composition	Each 4ml vial contains: Tocilizumab…….80mg
	Finished product specifications	Innovator Specifications
	Pharmacological Group	Monoclonal Antibody
	Shelf life	2years (15^0C-20^0C)
	International availability	Actemra of M/s Roche.
	Alternate Products already registered in Pakistan	Actemra of M/s Roche Pakistan Limited, Karachi.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5 Dy. No. 12904 Dated: 08-06-2020 Rs. 20000/- Dated 05-06-2020
	Demanded Price/Pack size	1's Vial (4ml)/ Not Provided.
	General documentation	Copy of DML by way of formulation No. 000072.
	Remarks of Evaluator (M. Zubair Masood)	The firm submitted the application on Form-5 instead of CTD format Form 5F. The enclosure of the application indicates the application for export registration of drug. The firm has not clarified the process of manufacturing in its application. Moreover, the firm has not provided any technical documents and only submitted different commitments such as i. they will follow Innovator brand ii. they will conduct Pharmaceutical product development iii. they will comply Drug Specification Rules, 1978. iv. they will use container/ packaging material as per Innovator Brand. v. they will conduct accelerated stability studies till completion. vi. they will conduct real time stability studies till assigned shelf life. The firm was telephonically asked about the status of bulk, its source and their indication of export registration. In response, the firm replied that they are in negotiations with different sources and yet not finalized any one. Moreover, they will import bulk drug substance and repack it locally. Furthermore, the registration for export was inadvertently mentioned and the said application is for local sale.
Discussion: Tocilizumab is a monoclonal antibody for which so far there is no known Biosimilar manufacturer in the world, the firm has not submitted any specifications and source of drug substance and has admitted that they are still looking for a supplier. So the application could not be evaluated under section 7 of the Drug Act 1976 and rules		

28, 29 and 30 of the Drugs (Licensing. Registering and Advertising) Rules, 1976, and guidelines approved in 278th Registration Board meeting hence the DBER and some of the members of Registration Board asked the chair that these kind of applications either for Pharma or Biological Drugs including this application should be rejected instead to defer.

Decision: Registration Board deferred the case for submission of data by the firm in light of guidelines approved in 278th meeting of Registration Board.

2.	**Name & Address of Manufacturer**	**Bulk Manufacturer:** **No source and description of drug substance is provided. (Explanation in Remarks of evaluator)** **Local Manufacturer** M/s Sami Pharmaceuticals (Pvt) Limited, F-95, Off Hub River Road, S.I.T.E, Karachi.
	Brand Name +Dosage Form + Strength	Tocab 162mg/0.9ml Injection
	Composition	Each 0.9ml PFS contains: Tocilizumab…….162mg
	Finished product specifications	Innovator Specifications
	Pharmacological Group	Monoclonal Antibody
	Shelf life	2years (15^0C-20^0C)
	International availability	Actemra of M/s Roche.
	Alternate Products already registered in Pakistan	Actemra of M/s Roche Pakistan Limited, Karachi.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5 Dy. No. 12905 Dated: 08-06-2020 Rs. 20000/- Dated 05-06-2020
	Demanded Price / Pack size	1's PFS (0.9ml)/ Not Provided.
	General documentation	Copy of DML by way of formulation No. 000072.
	Remarks of Evaluator (M. Zubair Masood)	The firm submitted the application on Form-5 instead of CTD format Form 5F. The enclosure of the application indicates the application for export registration of drug. The firm has not clarified the process of manufacturing in its application. Moreover, the firm has not provided any technical documents and only submitted different commitments such as i. they will follow Innovator brand ii. they will conduct Pharmaceutical product development iii. they will comply Drug Specification Rules, 1978. iv. they will use container/ packaging material as per Innovator Brand. v. they will conduct accelerated stability studies till completion. vi. they will conduct real time stability studies till assigned shelf life. The firm was telephonically asked about the status of bulk, its source and their indication of export registration. In response, the firm replied that they are in negotiations with different sources and yet not finalized any one. Moreover, they will import bulk drug substance and repack it locally. Furthermore, the registration for export was inadvertently mentioned and the said application is for local sale.

Discussion:
Tocilizumab is a monoclonal antibody for which so far there is no known Biosimilar manufacturer in the world, the firm has not submitted any specifications and source of drug substance and has admitted that they are still looking for a supplier. So the application could not be evaluated under section 7 of the Drug Act 1976 and rules

28, 29 and 30 of the Drugs (Licensing. Registering and Advertising) Rules, 1976, and guidelines approved in 278th Registration Board meeting hence the DBER and some of the members of Registration Board asked the chair that these kind of applications either for Pharma or Biological Drugs including this application should be rejected instead to defer.

Decision: Registration Board deferred the case for submission of data by the firm in light of guidelines approved in 278th meeting of Registration Board.

3.	**Name & Address of Manufacturer**	**Bulk Manufacturer:** No source and description of drug substance is provided. (Explanation in Remarks of evaluator) **Local Manufacturer** M/s Sami Pharmaceuticals (Pvt) Limited, F-95, Off Hub River Road, S.I.T.E, Karachi.
	Brand Name +Dosage Form + Strength	Tocab 200mg/10ml Injection
	Composition	Each 10ml vial contains: Tocilizumab…….200mg
	Finished product specifications	Innovator Specifications
	Pharmacological Group	Monoclonal Antibody
	Shelf life	2years (15^0C-20^0C)
	International availability	Actemra of M/s Roche.
	Alternate Products already registered in Pakistan	Actemra of M/s Roche Pakistan Limited, Karachi.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5 Dy. No. 12906 Dated: 08-06-2020 Rs. 20000/- Dated 05-06-2020
	Demanded Price / Pack size	1's Vial (10ml)/ Not Provided.
	General documentation	Copy of DML by way of formulation No. 000072.
	Remarks of Evaluator (M. Zubair Masood)	The firm submitted the application on Form-5 instead of CTD format Form 5F. The enclosure of the application indicates the application for export registration of drug. The firm has not clarified the process of manufacturing in its application. Moreover, the firm has not provided any technical documents and only submitted different commitments such as i. they will follow Innovator brand ii. they will conduct Pharmaceutical product development iii. they will comply Drug Specification Rules, 1978. iv. they will use container/ packaging material as per Innovator Brand. v. they will conduct accelerated stability studies till completion. vi. they will conduct real time stability studies till assigned shelf life. The firm was telephonically asked about the status of bulk, its source and their indication of export registration. In response, the firm replied that they are in negotiations with different sources and yet not finalized any one. Moreover, they will import bulk drug substance and repack it locally. Furthermore, the registration for export was inadvertently mentioned and the said application is for local sale.

Discussion:

Tocilizumab is a monoclonal antibody for which so far there is no known Biosimilar manufacturer in the world, the firm has not submitted any specifications and source of drug substance and has admitted that they are still looking for a supplier. So the application could not be evaluated under section 7 of the Drug Act 1976 and rules 28, 29 and 30 of the Drugs (Licensing. Registering and Advertising) Rules, 1976, and guidelines approved in 278th Registration Board meeting hence the DBER and some of the members of Registration Board asked the

chair that these kind of applications either for Pharma or Biological Drugs including this application should be rejected instead to defer.		
Decision: Registration Board deferred the case for submission of data by the firm in light of guidelines approved in 278th meeting of Registration Board.		
4.	**Name & Address of Manufacturer**	**Bulk Manufacturer:** No source and description of drug substance is provided. (Explanation in Remarks of evaluator) **Local Manufacturer** M/s Sami Pharmaceuticals (Pvt) Limited, F-95, Off Hub River Road, S.I.T.E, Karachi.
	Brand Name +Dosage Form + Strength	Tocab 400mg/20ml Injection
	Composition	Each 20ml vial contains: Tocilizumab…….400mg
	Finished product specifications	Innovator Specifications
	Pharmacological Group	Monoclonal Antibody
	Shelf life	2years (15^0C-20^0C)
	International availability	Actemra of M/s Roche.
	Alternate Products already registered in Pakistan	Actemra of M/s Roche Pakistan Limited, Karachi.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5 Dy. No. 12907 Dated: 08-06-2020 Rs. 20000/- Dated 05-06-2020
	Demanded Price / Pack size	1's Vial (20ml)/ Not Provided.
	General documentation	Copy of DML by way of formulation No. 000072.
	Remarks of Evaluator (M. Zubair Masood)	The firm submitted the application on Form-5 instead of CTD format Form 5F. The enclosure of the application indicates the application for export registration of drug. The firm has not clarified the process of manufacturing in its application. Moreover, the firm has not provided any technical documents and only submitted different commitments such as i. they will follow Innovator brand ii. they will conduct Pharmaceutical product development iii. they will comply Drug Specification Rules, 1978. iv. they will use container/ packaging material as per Innovator Brand. v. they will conduct accelerated stability studies till completion. vi. they will conduct real time stability studies till assigned shelf life. The firm was telephonically asked about the status of bulk, its source and their indication of export registration. In response, the firm replied that they are in negotiations with different sources and yet not finalized any one. Moreover, they will import bulk drug substance and repack it locally. Furthermore, the registration for export was inadvertently mentioned and the said application is for local sale.
Discussion: Tocilizumab is a monoclonal antibody for which so far there is no known Biosimilar manufacturer in the world, the firm has not submitted any specifications and source of drug substance and has admitted that they are still looking for a supplier. So the application could not be evaluated under section 7 of the Drug Act 1976 and rules 28, 29 and 30 of the Drugs (Licensing. Registering and Advertising) Rules, 1976, and guidelines approved in 278th Registration Board meeting hence the DBER and some of the members of Registration Board asked the chair that these kind of applications either for Pharma or Biological Drugs including this application should be rejected instead to defer.		

Decision: Registration Board deferred the case for submission of data by the firm in light of guidelines approved in 278th meeting of Registration Board.

2. Etanercept applied by M/s BF Biosciences, Lahore:

5.	**Name of Manufacturer/ Applicant**	M/s BF Biosciences Ltd., 5km- Sunder Raiwind Road, Raiwind, Lahore Bulk Manufacturer (Product License Holder in CoPP): M/s GEMABIOTECH S.A.U Fray Justo Sarmiento 2350 – 5°PisoEdificio E2, Olivos, Partido de Vicente Lopez, Provincia de Buenos Aires, Argentina.
	Brand Name +Dosage Form + Strength	Eterna 25mg Injection
	Composition	Each ml contains: Each PFS contains Etanercept…. 25mg/0.5mL
	Finished product specifications	As per innovator
	Approval status in Reference countries	Enbrel
	Products already registered in Pakistan	Enbrel (M/s Pfizer)
	Shelf life	24 months
	Type of Form Dy No & Date of application, Fee submitted	Form-5 1379(R&I) 24-11-2016 Rs. 20000/- dated 23-11-2016
	Demanded Price/ Pack size	1's PFS/ As per SRO
	General documentation	DML No. 000655 dated 30-01-2019 GMP inspection report dated 24-12-2018
6.	**Name of Manufacturer/ Applicant**	M/s BF Biosciences Ltd., 5km- Sunder Raiwind Road, Raiwind, Lahore Bulk Manufacturer (Product License Holder in CoPP): M/s GEMABIOTECH S.A.U Fray Justo Sarmiento 2350 – 5°PisoEdificio E2, Olivos, Partido de Vicente Lopez, Provincia de Buenos Aires, Argentina.
	Brand Name +Dosage Form + Strength	Eterna 50mg Injection
	Composition	Each ml contains: Each PFS contains Etanercept…. 50mg/0.5mL
	Finished product specifications	As per innovator
	Approval status in Reference countries	Approved
	Products already registered in Pakistan	Enbrel (M/s Pfizer)
	Shelf life	24 months
	Type of Form Dy No & Date of application, Fee submitted	Form-5 1379(R&I) 24-11-2016 Rs. 20000/- dated 23-11-2016
	Demanded Price/ Pack size	1's PFS/ As per SRO
	General documentation	DML No. 000655 dated 30-01-2014

		GMP inspection report dated 22-02-2016
The firm has submitted the documents/data in the light of regulatory guideline for biological products approved in 278th meeting of Registration Board as per following details:		
Sr. No.	**Documents required as per 278th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)**	**Documents submitted by firm**
1.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP certificate No. 20132021-000 013-18 dated 19-04-2018 of M/s ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', Parque TecologicoLitoral , of the Province of Santa Fe, of the Argentine.
2.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	The firm has provided legalized copy of CoPP from ANMAT (National Administration of Drugs, Foods and Medical Devices) which is signed electronically.
3.	The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity.	Details are included below.
4.	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (Not applicable).
5.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Provided
6.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform analytical studies(Physicochemical and biological) including protein content, appearance, pH, Osmolarity, composition of key excipients including stabilizers (if formulation is same), visible/subvisible particles, identity testing to parent molecule, purity testing, in vitro biological activity, sterility, Pyrogen content, safety, potency and toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques). The firm shall submit the results for processing of registration application.	The firm has submitted stability study data and CoA wherein the tests conducted are as under; i. Appearance ii. Leak test iii. pH iv. Extractable volume v. Immuno characterization vi. Potency vii. Sterility viii. Bacterial endotoxins ix. Particulate matter. x. Sialic acid content xi. Protein concentration xii. Peptide mapping xiii. Identification (by SDS page) xiv. Isoforms content xv. Dimers and related proteins of higher molecular mass
7.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event,	Provided

	immediate mandatory reporting procedure shall be followed.	
8.	The manufacturer shall perform all tests locally as detailed on Certificate of analysis.	Provided.
9.	The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form in any country of the world (if available).	Not Provided.
10.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Provided.
11.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Provided.

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.

WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	**Physicochemical Characterization** i. Appearance and pH determination by visual method and potentiometric method. ii. Protein content by Spectroscopy. iii. Osmolarity by Osmometric vapor pressure. iv. Amino acid sequence by UPLC-ESI-MS/MS. v. Molecular Mass determination by MALDI-TOF MS. vi. Peptide mapping by RP-HPLC. vii. Analysis of Secondary & Tertiary structure by circular Dichroism (CD) and Intrinsic Fluorescence. viii. Structure Analysis by NMR. ix. Analysis of free monossacharides, Reversed Phase HPLC. x. Determination of High molecular weight and impurities by SEC-HPLC.
Biological Activity	Determination of Biological Activity by Quantification of the protection activity by inhibition of the cytotoxic effect of TNF-alfa.
Immunochemical properties	Immuno Identification by western blot.
Impurities	Impurities by SEC-HPLC.
Stability Studies	Long term stability data is provided while accelerated stability data is not provided.
Non-clinical Studies i. In-vitro Studies ii. In-vivo Studies	1. In vitro studies include determination of TNF-α binding through the quantification of the protection activity by inhibition of the cytotoxic effect of TNF-α. In addition, TNF-αbinding analysed by ELISA and Surface Plasmon Resonance (SPR). 2. In vitro secondary pharacodynamic comparability assays (ADCC, CDC, TNF-β binding and Fcγ receptors binding) performed and detailed in this module. Studies are performed in *Cebusapella* monkeys and Wistar rats (WKAH/Hok/LAE).
Clinical Studies	**Safety** Open randomized balanced Phase 1, actively – controlled, single dose, crossover study with two treatment periods. Thirty subjects treated with two products i.e. Enerceptan® Gemabiotech S.A. laboratory against Pfizer reference Enbrel® (15 each)

	Efficacy A phase III randomized evaluator blinded, Multicenter, Non-inferiority study to evaluate the comparative Efficacy, Safety and Immunogenicity of Enerceptan® (Gemabiotech) with Enbrel® (Pfizer) in combination with methothotrexate in the treatment of patients with rheumatoid arthritis. (138 patients)

Remarks of Evaluator (Khurram Khalid):

i. The firm has provided legalized copy of CoPP from ANMAT (National Administration of Drugs, Foods and Medical Devices) which is signed electronically. However, the same certificates received earlier used to be manually signed. For this the firm has clarified that the document issuance process has been Digitalized in Argentina since January 2019. The firm also referred to online website of ANMAT which shows that *"depapelization program"* has been launched.

ii. The CoPPsubmitted by the firm reflects that**GEMABIOTECH S.A.U Fray Justo Farmiento2350 – 5º PisoEdificio E2, Olivos, Partido de Vicente Lopez, Provincia de Buenos Aires, Argentina**is Product License Holder while **MR Pharma S.A., Etados Unidos 5105, Malvinas Argentinas, Provincia de Beunos Aires, Argentina** is Manufacturer of pharmaceutical form.It is pertinent to mention that GMP certificate submitted by the firm is by the manufacturer**ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', Parque TecologicoLitoral , of the Province of Santa Fe, of the Argentine.**
In order to establish the relationship between
    a. GEMABIOTECH S.A.U
    b. MR Pharma S.A
    c. ZELLTEK S.A

The firm has submitted following clarification letter by GEMABIOTECH S.A.U

- *Gemabiotech S.A.U. is a pharmaceutical company and the Marketing Authorization (MA) holder of certain finished dosage forms, registered and located in Argentina.*
- *Zeltek S.A. is an API manufacturing company also registered and located in Argentina that produces some of the APIs of Gemabiotech S.A.U. marketed pharmaceutical products.*
- *The manufacturing process of Gemabiotech S.A.U. finished products is outsourced to a contract manufacturing organization called MR Pharma S.A., which is a third party company registered and located in Argentina too.*
- *Gemabiotech S.A.U. performs the quality control and releases all the finished products to the market after a Quality Assurance final inspection.*
- *There exist a manufacturing contract between Gemabiotech S.A.U. and MR Pharma S.A., ruling the relationship between them and the responsibilities of each party.*
- *The three companies, Zeltek S.A., Gemabiotech S.A.U and MR Pharma S.A., are inspected and approved by A.N.M.A.T, the Argentina Drug Agency, regarding GMP normative compliance.*

Discussion: It was pointed out by the DBER that the firm representative was present in the committee that finalized the Biosimilar evaluation guidelines hence their data should be exemplary.

Decision: Registration Board deferred the case for submission of data of complete test results as mentioned above in section 6 of guidelines approved in 278th meeting of Registration Board and Board advised the DBER that the test not performed by the firm or not required should clearly be mentioned.

B: Miscellaneous/ Deferred Cases

1. Change in source of bulk of already approved human biological applied by M/s Amson Vaccines & Pharma Pvt. Ltd., Islamabad.

M/s Amson Vaccines & Pharma Pvt. Ltd Islamabad has applied for addition/change of source of already registered product as per following details;

Brand Name & Composition	Name of existing source	New applied source
Typbar Injection Each 0.5mL contains Purified Vi capsular Polysaccharides (Strains name	M/s Bharat Biotech, Hyderabad, India.	M/s CADILA HEALTHCARE LTD, PLOT SURVEY NO. 23, 25/P, 37, 40/P, 42 TO 47, SARKHEJ-BAVLA N.H.NO-8 A, OPP, RAMDEV

Salmonella Typhi Ty 2 B.P…...0.025mg		MASALA, VILLAGE CHANGODAR TAL: SANAND, DIST-AHMEDABAD-382 213

In the above context, the firm has submitted following documents;

i. Cover letter with fee of Rs. 1,00,000/-
ii. Registration letter and transfer of registration
iii. Last renewal which is within time.
iv. Complete stability study data from manufacturer
v. Certificate of analysis of manufacturer
vi. Legalized GMP and manufacturing license
vii. An Undertaking that:
   a. Shelf life of finished product would be assigned after conducting product development studies, real time and accelerated stability studies on 3 batches of commercial scale, validation of manufacturing process and method of analysis before sale of drug.
   b. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
   c. That the provided information is true & correct.

It is submitted that the firm was further asked to provide following documents detailed as under;

Documents Required	**Documents provided by the Firm**
Free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	The firm has submitted copy of free sale certificate. Moreover, the certificate mentions that the mentioned product is permitted to manufacture and market the product to be exported freely. Such type of similar product is available in country of origin subject to laws of land in question.
The firm shall provide clinical trial data of the product being manufactured from the same bulk.	Report of clinical trial of an open label, comparative study with Typherix in 79 individuals.
The manufacturer shall perform all tests locally as detailed on Certificate of analysis.	The firm has not provided CoA from the manufacturer and has submitted its own CoA.
Real time & Accelerated stability data of 06 months of finished product manufactured locally.	The firm has not submitted the data, instead submitted the undertaking.
The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	The firm has submitted real time & 6 month stability data of material taken from ready to fill bulk.
WHO PQ status of the finished product being manufactured from the same bulk.	The finished product from this bulk is not WHO PQ.

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

a. Valid legalized Free Sale Certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk.
b. Clarification regarding submitted copy of FSC indicating that product is permitted to be exported freely instead of indicating product availability in country of origin.
c. Certificate of analysis of finished product manufactured from the same bulk by bulk manufacturer.
d. Real time & Accelerated stability data of 06 months of finished product manufactured locally.

C. Division of Quality Assurance & Laboratory Testing

CASE NO.1: REQUEST OF M/s NOVARTIS PHARMA (PAKISTAN) LTD, FOR EXEMPTION OF NDMA TESTING IN VALSARTAN CONTAINING PRODUCTS.

The firm has requested exemption for testing of carcinogenic impurities i.e. NDMA and NDEA in Valsartan containing products because API's manufacturers are testing the said impurities before release. The request of M/s. Novartis Pharma to grant exemption of testing of their imported batches which would have created issue of availability of their product in the market was taken up in 294th Registration Board meeting the proceedings and decision of which is reproduced as under;

"Proceeding of 294th Meeting:

The Board deliberated on the matter in detail. At the time when Registration Board decided to make NDMA and NDEA testing compulsory for every consignment of valsartan before utilization, there was no arrangement of worldwide testing of said impurities before in their country of origin. The Board further deliberated that as M/s Novartis Pharma Pakistan has provided CoA of API confirming testing of NDMA and NDEA and results are within acceptable limits. The Board also considered M/s Novartis statement apprehending delay of the access of medicine to the patients due to current scenario due to none or delayed local testing.

Mr.Tipu Sultan Akram Representative of PPMA also informed that after emergence of NDMA and NDEA impurities issues, now other API manufacturers have also started testing NDMA and NDEA in APIs.

Decision of 294th Meeting:

After thorough deliberations and discussion by the Board and considering documents submitted by M/s Novartis Pharma Pakistan, the Board decided as under;

i. The imported finished products of above products containing Valsartan of M/s Novartis (Pakistan) Limited shall be allowed for utilization.

ii. A comprehensive proposal will be presented in forthcoming meeting regarding future strategy for testing of NDMA and NDEA in valsartan containing products and API".

In light of decision of the Board and request of M/s. Novartis Pharma the following agenda is being placed before the Registration Board for consideration.

Background of the case:-

Valsartan is an orally active antihypertensive drug developed in the 1990s and is a selective angiotensin II receptor blocker (ARB)

It relaxes the blood vessels and thus reduces blood pressure; it is also used for treating patients with congestive heart failure and post myocardial infarction.

N-nitrosodimethylamine (NDMA) AS SAFETY ISSUE IN VALSERTAN

1. On 5 July 2018 the European Medicines Agency (EMA) reviewed medicines containing valsartan following detection of an impurity, N-nitrosodimethylamine (NDMA), **a probable human carcinogen**, in medicines from Zhejiang Huahai Pharmaceutical Co Ltd, Linhai, China. Since the batches manufactured from this valsartan-active substance have been administered to many patients, the EMA's review focused on investigating the levels of NDMA in the products and the potential impact on patients who have been taking them. The agency further issued advisory notices on their website for patients not to stop taking their medicine.

2. The US Environmental Protection Agency found an association between NDMA and liver toxicity, which could lead to liver cancer: NDMA exposure may be associated with bladder, renal, pancreatic, intestinal, colon, and stomach cancers.

3. Immediately following the EMA's review, 24 countries recalled approximately 2300 batches of valsartan products (Germany, Norway, Finland, Sweden, Hungary, The Netherlands, Austria, Ireland, Bulgaria, Italy, Spain, Portugal, Belgium, France, Poland, Croatia, Lithuania, Greece, Canada, Bosnia and Herzegovina, Bahrain, and Malta.

4. Hong Kong recalled 5 products of 2 companies and Canada recalled drug products of 5 companies.

5. **The Drug Regulatory Authority of Pakistan** on 12 July recalled valsartan-containing drugs of nine manufacturers becoming the first developing country to announce separately the recall as a precautionary measure to protect patient health.

6. The US Food and Drug Administration (FDA) on 13 July announced the voluntary recall of five valsartan-containing products.

ACTION TAKEN BY DRAP

The Drug Regulatory Authority of Pakistan on 12 July recalled valsartan-containing drugs of nine manufacturers becoming the first developing country to announce separately the recall as a precautionary measure to protect patient health. Accordingly the case was placed before 291st meeting of DRB held on 02-04 September 2019.wherein the board decided as under;

"Decision of the 291st meeting of Registration Board. Registration Board deliberated about the identification of NDMA & EDMA as impurities which are carcinogenic and limits has been prescribed by US FDA and EMA. Above the limits API as well as products poses threat to the consumers. Keeping in view risk the Board decided as under:

i. Product registration holders shall ensure that the API as well as products containing valsartan are within the prescribed limits impurities i.e. NDMA & EDMA. Every manufacturer holding registration of valsartan containing products are under obligation of law to provide testing facilities of these impurities for every consignment imported and brought into Pakistan. The consignments should be accompanied with the certificates of analysis by the API manufacturers. Meanwhile the manufacturers/importers may temporarily avail testing facilities of the any public sector institutions till the establishment of their own facility. However sampling will be done by the area AD, DRAP and meanwhile the consignment will be released with the restriction that it could only be used if it has qualified requisite tests from the public institutions/testing laboratories and the certificate has been endorsed by the DRAP.

ii. Board constituted standard panels comprising of following for destruction of seized stocks of valsartan API as well as finished products containing NDMA manufactured from the raw material of M/s Zheijhiang Huahai pharmaceuticals, China/any other manufacturer contaminated batches as the API has been withdrawn and banned internationally.

a) Area Additional Director. b)
Area Federal Inspector of Drugs. c)
Assistant Director I&E.
Any two of the above with the permission of Additional Director.

iii. The above mentioned panels will make coordination with the respective manufacturer for the destruction of stocks and will prepare destruction certificates for the consideration of the Registration Board. It shall be ensured that destruction /incineration is conducted in the presence of panels and incineration certificates from the environment protection agency is also accompanied with the panel report"

ACTION TAKEN BY EMA ON OTHER ARBs

On 31 January 2019, EMA recommended that companies making sartan blood pressure medicines (also known as angiotensin II receptor blockers) review their manufacturing processes so that they do not produce nitrosamine impurities.

Companies will have a transition period to make any necessary changes, during which strict temporary limits on levels of these impurities will apply. After this period, companies will have to demonstrate that their sartan products have no quantifiable levels of these impurities before they can be used in the EU.

These recommendations follow EMA's review of N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA), which are classified as probable human carcinogens and have been detected in some sartan medicines. For the vast majority of sartan medicines, impurities were either not found or were present at very low levels. The review estimated the highest possible cancer risk with these impurities. It concluded that if 100,000 patients took valsartan from Zhejiang Huahai (where the highest levels of impurities were found) every day for 6 years at the highest dose, there could be 22 extra cases of cancer due to NDMA over the lifetimes of those 100,000 patients. NDEA in these medicines could lead to 8 extra cases in 100,000 patients taking the medicine at the highest dose every day for 4 years (The 6 and 4 years refer to the duration of time NDMA and NDEA are believed to have been present in valsartan from Zhejiang Huahai). The estimates have been extrapolated from animal studies and are very low compared with the lifetime risk of cancer in the EU (1 in 2).

How impurities came to be present in sartans

Before June 2018, NDMA and NDEA were not among the impurities identified in sartan medicines and were therefore not detected by routine tests. It is now known that these impurities can form during the production of sartans that contain a specific ring structure known as a **tetrazole** ring under certain conditions and when certain solvents, reagents, and other raw materials are used. In addition, it is possible that impurities were present in some sartans because manufacturers had inadvertently used contaminated equipment or reagents in the manufacturing process. Companies must now take measures to avoid the presence of these impurities and carry out rigorous testing of their products.

Testing during and after the transition period

While the goal is to have no quantifiable nitrosamine impurities in sartans, interim limits have been set for NDMA and NDEA in line with current international guidelines (International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH) Guidance: M7(R1)). Products containing either impurity above these limits or products containing both nitrosamines at whatever level will not be allowed in the EU. The limits are based on the maximum daily intake for each impurity derived from animal studies: 96.0 nanograms for NDMA and 26.5 nanograms for NDEA. Dividing these by the maximum daily dose for each active substance gives the limit in parts per million. **The transition period, which will last for 2 years,** will allow companies to make the necessary changes to their manufacturing processes and to put in place testing regimes able to detect the smallest amounts of these impurities. After the transition period, companies must exclude the presence of even lower levels of NDEA or NDMA in their products (< 0.03 parts per million).

More about the medicine

The review concerns candesartan, irbesartan, losartan, olmesartan and valsartan, which belong to a class of medicines called sartans (also known as angiotensin-II-receptor antagonists). These sartan medicines have a specific ring structure (tetrazole) whose synthesis could potentially lead to the formation of nitrosamine impurities. Other medicines of the class which do not have this ring, such as azilsartan, eprosartan and telmisartan, were not included in the review. These medicines are used to treat patients with hypertension (high blood pressure) and those with certain heart or kidney diseases. They work by blocking the action of angiotensin II, a hormone that constricts blood vessels and causes blood pressure to rise.

16. **What limits will apply for nitrosamines in medicinal products based on lifetime and less than lifetime use?**

Long-term limits of nitrosamines for non-sartan products are still under consideration. For any new cases of nitrosamine detection in a medicinal product, the MAH should apply, whilst

waiting for the outcome of the CHMP Art 5(3) procedure, interim limits calculated for a lifetime

treatment and based on a maximum daily dose of the medicine. These interim limits (ILs) have been defined for NDMA and NDEA impurities in the Article 31 referral assessment report. Furthermore, for NMBA, NDBA, DIPNA and EIPNA, additional interim limits calculated by the Safety Working Party (SWP) and agreed by the CHMP and CMDh are summarised in the table below and are available for reference at the following ink: https://www.ema.europa.eu/en/documents/other/temporary-interim-limits-nmba-dipna-eipnaimpurities-sartan-blood-pressure-medicines_en.pdf (calculation for NDBA not yet published).

Nitrosamine	**Interim Limit***
NDMA, NMBA	96 ng/day
NDEA, NDBA, DIPNA, EIPNA	26.5 ng/day

**These limits are not applicable for batches where more than one of the above N-nitrosamines has been identified simultaneously; such batches should be rejected* If this interim limit is not exceeded, competent authorities shall be informed on the levels of the impurities detected (see Q6). MAHs should also follow the Notice to MAHs through step 1 and step 2 as described in that notice. Where the interim limit is exceeded for medicinal products with a limited treatment period or intermittent treatment (e.g. once a week), higher daily exposures may be used as an adjusted interim limit. The approach described in the ICH M7 guideline as the Less Than Lifetime (LTL) approach can be used to calculate adjusted interim limits for impurities present in medicinal products given for LTL and these are described in the following table:
Questions and answers on "Information on nitrosamines for marketing authorization holders" EMA/667965/2019 Page 10/10

Duration	1 day - 1 month	1 month – 1 year	1 year - 10 years	10 years - lifetime
Daily intake	80 x IL	13.3 x IL	6.7 x IL	IL

The risk approach is applicable to all routes of administration and no corrections to interim limits are generally warranted unless data justify route-specific differences that should be evaluated case by case. If nitrosamine impurities are detected, levels should be reported in ng and ppm, along with the relevant calculations used to describe the potential exposure to the detected nitrosamine based on the maximum daily dosage and duration of treatment described in the SmPC. If the SmPC varies between Member States, then the calculations for each different maximum exposure should be provided. These exposures should then be compared to the interim lifetime or less than lifetime approaches set out in the table above. Sufficient detail should be provided to enable the calculations to be reviewed and verified. MAHs should in all cases also follow the Notice to MAHs through step 1 and step 2 as described in that notice. MAHs should always take precautionary measures to mitigate the risk of nitrosamine formation or presence during the manufacture of their product.

1. *DRAP in its 291st meeting of DRB held on 02-04 September 2019 made the NDMA and NDEA test compulsory for every consignment of valsartan before utilization. The request of the firm for exemption of local N-nitrosodimethylamine (NDMA) testing of valsartan is placed before the board in view of the decision taken in 291st meeting of Registration Board.*
2. *Due to the safety issues, NDMA and NDEA testing in ARBs having tetrazole ring is internationally made mandatory because their carcinogenic activity has been established. In light of EMA recommendations the case of testing of ARB's for NDMA & NDEA impurities is placed before the Registration Board.*

<u>Proceeding and Decision of 295th Meeting.</u>

The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under:

i. **Finished products of valsartan imported to Pakistan from Reference Regulatory Authorities (RRAs) shall be accompanied with Certificate of Analysis (COA) of API manufacturer. If impurities i.e. NDMA & NDEA are within the prescribed**

limits of impurities as per USFDA/EMA, then local testing for determining levels of NDMA & NDEA shall be exempted.

ii. **Valsartan registration holders shall ensure that the API of valsartan imported to Pakistan are within the prescribed limits of impurities i.e. NDMA & NDEA as per USFDA/EMA and local testing for such API of Valsartan (imported to Pakistan is mandatory as already decided by Regiatration Board. The Board further advised PPMA and Pharma Bureau to submit proposal for local testing of API and to ensure presence of acceptable levels of NDMA and NDEA in APIs are used in manufacturing of finished drug products.**

iii. **As other ARBs are also under review / evaluation by RRAs for impurities, thus Registration Board advised to place such decisions immediately for its consideration.**

iv. **Any decision taken by the RRAs regarding impurities i.e. NDMA & NDEA in valsartan and other products containing products shall be placed before the Registration Board for further considerations.**

Case No.2: FDA Alerts Patients and Health Care Professionals to Nitrosamine Impurity Findings in Certain Metformin Extended-Release Products.

The U.S. Food and Drug Administration announced that agency laboratory testing revealed levels of the nitrosamine impurity N-Nitrosodimethylamine (NDMA) above the agency's acceptable intake limit in several lots of the extended-release (ER) formulation of metformin, a prescription drug used to control high blood sugar in patients with type 2 diabetes. The agency is in contact with five firms to recommend they voluntarily recall their products. Company recall notices will be posted on FDA's website. There are additional manufacturers of the metformin ER formulation that supply a significant portion of the U.S. market, and their products are not being recalled. The FDA is continuing to work closely with manufacturers to ensure appropriate testing. Assessments are underway to determine whether metformin ER recalls will result in shortages and the agency will work closely with manufacturers to prevent or reduce any impact of shortages.

"The FDA has strict standards for safety, effectiveness and quality, and the agency makes every effort based on science and data to help keep the U.S. drug supply safe. We understand that patients may have concerns about possible impurities in their medicines, and want to assure the public that we have been looking closely at this problem over many months in order to provide patients and health care professionals with clear and accurate answers," said Patrizia Cavazzoni, M.D., acting director of the FDA's Center for Drug Evaluation and Research. "Now that we have identified some metformin products that do not meet our standards, we're taking action. As we have been doing since this impurity was first identified, we will communicate as new scientific information becomes available and will take further action, if appropriate."

As per information given in FDA's press release "Patients should continue taking metformin tablets even after recalls occur, until they consult with their health care professional who can prescribe a replacement. Patients with type 2 diabetes could face dangerous health risks if they stop taking their prescribed metformin. The FDA recommends that health care professionals continue to prescribe metformin when clinically appropriate; FDA testing has not shown NDMA in immediate release (IR) metformin products (the most commonly prescribed type of metformin). The agency is working with manufacturers of the recalled tablets to identify the source of the NDMA impurity. At this time, the elevated levels of NDMA have been found in some finished-dose tablets of the ER formulation but have not been detected NDMA in samples of the metformin active pharmaceutical ingredient.

The agency is also asking all manufacturers of metformin containing ER products to evaluate the risk of excessive NDMA in their product and to test each batch before it is released into the U.S. market. If testing shows NDMA above the acceptable intake limit, the manufacturer should inform the agency and should not release the batch to the U.S. market."

In late 2019, the FDA announced it had become aware of NDMA in some metformin products in other countries. The agency immediately began testing to determine whether the metformin in the U.S. supply was at risk, as part of the ongoing investigation into nitrosamine impurities across medication types. By February 2020, the agency had identified very low levels of NDMA in some samples, but at that time, no FDA-tested sample of metformin exceeded the acceptable intake limit for NDMA. The FDA has maintained that it would continue with ongoing testing of metformin and other medications, and if any levels of NDMA or other impurities were identified, swift action would be taken.

Recently, the FDA became aware of reports of higher levels of NDMA in certain ER formulations of metformin via a citizen petition filed by a private laboratory. FDA laboratories tested the same metformin lots that the private laboratory found to contain NDMA above the acceptable intake limit. The agency confirmed unacceptable NDMA levels in some, but not all, of those lots. In other instances, FDA laboratory detected NDMA in lots that the private laboratory did not. The agency also found that the levels of NDMA, when present, were generally lower than reported by the private laboratory. Given FDA scientists' deep experience quantifying these impurities in drugs, the agency is confident in the reliability of the FDA's testing method and results and will continue to take action based on the latest scientific information. The results have also been consistent with the findings of other regulatory agencies' laboratories around the world.

Due to the safety issue NDMA and NDEA testing in Valsartan, Ranitidine, Nizatidine and Metformin ER and API is internationally made mandatory because of its carcinogenic activity has been established.

1. ***DRAP in its 291st meeting of DRB held on 02-04 September 2019 made the NDMA and NDEA test compulsory for every consignment of valsartan before utilization***

"Decision of the 291st meeting of Registration Board. Registration Board deliberated about the identification of NDMA & EDMA as impurities which are carcinogenic and limits has been prescribed by US FDA and EMA. Above the limits API as well as products poses threat to the consumers. Keeping in view risk the Board decided as under: i. Product registration holders shall ensure that the API as well as products containing valsartan are within the prescribed limits impurities i.e. NDMA & EDMA. Every manufacturer holding registration of valsartan containing products are under obligation of law to provide testing facilities of these impurities for every consignment imported and brought into Pakistan. The consignments should be accompanied with the certificates of analysis by the API manufacturers. Meanwhile the manufacturers/importers may temporarily avail testing facilities of the any public sector institutions till the establishment of their own facility. However sampling will be done by the area AD, DRAP and meanwhile the consignment will be released with the restriction that it could only be used if it has qualified requisite tests from the public institutions/testing laboratories and the certificate has been endorsed by the DRAP. ii. Board constituted standard panels comprising of following for destruction of seized stocks of valsartan API as well as finished products containing NDMA manufactured from the raw material of M/s Zheijhiang Huahai pharmaceuticals, China/any other manufacturer contaminated batches as the API has been withdrawn and banned internationally. a) Area Additional Director.b) Area Federal Inspector of Drugs. c) Assistant Director I&E.

Any two of the above with the permission of Additional Director. iii. The above mentioned panels will make coordination with the respective manufacturer for the destruction of stocks and

will prepare destruction certificates for the consideration of the Registration Board. It shall be ensured that destruction /incineration is conducted in the presence of panels and incineration certificates from the environment protection agency is also accompanied with the panel report"

2. DRAP in its 293rd meeting of DRB held on 6-8th January 2020 due to the shelf life related NDMA impurities in Ranitidine took the following Decision;

Proceeding and Decision of the 293rdmeeting of Registration Board.

"Registration Board deliberated about the identification of NDMA a potential carcinogenic impurity in Ranitidine containing products which poses threat to the consumers if found above the prescribed limits. Keeping in view risk, the Board decided as under: i. Based on decision of USFDA and EMA regarding Ranitidine containing products, the Board decided to allow the sale of ranitidine as long as the impurities (NDMA) is well within the daily acceptable limits (96 nanograms per day or 0.32 parts per million for ranitidine). ii. The manufacturers are required to test NDMA impurity in finished products (including already manufactured batches / not to disposed off / seized stocks) and it should be routinely tested on each batch before the product is released for market. Meanwhile the manufacturers may temporarily avail testing facilities of any public sector institutions till the establishment of their own facility for testing of NDMA in ranitidine containing finished Pharmaceutical Products. However sampling will be done by area FID or authorized officer by Additional Director, DRAP. iii. If testing shows NDMA above the acceptable daily intake limit (96 nanograms per day or 0.32 parts per million for ranitidine) in finished products, the manufacturer must inform respective DRAP and QA Division, DRAP and should not release the batch of finished Pharmaceutical Products for use. The Board constituted following panel (any two of following) Minutes of 293rd Meeting of Registration Board (6 – 8 th January, 2020) | 1757 for destruction of such batches of ranitidine containing products in coordination with manufacturer and Environment Protection Agency:a) Additional Director.b) Area Federal Inspector of Drugs.c) Assistant Director I&E"

3.**Proceeding and decision of 294th meeting.**

The Board deliberated the matter considering the facts of the case and decided as under:

i. **Registrations of all Ranitidine containing products shall remain suspended. Meanwhile status of ranitidine containing products will be reviewed in Reference Regulatory Authorities and a comprehensive case shall be submitted before Registration Board for its consideration. However during suspension period, the manufacturers/importers shall submit the prescribed product renewal fee as and when applicable to them.**
ii. **Manufacturer/importer of ranitidine containing product(s) shall withdraw/remove all stocks from the market immediately.**
iii. **Cases pertaining to any seizures / not to dispose of / withheld shall be placed before Registration Board if required.**

Recall issues by Pharmaceutical Companies;

1.Apotex corp. issues voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets 500 mg due to the detection of NDMA.

2.Amneal Pharmaceuticals LLC issues voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets,USP, 500 mg due to the detection of NDMA.

3. FDA Safety Alert: Marksans Pharma Limited issues voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets, USP, 500mg due to the detection of NDMA.

4. FDA Safety Alert: Teva Pharmaceuticals USA, Inc. initiates voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets USP 500mg due to the detection of NDMA.

Due to the presence of carcinogenic impurity NDMA inMetformin ER and its API's FDA issued press release and subsequent voluntary recall issued by various Pharma

Industries and in the light of the Registration Board Meetings i.e 291st, 293rdand 294thregarding the NDMA and NDEA containing products and its API's, the case of Metformin ER products& its API's is placed before the Board.

Proceeding and Decision of 295th Meeting.

The Board was appraised that FDA has recommended voluntary recall of Metformin HCl Extended Release tablets of following five (5) companies/ brands.

- M/s Time-CAP Labs, Inc., 7-Michael Avenue, Farmingdale, New York, USA. (Manufactured by: M/s Marksans Pharma Limited, Plot NO. L-82, L-83, Verna Industrial Estate, India.)
- M/s Teva Pharmaceuticals USA, Inc. Labeled as M/s Actavis Pharma, Inc., Parsippany, New Jersey, USA (Manufactured by: M/s Watson Pharma (Pvt.) Ltd., Verna, Salcette, Goa, India.)
- M/s Amneal Pharmaceruticals LLC., Bridgewater, New Jersey, USA. (Manufactured by: M/s. Amneal Pharmaceuticals (Pvt.) Ltd., Oral Solid Dosage Unit Ahmedabad, India.)
- M/s. Lupin Pharmaceuticals Inc. Baltimore, Maryland, USA (Manufactured by: M/s Lupin Limitied, Goa, India.)
- M/s Apotex Corps. Weston, Florida, USA. (Manufactured by M/s. Apotex Inc. Toronto, Ontario, Canada).

The FDA is also asking all companies manufacturing ER metformin tablets to evaluate the risk of their product containing NDMA above the acceptable intake limit and to test at-risk product before each batch is released onto the U.S. market.

The Registration Board considering the facts of the case and after thorough deliberation decided as under:

i. **Registrations of all Ranitidine containing products shall remain suspended.**
ii. **As no product of the above said manufacturers is registered in Pakistan, so there is no need to take action.**
iii. **Any decision taken by the RRA's shall be adopted by the Drug Regulatory Authority of Pakistan (Registration Board) regarding impurities i.e. NDMA & NDEA in Metformin Hydrochloride Extended-Release containing products.**

The meeting ended with the vote of thanks to and from the Chair.
